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Development and validation of biosafety climate scale and survey-based analyses of safety perceptions in biological research and teaching laboratories at public Universities in the USA.

Sivarchana Mareedu
University of Louisville

DEVELOPMENT AND VALIDATION OF BIOSAFETY CLIMATE SCALE AND SURVEY-BASED ANALYSES OF SAFETY PERCEPTIONS IN BIOLOGICAL RESEARCH AND TEACHING LABORATORIES AT PUBLIC UNIVERSITIES IN THE USA

By

Sivarchana Mareedu
MS., University of Findlay, 2012
PG., Osmania University, 2010
BSC., Osmania University, 2009

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A Dissertation Approved on

June 28, 2021

by the following Dissertation Committee:

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Dissertation Committee Co-Chair, Torsten Hopp, PhD

_____
Dissertation Committee Co-Chair, Gary Hoyle, PhD

_____
Riten Mitra, PhD

_____
David Tollerud, MD, MPH

_____
Robert Jacobs, PhD

DEDICATION

This dissertation is dedicated to

Kali
(Sravanthi Mareedu)
my sister, for teaching me the true essence of learning – to transcend challenges and reach one's full potential.

Philip Anthony Boada
my husband, best friend and companion who supports me with love and patience.

Sruthi Mareedu
my big sister, role model, and mentor for supporting and believing in my abilities.

Vijay Kumar Mareedu and Krishnaveni Mareedu
my parents, for their unconditional love and support.

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Maatru devo bhava pitru devo bhava
accharya devo bhava atithi devo bhava.

The above saying in Taittirīya Upanishad, a vedic Sanskrit text from 6th century B.C., translates to, 'Respects to mother, father, guru (teacher) and guests. They are all forms of God.' I take this opportunity to pay my respects to my mother, father, teachers, friends and everyone who helped me in completion of my doctoral studies in public health that led me on a journey of intellectual and personal growth.

I am grateful to Dr. Torsten Hopp, my dissertation co-chair for his guidance through the years in pursing my research in biological laboratory safety. His guidance and support have been crucial in the conception of this research project as well as its successful completion. I thank Dr. Gary Hoyle, my dissertation co-chair for his support and expertise that aided in formulating the research questions. His constant support and feedback helped me be accountable and reach the project milestones on time.

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Thanks to Kali, my angel on earth and in heaven whose love for learning transcended many obstacles. Kali, my big sister is my hero, role model, teacher, friend, baby, and guide. Though Kali was few years older to me, we went to preschool together. However, we soon had to part ways as classmates as the schools in India was not equipped to meet the needs of someone with downs syndrome at that time. Even though there were no incentives like a grade, degree, or employment opportunities, Kali never stopped learning. She taught me the true essence of learning - to grow and reach one's full potential. She is a powerful example of love and determination and my inspiration to learn and grow intellectually. Kali's support and confidence in my abilities helped me dream big, aim high and do my best in personal, professional, and academic endeavors. Everything I am today; I owe it to Kali.

ABSTRACT

DEVELOPMENT AND VALIDATION OF BIOSAFETY CLIMATE SCALE AND SURVEY-BASED ANALYSES OF SAFETY PERCEPTIONS IN BIOLOGICAL RESEARCH AND TEACHING LABORATORIES AT PUBLIC UNIVERSITIES IN THE USA

Sivarchana Mareedu

June 28, 2021

Biosafety plays a key role in ensuring safety of researchers' as well as the public from unintentional exposures to infectious agents. However, the occurrence of lab acquired infections, exposures, and safety lapses in biological laboratories underscores challenges in biosafety program management. The raise in emerging and reemerging infectious diseases and the ongoing COVID-19 pandemic reiterates the need for biosafety and research community to work together. Literature recommends the application of safety climate in measuring safety culture. The goal of this dissertation is to quantify biosafety climate and examine associated factors to understand the gaps between research and biosafety professionals in ensuring safety in biological laboratories. Multiple studies were conducted to collect primary data through surveys, interviews, and program evaluation on perceptions of biosafety climate, practices, and measures in place at public universities in the US. A biosafety climate scale specific to biological laboratories was developed utilizing exploratory factor analysis and confirmatory factor analysis. The impact of COVID-19 pandemic and biosafety program management on biosafety climate perceptions of research

professionals was examined. A national survey was administered to research and biosafety professionals to collect data on biosafety climate perceptions at public universities in the US. Analyses were conducted utilizing appropriate statistical tests such as Chi square, T-test, Wilcoxon methods, logistic regression, linear modeling, and ordinal regression.

Chapter one provides an outline of the studies undertaken. Chapter two describes biosafety climate scale development process. Chapter three explores the relationship between COVID-19 pandemic and biosafety climate. Chapter four examines relationship between biosafety climate perceptions of research and biosafety professionals. Chapter five investigates the relationship between biosafety program management and biosafety climate. Chapter six presents a discussion on biosafety program management in the era of COVID-19 and beyond. The seventh and final chapter summarizes the key findings of this dissertation.

Biosafety climate scale has applications as risk assessment tool as well as a key performance indicator of biosafety program management. This dissertation makes significant contribution to biosafety climate literature as the insights gained from it could assist in developing biosafety programs that facilitate collaboration between research and biosafety professionals leading to biosafety advancement.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1: INTRODUCTION

In the recent years, biological laboratory safety or biosafety has received increased awareness in the field of occupational safety. Biosafety is the discipline that addresses practices, procedures, and use of equipment for safe handling and containment of infectious microorganisms and hazardous biological materials.[1] Safe handling of hazardous biological materials is essential for safeguarding the health of not only those who work in biological laboratories but also the public and the environment.[1-8] Exposures to infectious agents and infectious outbreaks at research and teaching laboratories emphasizes the risk involved in biological research.[4-10] Incidents of potential exposures[3] leading to lab acquired infections to Salmonella typhimurium,[9-10] and deaths due to lab acquired infections such as Yersinia pestis,[3] and Neisseria meningitidis[6] have occurred in the recent times, underscoring the challenges in biosafety. The risk posed by accidents in biological laboratories is not just limited to personnel working with these agents but also the public and the environment.[1-3] A need to address the challenges in ensuring safety and compliance in research and teaching laboratories is reflected by current literature[8-7] as well as existing evidence of occurrence of incidents.[3,10-11] The need for a stronger safety culture in biological laboratories has been suggested in literature.[12-14] Occurrence of infectious disease outbreaks, lab acquired infections, exposures, and accidents in biological research laboratories in US universities reflects the persistent challenges in risk mitigation and safety compliance, that needs to be addressed. Literature recommends use of concepts such as safety culture utilized in high reliability organizations to mitigate risks to hazardous organism in research laboratories.[13-14] Examining the drivers of biosafety program can also assist in advancement of the biosafety profession.[15-16]

However, there are limited studies that provide insights into biosafety programs at research and teaching biological laboratories leading to gaps in comprehending the drivers of biosafety. Safety climate provides a snapshot of culture and is considered a measurable aspect of safety culture.[17-22] It can be used as a leading (prospective) indicator of safety[23-24] and has wide applications in occupational safety. Few studies explored the application of safety climate in academic laboratories[25-28] but nothing specific to biological laboratories. Therefore, the overall goal of this dissertation is to evaluate safety climate and its associated factors to gain insights on safety perceptions of research and biosafety professionals at biological laboratories at public universities in the US. To accomplish this objective, the following specific aims were addressed in chapters 2 to 6 of this dissertation:

Specific Aim 1: Development and validation of biosafety climate scale for biological and biomedical science laboratories in the United States. To develop a biosafety climate scale that is specific to biological laboratories based on existing safety climate literature.

Specific Aim 2: Impact of COVID-19 pandemic on biosafety climate at University of Louisville. To determine the associations of biosafety climate perceptions and COVID-19 pandemic.

Specific Aim 3: Assessment of biosafety climate in biological and biomedical laboratories at public universities in the US. To evaluate biosafety climate perceptions of research and biosafety professionals and its associations with biosafety practices and biosafety perceptions.

Specific Aim 4: Impact of biosafety program management on biosafety climate at University of Louisville. To determine the associations of biosafety climate perceptions and biosafety program management.

Specific Aim 5: Biosafety program management in the era of COVID-19 and beyond. To examine the perspectives of researchers and biosafety professionals in improving biosafety program management.

Chapter 2 presents a manuscript that has been accepted for publication in Applied Biosafety journal. It provides a background on the need and application of safety climate as a leading indicator of safety. This chapter details the study taken up to develop and validate a biosafety climate scale specific to biological and biomedical research laboratories using psychometric scale development process.

Chapter 3 provides results from test-retest analysis to test the reliability of the biosafety climate scale and confirmatory factor analysis to confirm the biosafety climate scale construct. It investigates the impact of COVID-19 pandemic on biosafety climate at University of Louisville by comparing biosafety climate, biosafety practices, and perceptions of researchers before and during the pandemic.

Chapter 4 comprises of a national survey of research and biosafety professionals conducting biological and biomedical research activities at public universities in the US. The results from confirmatory factor analysis to confirm the biosafety climate scale construct using the national biosafety climate data are presented.

Chapter 5 examines the impact of biosafety program management on biosafety climate at University of Louisville. It evaluates the changes made to biosafety program over the period of 2011 to 2021 and its impact on biosafety climate. This chapter presents the perspectives of researchers on biosafety program management in biological laboratories at University of Louisville.

Chapter 6 summarizes the perspectives of biosafety subject matter experts on biosafety program management in biological laboratories. Drawing upon the conclusions of the previous chapters, the important aspects of biosafety program management in the era of COVID-19 and beyond were further explored, taking into account the perspectives of research and biosafety professionals.

Chapter 7 summarizes the overall findings, strengths, limitations, significance, and future recommendations of this dissertation.

The findings of this dissertation will add significant knowledge to safety climate and occupational safety literature specific to biological laboratory safety. An important outcome of this study would be the development of a biosafety climate scale that has a multitude of applications as a tool to quantify safety climate in biological laboratories. The results of this study will aid in understanding the status of biosafety climate in US public universities and provide insights on biosafety program management from the perspectives of researchers and biosafety professionals.

CHAPTER 2: DEVELOPMENT AND VALIDATION OF BIOSAFETY CLIMATE SCALE FOR BIOLOGICAL AND BIOMEDICAL SCIENCE LABORATORIES IN THE UNITED STATES

Introduction

[1]Biological laboratory safety or biosafety is the discipline addressing practices, procedures, and use of equipment for safe handling and containment of pathogenic microorganisms and hazardous biological materials in laboratories utilizing principles of risk assessment and containment.[1] Ensuring safe handling of hazardous biological materials is crucial for protecting not only those who work in biological laboratories but also the public and the environment.[1,2,3] Infectious exposures and/or outbreaks at research[4-8] and teaching[9-10] institutions underscore the risk involved in biological research. Lab acquired infections and accidental exposures in biological laboratories could be minimized by improving biosafety programs as reported by Byers and Wooley.[11] Experts recognized the need for a stronger safety culture in biological laboratories to address deficiencies.[12] Interest in application of safety culture concepts in biosafety has been expressed by the biosafety professional community during symposiums, webinars, professional discussions, and in published literature.[13-14] There is a need for identifying key performance indicators, client satisfaction, and program drivers in biosafety programs.[15] Emery et al., highlighted the need to benchmark performance indicators that track biosafety program outcomes to advance the

[1] This chapter presents the manuscript[62] that has been published in Applied Biosafety Journal and is being shared in this dissertation after receiving the copyright permission from Mary Ann Liebert, Inc., publishers, Appendix A.

biosafety profession.[15-16] Trevan argued that lessons can be learned from other fields that also focus on prevention and safety culture to improve biosafety.[13]

The UK nuclear safety panel first defined safety culture as "the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that can determine commitment to, and the style and proficiency of an organization's health and safety management system".[17] Safety climate is considered to be a measurable aspect of safety culture as it provides a "snapshot" of culture at a given time.[18-19] Zohar defined safety climate as the perceptions of employees on policies, procedures, and practices about safety within the organization.[20] Safety status is reflected by safety climate, a multi-dimensional construct that evaluates management and workers' attitudes and safety commitment.[20-22] Over the years, safety climate has been recognized to evaluate the link between an organization's characteristics and safety at work.[22]

Often, lagging (retrospective) indicators[23] of safety such as data on exposures, incidents and lab acquired infections (LAIs) are not readily available making it difficult to assess the safety status of biological laboratories. Safety climate can be used as a leading (prospective) indicator of safety without the need for analyzing negative safety outcomes.[23-24] This highlights the potential of safety climate as a useful tool to evaluate safety status in biological laboratories. There are few studies on safety climate in chemical laboratories[25] and higher education institutions[26-28] but nothing specific to biological laboratories. However, the ability of safety climate to predict safety behavior and safety outcomes has long been established in various fields such as vineyards, manufacturing, construction, transport, rail, and other industries. [19,22,29-30] Therefore, safety climate literature from other fields can also inform biosafety. In 2012, a Danish study on how work environments influence health concluded that higher number of safety climate problems were associated with increased odds for experiencing accidents in the general working population of Denmark.[22] In a study of residential roofers, safety promotion increased safety behavior

indicated by both an increase in use of personal protective equipment (PPE) and decrease in injuries, indicating positive association of safety climate with better workplace safety.[31] Research instruments like measurement scales are utilized to measure theoretical constructs.[32] De Vellis defined scales as "collections of items combined into a composite score intended to reveal levels of theoretical variables not readily observable by direct means".[33] Scales can be unidimensional with a single underlying dimension or multidimensional with two or more underlying dimensions (factors).[33] The number of dimensions in a construct might increase with the abstractness of the construct.[33] A multidimensional scale is made up of subscales that represent one composite score of the construct.[33] A construct can thus be quantified via a scale with items (questions) that can measure a set of factors (dimensions).[19,34]

Literature on existing safety climate scales have identified different factors important to improve safety outcomes. Bronkhorst et al., utilized a safety climate scale to collect and analyze data from health care workers to study the effectiveness of a multifaceted intervention on safety climate perceptions and safety behavior.[21] They identified three factors in improving safety climate and safety behaviors. These include leadership priority for safety, supervisor commitment and co(workers) norms in relation to safety.[21] A safety climate scale developed for utility industry identified that organizational and managerial aspects can be a strong indicator of safe behavior and safety outcomes.[18] Safety climate perceptions among laboratory users was found to be important in improving safety conditions in college chemical laboratories.[25] To identify novel and context dependent indicators of safety climate perceptions within respective industries, safety climate scales that are industry specific rather than universal are encouraged.[18,34-35] This study aims to develop a safety climate scale to measure factors affecting workplace environment, behaviors, and perceptions specific to biological laboratories. It specifically focuses on research and teaching laboratories at public universities in the United States, as they function under similar guidelines and regulations set at federal, state, and institutional levels.

Rationale & Purpose of the Study

This study's objective is to develop an industry specific Biosafety Climate (BSCL) scale to measure perceptions of safety in biological and biomedical science laboratories at public universities in the USA and validate it using qualitative and quantitative methods. Research professionals (RPs) and biosafety professionals (BPs) represent two groups with distinct roles. RPs directly work with potentially infectious microorganisms and hazardous biological materials utilizing biosafety practices in laboratories. In contrast, BPs facilitate implementation of biosafety practices and policies in the laboratories by providing on-site policy compliance, guidance, and administrative support. Although RPs and BPs have distinct roles, they share a common goal of ensuring safety in biological laboratories. Hence, this study proposes to develop and validate a BSCL scale that is unique to each group.

Methods

Literature on scale development recommends theoretical and empirical assessments for a thorough and satisfactory validation of a scale,[32-33] which were employed in this study. The methods consisted of literature review, item identification, feedback from experts, survey administration and data analysis. The study design and protocols have been approved by the Institutional Review Board of University of Louisville (UofL), Appendix B. The study participants did not receive any form of compensation and their identity was kept anonymous. The development and validation process has been outlined in Appendix C.

A literature review on instrumentation process, scale development, validation methods[27,33-34,36-40] and existing safety climate scales across various fields such as utility[18], vineyard[19], chemical laboratory[25], manufacturing[41], rail[30] was conducted. The factors (dimensions) and items

(questions) important to biosafety climate construct were identified. The five factors identified were: 1) senior management priority, 2) supervisor commitment, 3) communication, 4) safety participation and 5) group norms. Senior management (or university administration) priority is considered a main influencer of safety climate for its role in establishing organizational priorities and resource allocation.[21,42-43]

Supervisor commitment is regarded as the building blocks of safety climate given the daily interaction between management and employee.[21] Communication is considered an important factor for its link to safety promotion and motivation.[21,44] Safety participation plays an important role as it contributes to an environment that supports safety.[21] Group norms are considered important due to the influence of coworkers on safety behavior.[21,38] Items important to measure the factors were identified by reviewing safety climate scales developed for Australian workplaces and Italian manufacturing companies.[21,37-38] First, items were examined for face validity and those that were not appropriate for biological laboratories were removed. Second, the original items were modified to make them specific to biological laboratories. Example: employee health and safety were changed to safety; workplace to laboratory. A 15 item Biosafety Climate (BSCL-15) scale consisting of five factors with three items each was developed.

The Flesch–Kincaid Grade Level (FKGL), a readability test which determines the comprehension difficulty of written material[45-46] was performed using an online tool[47] to assess the readability of the scale. A FKGL indicates the US academic grade level required to comprehend the written material. Example: a score 10 reflects a grade level appropriate for someone who completed tenth grade education. A readability rating of 8 is recommended, whereas a rating of 12 is considered difficult.[46]

Assessment of psychometric properties (reliability and validity) ensure that the scale measures a) the intended construct and b) the construct's consistency and precision. Cronbach's coefficient alpha is commonly used for reliability analysis to measure internal consistency of a scale.[48-49] Content validity measure assess if the objectives of the study match with the contents of the items in the scale.[32,50] All statistical analysis performed in the current study utilized IBM SPSS version 27.

Methods Study 1: Development of BSCL Scale

Participant Sampling and Subject Recruitment

The study participants consisted of RPs and BPs. RPs engaged in biological research activities at UofL were identified with the assistance of biosafety team at UofL. The RPs consisted of students, principal investigators, and institutional biosafety committee (IBC) members. BPs participating in biosafety matters at public universities in the USA, who attended the Midwest Area Biosafety Network's (MABioN) annual biosafety symposium in 2018 were contacted to participate in the study.

Survey Administration

A biosafety climate questionnaire was administered to RPs and BPs through SurveyMonkey® in September 2019. The questionnaire consisted of BSCL-15 scale as well as questions on background information such as age, gender, educational level, trainings, type of work conducted, and work environment. All the items were positive, optional to respond and measured on a five-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree).

Data Management and Analysis

The survey data collected was exported into Microsoft Excel for data cleaning and management. Surveys with at least 85% or more completed responses on the 15 items were included in the analysis. Any surveys completed by participants who identified their roles as other or both RP and BP were excluded from the analysis. Readability analysis of the scale was conducted using FKGL test. Descriptive statistics was employed to describe the individual characteristics of the survey participants. The items were assessed for internal consistency using Cronbach's alpha. Content validity was validated through feedback from the study participants on issues of clarity, ambiguity, general syntax, semantics, and relevance of the item to the BSCL scale.

Results

Sample Size and Participant Characteristics

The biosafety climate questionnaire was sent out to 30 RPs and 13 BPs who agreed to participate. After three weeks of data collection in September 2019, 9 RPs, 7 BPs and 1 respondent who identified as both RPs & BPs completed the survey. Sample size requirements were met as a sample of greater than 5 to 100 is acceptable for pretest.[33] The response rate was 30% for RPs and 53.8 % for BPs. The average time to respond to the questionnaire was 13.5 minutes. Only 2 item responses were missing which was addressed by substituting the missing value with 3 (neither agree nor disagree) to enable quantitative analysis. Table 1 reports the characteristics of the study participants. Most respondents of RP survey were male; had a role as principal investigator; had doctoral level of education and worked in biosafety laboratory level (BSL) 2 settings that utilize risk group (RG) 2 and 3 agents. The gender for respondents of BP survey was uniformly distributed between male and female. Most respondents of BP survey had a role as assistant biosafety officers; had master's level of education and worked in universities with mostly BSL-3 or lower settings utilizing RG-3 or lower agents.

Scale Reliability and Validity

The readability of the BSCL-15 scale had a FKGL score of 12.3 for RPs and 12.5 for BPs. The feedback received from the study participants was organized in Microsoft Excel and reviewed by Sivarchana Mareedu and Torsten Hopp. Feedback was received on the questionnaire such as having the need for an introduction page, definitions, revise phrases for clarity and the need for additional questions to evaluate research professional's participation and group behavior in the laboratory. The Cronbach's alpha scores range from 0 to 1, where: 0.7 and above - good; 0.80 and above - better; and 0.90 and above - best.[48-49] The overall scale alpha score was 0.928, implying the scale is highly reliable in measuring safety climate. The alpha values for factors on university administration priority, supervisor commitment and communication were acceptable ranging from 0.7 to 0.98. However, factors on participation and group norms had alpha values <0.7 indicating the items were not consistent. Low alpha score indicates poor correlation between items[51], underlining the need to revise the items. Cronbach alpha scores are presented in Table 2.

Based on the results of reliability and content validity analysis, the 15 items were revised by adding one additional item each to participation and group norms factors, resulting in a revised 17 item Biosafety Climate (BSCL-17) scale for both RPs and BPs. Changes were made to items, for example: senior management was changed to university. The items 4, 14, 15, 16 and 17 in BSCL-17 for RPs are based on perceptions at the laboratory level whereas in BSCL-17 for BPs they are based on perceptions at the university level. The proposed BSCL-17 scale for both RPs and BPs are reported in Table 3. The proposed BSCL-17 scale was assessed for reliability to verify if alpha score improved. The average means of participation and group norm factors was substituted as the average mean of the two newly added items respectively, to conduct reliability analysis.

The revised BSCL scale showed alpha values greater than 0.7 for participation and group norms indicating improved reliability of the items, as shown in Table 2.

Methods Study 2: Validation of BSCL Scale

Participant Sampling and Subject Recruitment

The study participants consisted of RPs and BPs. RPs included principal investigators, IBC members, research associates, students, graduate research assistants, lab personnel and equivalent positions at UofL. BPs consisted of biosafety officers, training specialists, responsible officials, or equivalent positions with responsibilities in biosafety administration and management at public universities in the USA. The biosafety administration at UofL provided a list of individuals engaged in biological research activities at UofL in 2019. A list of individuals involved in biosafety matters was compiled by reviewing the Association for Biosafety and Biosecurity (ABSA International) directory available online in 2019.[52]

Survey Administration

The biosafety climate questionnaire was shared with RPs and BPs through REDCap™ from November 19, 2019, to March 17, 2020. The survey consisted of BSCL-17 scale and questions on background information such as age, gender, educational level, training, type of work conducted, and work environment. To complete the survey, answers to the 17 items was mandatory whereas other questions were optional. All the items were positive and measured on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree).

Data Management and Analysis

The data collected through REDCap™ was exported into Microsoft Excel for data cleaning and management. Surveys completed by RPs and BPs were included in the analysis. Any surveys

completed by participants who identified their role as both BP and RP, or other role was excluded from the analysis. The BSCL-17 scale's readability was assessed using the FKGL readability test. Internal consistency test was performed using Cronbach's alpha analysis.

Statistical Analysis

Exploratory factor analysis (EFA) is routinely employed for developing and validating a new scale.[36] EFA procedures identify correlations among the variables, common variance between variables, number of factors and pattern of factor loadings in a scale.[32-33,53-55] To evaluate the suitability of EFA in a study, sample size requirements,[33,56] correlations[53], communalities[33], Kaiser-Mayer-Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity[33,36,57] are examined prior to conducting EFA. Correlation coefficients between items are used to estimate communalities and factor loading.[53] Communality is the total proportion of variance of an item accounted for by the extracted factors.[33] Maximum likelihood (ML) is recommended as a data extraction method, wherein a certain number of components are initially formed by putting the variables together based on their mutual correlations and then combined.[33-48] To improve the interpretability of the extraction procedure, rotations are utilized along with extraction procedure,[36] such as promax when factors are correlated with each other.[58-59] The correlation between the original item and factors extracted in EFA are interpreted by means of factor loadings.[36] Higher values of factor loadings are desirable to show that the item measures the factor, with 0.32 factor loading considered minimum.[36]

EFA was used to assess the validity of the proposed biosafety climate construct and assess if the proposed underlying five factor structure was validated in the BSCL-17 scale for RPs and BPs. Prior to conducting EFA, the suitability of using EFA in this study was evaluated by examining correlations, KMO and Bartlett's test of sphericity. EFA analysis was conducted using maximum

likelihood extraction with promax rotation. The number of factors to extract was determined by examining the eigenvalues and scree plots.[33,60]

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Results

Sample Size and Participant Characteristics

The biosafety climate questionnaire with BSCL-17 scale was shared with 1055 RPs and 410s BP. A total of 377 responses were received. Of these 377 responses, 229 (91 RPs, 88 BPs, 4 RP & BP, 46 other role) were completed responses and 148 were incomplete. Only the completed responses i.e., 91 RPs and 88 BPs were included in data analysis. Sample size requirements were met. In a scale, a 5:1 ratio of participants to number of variables in a scale is acceptable[33,56]The characteristics of study participants is presented in Table 1. Most respondents of RP survey were male; had a role as principal investigator or professor; had doctoral level of education and worked in BSCL-1 & 2 settings that utilize RG 1 & 2 agents. The gender for respondents of BP survey were uniformly distributed between male and female. Most respondents of BP survey had a role as biosafety officers; had either masters or doctoral level of education and worked in universities with mostly BSCL-2 or BSCL-2+ or lower settings that utilize RG-1 and 2 agents.

Exploratory Factor Analysis (EFA)

The readability of the BSCL-17 scale had a FKGL of 12.6 for RPs and 12.5 for BPs. Correlation coefficients for both RPs and BPs datasets were found to be >0.30 within the acceptable range of 0.30 to 0.70. [33,36,53] Communalities for both RPs and BPs datasets ranged from 0.52 to 0.93 which were acceptable. Communalities can range from 0 to 1, with 0.40 to 0.70 considered acceptable in social sciences.[33,36,53] KMO measure of sampling adequacy was 0.898 for RPs dataset and 0.896 for BPs dataset. The KMO values can range from 0.6 or higher to be accepted, with values >0.9 considered to be marvelous.[33,37,57] The Bartlett's test of sphericity was significant ($p < 0.001$) for both BPs and RPs datasets, which was within the acceptable range of ≤ 0.05.[33,37,57] All the assumptions of EFA were met, implying EFA is suitable on the datasets of study 2. Table 4

shows EFA results for both RPs and BPs BSCL scales. EFA was performed with ML extraction, promax rotation and factor loading cut off set at 0.32 for both RPs and BPs BSCL-17 scales. For RPs, it resulted in three factors: management priority, communication & participation (RP-F1) consisting of items 1, 2, 3, 7, 8, 9, 10, 11, 12 & 13; group norms (RP-F2) consisting of items 14,15,16 & 17; and supervisor commitment (RP-F3) consisting of items 4, 5 & 6. The three factors RP-F1, RP-F2 and RP-F3 explained 60.08%, 13.30% and 5.79% of variance respectively with a total variance of 79.17%. For BPs, it yielded three factors: management priority & communication (BP-F1) consisting of items 1, 2, 3, 7, 8, 9 & 12; group norms & participation (BP-F2) consisting of items 10, 11, 13, 14, 15, 16 & 17; and supervisor commitment (BP-F3) consisting of items 4, 5 & 6. The three factors BP-F1, BP-F2 and BP-F3 explained 50.38%, 9.71% and 8.93% of variance respectively with a total variance of 69.03%. In social sciences, 60% of the total variance is considered as the minimum threshold for such analysis.[61] Clearly, the extracted variances met the criterion.

In RP BSCL-17 scale, the first extracted factor (RP-F1) combined the three proposed factors of university administration priority, communication, and participation which can be explained as items that reflect initiatives taken at the university level. The second factor (RP-F2) and third factor (RP-F3) consisted of proposed group norms, and supervisor commitment respectively, corresponding to the factors envisioned by Bronkhorst et al.[22,38,44] RP-F2 can be explained as items that indicate initiatives taken at the laboratory level. RP-F3 are reflective of initiatives taken at department or laboratory level.

In BP BSCL-17 scale, the first factor (BP-F1) combined the 2 proposed factors of university administration priority and communication along with item-12 from the participation factor. BP-F1 like RP-F1, can be explained as items that reflect initiatives taken at the university level. The second factor (BP-F2) combined proposed items of group norms as well as items 10, 11 & 13 of

participation which can be interpreted as activities that influence safety at laboratory level. The third factor (BP-F3) consisted of proposed supervisor commitment like the factor envisioned by Bronkhorst et al,[22,38,44] which are indicative of activities taken at department level. The validated 17 items of BSCL-17 scale and its underlying structure for both RPs and BPs are reported in Figure 1a and 1b respectively. The alpha values were used to assess the reliability of the BSCL-17 scale and underlying three factors; it was acceptable at 0.88 or higher as shown in Table 5.

Discussion

The objective to develop and validate a scale for measuring safety perceptions at academic biological and biomedical science laboratories in the USA was accomplished. During scale development, it is recommended that research should include at least a) literature review b) qualitative research c) feedback from experts and d) pre-test of the scale factors and items,[33] which were all done in the current study along with e) analysis of reliability and validity of underlying factors and items.

BSCL-15 scale with 15 items and five factors for RPs and BPs was proposed based on existing safety climate scales. The number of items and perceptions measured in BSCL-15 scale is similar for both RPs and BPs except for item 4. Item 4 in BSCL-15 for RPs measured perceptions at laboratory level whereas in BSCL-15 for BPs it measured at institution level.

BSCL-15 scale was pretested on a small sample of RPs and BPs. Feedback from the experts, analysis of preliminary data, reliability, and validity analysis pointed out concerns with participation and group norm factors. To address this, items were revised that resulted in a BSCL-17 scale with 17 items. The number of items and perceptions measured in BSCL scale is similar for both RPs and BPs. The items 4, 14, 15, 16 and 17 in BSCL-17 scale measured perceptions at

laboratory level for RPs whereas for BPs it measured at university level to imply their respective work settings, as shown in Table 3.

To validate the BSCL-17 scale and identify the underlying structure, EFA was conducted for both RPs and BPs datasets, Table 4. Factors were extracted based on evaluation of scree plots and eigenvalues. For RP BSCL-17 scale, EFA identified a three-factor structure that explained 79.18% of variance with factor loadings greater than 0.53 on all the 17 items. For BP BSCL-17 scale, EFA identified a three-factor structure, that explained 69.03% of variance with factor loadings greater than 0.33 on all the 17 items. The themes identified in BSCL for RPs and BPs in BSCL scale has been presented in Figure 2a and 2b respectively. The three factors in BSCL-17 scale for RPs can be interpreted as 1) management priority, communication and participation that indicate safety perceptions at university level, 2) supervisor commitment that indicate safety perceptions at department or laboratory level and 3) group norms that indicate safety perceptions of (co)workers at laboratory level. The three factors in BSCL-17 scale for BPs can be interpreted as 1) management priority and communication that indicate safety perceptions at university level, 2) supervisor commitment that indicate safety perceptions at department level and 3) group norms & participation that indicate safety perceptions of (co) workers and participation by researchers at laboratory level. Three items (10, 11 and 13) of the four items initially proposed to assess the participation factor, load along with the items in the group norms factor for BPs whereas they load in the management and communication factor for RPs. This could be explained as the items 10 to 13 of BP BSCL-17 scale measures participation of researchers which directly effects the safety perceptions at the laboratory level. It should be noted that items 9 for RPs and 10 & 11 for BPs cross loaded with a loading of <0.32 on more than one factor. Taking theoretical and practical aspects into consideration, these items were loaded into the factor in which they had the greatest loading score, Table 4. The FKGL was around 12 for the BSCL scales for both RPs and BPs, which implies that the scale is targeted towards those who have at least high school education.

This study identified all the 17 items as appropriate and an underlying three factor structure to evaluate biosafety climate. The item groupings identified through EFA are indicative of the three underlying factors in the BSCL-17 scale for both RPs and BPs. The themes of management priority, group norms and supervisor commitment that were identified as important to biosafety climate in this study are consistent with the finding of previous studies[22,48]. Given the preliminary nature of the current study, more studies are recommended to confirm the underlying factor structure before considering factor scoring. However, the 17 items in the BSCL scale have been validated and can be used to quantify safety climate with scores ranging from 17 to 85, higher scores indicating better safety climate. Preliminary findings at UofL have shown positive association of leading indicator (biosafety climate) and negative association of lagging indicator (incidence risk), with safety status in biological laboratories. However, additional correlations studies are encouraged to examine the relationship between biosafety climate and safety status in biological laboratories.

There are a few limitations to this study. As a study based on self-reported survey data it is prone to implicit bias in responses. Researchers from only one public university were included in the survey warranting caution when generalizing the study findings to other public, private, research and diagnostic laboratories across the country or countries. However, there are considerable strengths of the study as well. A process to develop an instrument to measure occupational safety perceptions specific to biological laboratories affiliated with public universities has been established. This study adds on to the literature of safety climate scale targeted for university laboratories. The gap in lack of safety climate scales specific to biological laboratories has been addressed by this study.

There are several theoretical and practical implications of this study. The scale is simple with only 17 items and consequently does not require a lot of time from the respondents and survey administrators. There are numerous applications of a BSCL scale. These include prospective indicator of safety, risk assessment tool, quantify current safety status at a specific laboratory or university, identify areas that can be improved, develop targeted interventions, measure change in safety status pre- and post-intervention, use as a standardized scale across different universities, and compare perceptions of RPs and BPs. BSCL-17 scale can be used to quantify safety culture within a biological laboratory. By evaluating biosafety climate and safety culture within an organization, shortcomings in safety programs can be addressed proactively. The results from BSCL scale can be used as part of process improvement in biological safety programs. The BSCL scale can be utilized before and after the implementation of any new biological safety programs to study its impact on safety outcomes.

Further studies to cross validate the BSCL-17 scale and underlying factor structure across universities in USA and other countries can be taken up. The BSCL-17 scale can be re-tested at a later point at UofL to verify reliability. Additional studies on associations between biosafety climate and safety related outcomes i.e., decreased exposure to biological hazards, fewer lab acquired infections or near misses, increased participation, resource awareness and university administrations' priority are recommended. Further research to determine variables that might contribute to safety climate such as lab settings, type of agents, experience, mode of training and inspections are encouraged.

Conclusion

The study was conducted to address the lack of in-depth literature on safety climate measures specifically designed for the field of biological laboratory safety. A thorough discussion on the

steps to develop and validate a scale has been provided to aid interested scholars in understanding and utilizing scale development concepts. The BSCL-17 scale can be a beneficial risk assessment tool to personnel involved in research activities, biosafety management, university administration, and occupational safety matters. It can be used as a key performance indicator of biosafety programs and aid in developing targeted interventions to improve safety climate. BSCL-17 scale developed in this study could serve as a benchmark for evaluating biosafety climate status across institutions conducting biological research.

Variable	Study 1		Study 2	
	RPs[a] (n=9)	BPs[b] (n=7)	RPs[a] (n=91)	BPs[b] (n=88)
Gender				
Female	1	3	38	41
Male	6	4	48	43
Prefer Not to Answer	2		5	4
Role				
Principal Investigator	7		36	
Professor			33	
Lab Manager			15	
Research Assistant			19	
GRA/TA*			7	
Student			7	
Other-Research Role				
Biosafety Officer		2		55
Assistant Biosafety Officer		4		8
Research Training Professional				7
Research Safety Professional		1		15
Other-Biosafety Role				25
No Answer	2			
Educational Background				
High School			3	
Bachelors		1	12	23
Masters	1	4	16	34
PhD	8	1	57	31
BSL Level				
BSL-1			40	82
BSL-2	5		69	88
BSL-2+	2	2	13	64
BSL-3	2	5	8	53
BSL-3+			0	3
RG Level				
RG-1	1		53	86
RG-2	5	1	45	88
RG-3	4	6	9	60
RG-4			0	4

Table 1: Characteristics of study 1 and study 2 participants

Note: a) Study 1 & 2 research professionals (RPs) at UNIV-1 b) Study 1 & 2, biosafety professionals (BPs) at public universities in the USA. *Graduate research assistants (GRA), teaching assistants (TA).

Biosafety Climate Scale & Proposed Factors	Cronbach's Alpha			Cronbach's Alpha		
	Number of items BSCL-15	Study 1 RPs (n=9)	Study 1 BPs (n=7)	Number of items Proposed BSCL-17	Study 1 RPs (n=9)	Study 1 BPs (n=7)
F1: University Administration Priority	3	0.730	0.930	3	0.730	0.930
F2: Supervisor Commitment	3	0.980	0.960	3	0.980	0.960
F3: Communication	3	0.730	0.840	3	0.730	0.840
F4: Participation	3	0.510	0.690	3(+1)	0.760	0.840
F5: Group Norms	3	0.620	0.930	3 (+1)	0.810	0.970
Biosafety Climate Scale	15	0.928	0.950	15(+2)	0.935	0.956

Table 2: Cronbach's alpha coefficients of proposed and revised BSCL scale and factors in Study 1

Note: Factors 1 to 5 are represented as F1, F2, F3, F4 and F5 respectively. Study 1 proposed BSCL scale consisted of 15 items and 5 factors for research professionals (RP) and biosafety professionals (BP). Revised BSCL-17 scale consisted of revised 15 items from BSCL-15 and one additional item in each of factor 4 and 5.

Biosafety Climate Scale (BSCL-17)
Items in the Scale
1. The safety of research professionals' is a priority for my institution. 2. University administration considers research professionals' safety to be as important as productivity. 3. University administration shows support for prevention of biological hazards and incidents through involvement and commitment. 4. In the laboratory (At my institution), my supervisor acts quickly to correct problems/issues that affect research professionals' safety.
5. My supervisor clearly considers the safety of research professionals' to be of great importance. 6. My supervisor acts decisively when a concern of a research professionals' safety practices is raised.
7. There is good communication at my institution about biosafety issues which affect me.
8. Information about proper biosafety practices is always brought to my attention in my institution.
9. My contributions to resolving biosafety concerns in the institution are listened to.
10. Research professionals participate in developing best biosafety practices in my institution.
11. Research professionals are encouraged to become involved in biosafety matters. 12. At my institution, the promotion of best biosafety practices involves all levels of the organization. 13. Consultation in developing best biosafety practices involves researchers and biosafety professionals. 14. In the laboratory (At my institution), we discuss research professionals' safety, biological hazards, and incident prevention.
15. In the laboratory (At my institution), we care about each other's safety awareness. 16. In the laboratory (At my institution), we remind each other of the regulations and guidelines regarding research professionals' safety.
17. In the laboratory (At my institution), we care about each other's safety compliance.

Table 3: Biosafety Climate Scale
17 item Biosafety climate (BSCL-17) scale to measure safety perceptions at biological science laboratories. For Items 4 and 14 to 17, the phrase 'In the laboratory' is used in the scale for research professionals whereas for biosafety professionals the phrase, 'At my institution' is used to imply their respective work settings. BSCL-17 is a 5-point Likert scale with score ranging from 17 to 85.

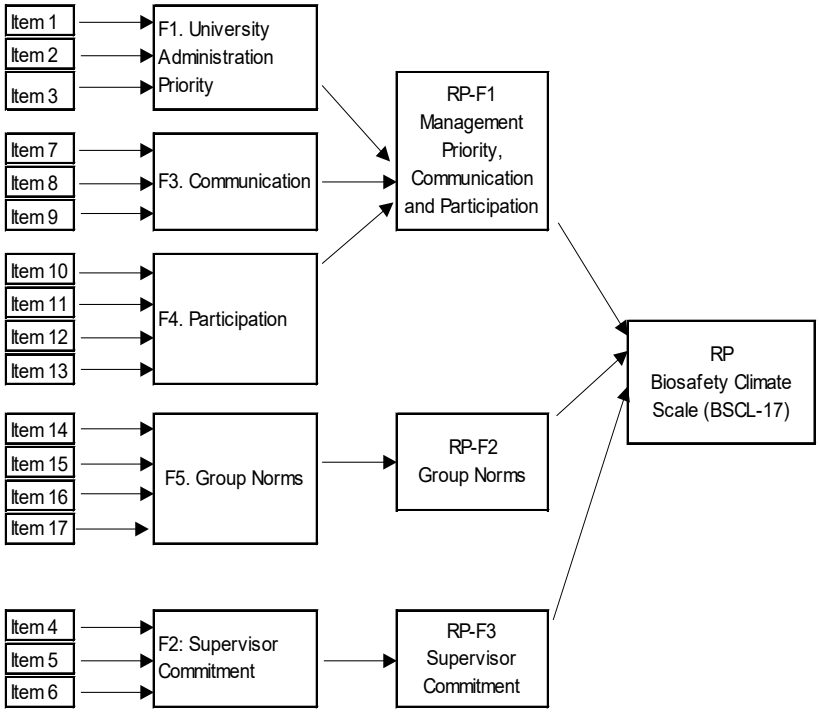
BSCL-17 Scale	Factor					
	RPs (n=91) [a]			BPs (n=88) [b]		
Items	F1	F2	F3	F1	F2	F3
Item 1	0.836				0.728	0.129
Item 2	0.881	-0.124			0.881	-0.131
Item 3	0.940	-0.196		-0.213	0.984	
Item 4	0.106		0.856			1.003
Item 5		0.108	0.875	0.156		0.817
Item 6			0.892	-0.155	0.212	0.814
Item 7	0.872			0.128	0.542	0.201
Item 8	0.755	0.219		0.300	0.316	0.137
Item 9	0.737			0.351	0.354	0.149
Item 10	0.554	0.389		0.643	0.316	-0.374
Item 11	0.653	0.365	-0.209	0.826	-0.152	
Item 12	0.891	-0.157		0.258	0.507	
Item 13	0.509	0.141		0.639	0.237	-0.168
Item 14		0.753		0.773		0.137
Item 15	-0.133	0.966		0.630		0.239
Item 16		0.883		0.763		0.102
Item 17		0.940		0.684		0.173
Eigenvalues	10.214	2.262	0.985	8.565	1.652	1.519
Percentage variance	60.080	13.305	5.793	50.381	9.717	8.933
Cumulative variance	60.080	73.385	79.178	50.381	60.098	69.031

Table 4: Exploratory Factor Analysis (EFA) Results for Study 2
Note: Extraction and Rotation Method used: Maximum Likelihood and Promax with Kaiser Normalization. Higher values of factor loadings are desirable to show that the item measures the factor, with 0.32 factor loading considered minimum. Bolded values indicate highest factor loading appropriate for each factor. For RP BSCL-17 scale, EFA identified a three-factor structure that explained 79.18% of variance with factor loadings greater than 0.53 on all the 17 items. For BP BSCL-17 scale, EFA identified a three-factor structure, that explained 69.03% of variance with factor loadings greater than 0.33 on all the 17 items. The 3 factors for BSCL for RPs are represented as Management Priority, Communication & Participation (F1), Group Norms (F2) and Supervisor Commitment (F3). b) The 3 factors for BSCL for BPs are represented as Management Priority, Communication & Participation (F1), Group Norms & Participation (F2) and Supervisor Commitment (F3).

RP Biosafety Climate Scale & Validated Factors	Cronbach's Alpha		BP Biosafety Climate Scale & Validated Factors	Cronbach's Alpha	
	Number of items	Study 2 RPs (n=91) [a]		Number of items	Study 2 BPs (n=88) [b]
RP-F1: Management Priority, Communication & Participation	10	0.947	BP-F1: Management Priority & Communication	7	0.895
RP-F2: Group Norms	4	0.935	BP-F2: Group Norms & Researchers' participation	7	0.889
RP-F3: Supervisor Commitment	3	0.972	BP-F3: Supervisor Commitment	3	0.914
Biosafety Climate Scale	17	0.957	Biosafety Climate Scale	17	0.936

Table 5: Cronbach's alpha coefficients of validated BSCL-17 scale and factors in Study 2

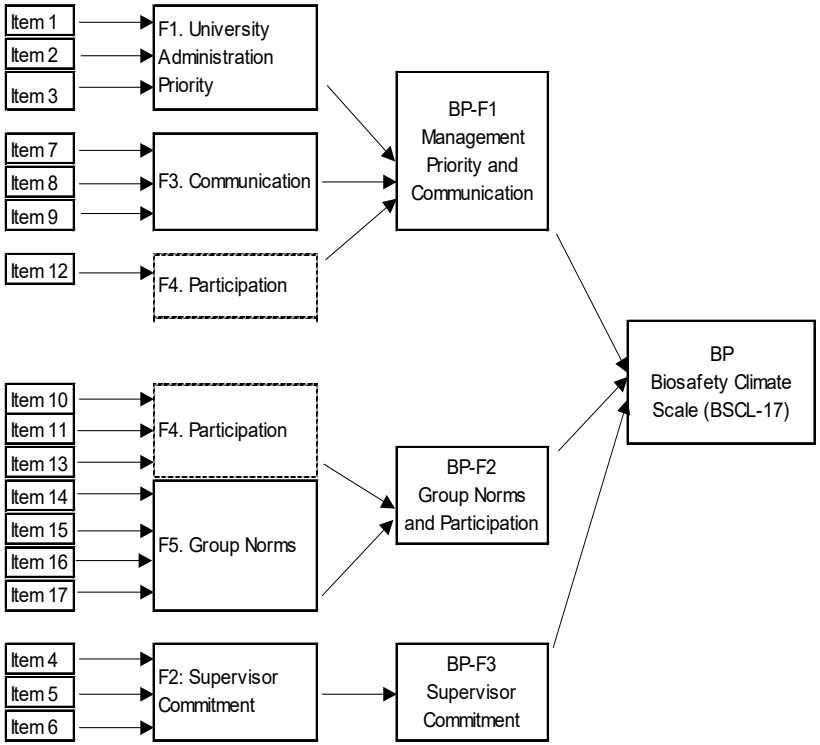
Note: a) The validated biosafety climate scale for research professionals (RP) in study 2 consisted of 3 factors: RP-F1 with items 1,2,3,7,8,9,10,11,12 & 13, RP-F2 with items 14,15,16 & 17 and RP-F3 with items 4,5 & 6. b) The validated biosafety climate scale for biosafety professionals (BP) in study 2 consisted of 3 factors: BP-F1 with items 1,2,3,7,8,9 & 12, BP-F2 with items 10,11,13,14,15,16 & 17 and BP-F3 with items 4,5 & 6.



Proposed items and factors of BSCL-17 from study 1 | Validated items and factors of BSCL-17 from study 2

Figure 1a: Structure of proposed and validated BSCL-17 scale for research professionals

Note: Proposed factors are represented as F1 to F5 and validated factors are denoted as RP-F1 to RP-F3.



Proposed items and factors of BSCL-17 from study 1 | Validated items and factors of BSCL-17 from study 2

Figure 1b: Structure of proposed and validated BSCL-17 scale for biosafety professionals

Note: Proposed factors are represented as F1 to F5 and validated factors are denoted as BP-F1 to BP-F3.

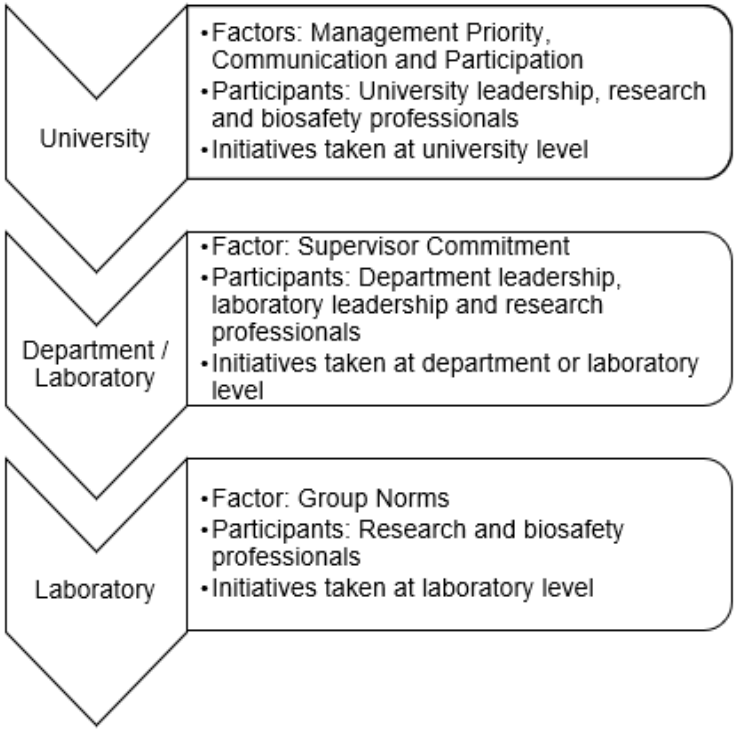


Figure 2a: Themes identified in Biosafety Climate (BSCL) scale for research professionals

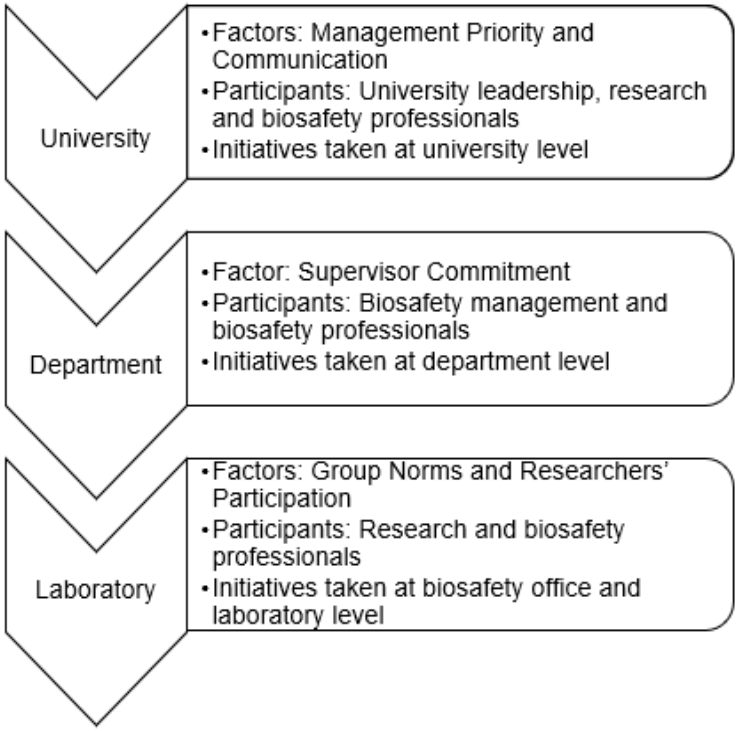


Figure 2b: Themes identified in Biosafety Climate (BSCL) scale for biosafety professionals

CHAPTER 3: IMPACT OF COVID-19 PANDEMIC ON BIOSAFETY CLIMATE AT UNIVERSITY OF LOUISVILLE

Introduction

In the earlier chapter, an industry specific Biosafety Climate (BSCL) scale to measure perceptions of safety in biological and biomedical science laboratories at public universities in the USA was developed and validated.[62] This chapter focuses on validating the BSCL scale construct for researchers at biological and biomedical science laboratories at public universities in the USA and determining the factors that influence biosafety climate.

This study attempts to confirm the construct structure of BSCL scale specific to biological and biomedical science laboratories that measure biosafety climate among researchers at biological and biomedical laboratories. A combination of confirmatory factor analysis (CFA) and exploratory factor analysis (EFA) are commonly utilized in scale development.[48,63-68] The underlying psychometric properties of an unknown scale can be evaluated utilizing EFA whereas CFA utilizes a pre-determined factor structure to verify the underlying psychometric structure of a known scale.[69] Literature on development of scales recommends development of a scale utilizing one sample followed by a longitudinal study on a different sample to give credibility to the reliability of the scale.[70] Test-retest method ensures the stability of a research instrument over time by measuring the participants responses to a survey twice across time.[32,71-72] The precision of a construct over time can be assessed by measuring the stability of scores over time.[73] In scale development, EFA is routinely employed for developing and validating a new scale.[33] The proposed structure of a scale based on the results of EFA is then confirmed by CFA in scale

development utilizing a separate sample.[25,36,41] Hence, this study utilized test-retest method to examine the reliability and CFA to confirm the construct of the BSCL scale for research professionals (RPs) in biological and biomedical science laboratories at a public university in the USA.

In December 2019, a new human coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes coronavirus disease 2019 (COVID-19) was discovered.[74-76] By March 2020, COVID-19 outbreak was officially declared as a global pandemic.[77-78] To mitigate the spread of COVID-19 at work, Occupational Health and Safety Administration (OSHA) in USA provided guidance on implementing a workplace COVID-19 prevention program.[79] This program provided measures to limit spread of COVID-19 in the workplace, such as: eliminate the hazard by isolating infection employees at their homes, implement physical distancing, enable remote or telework, install barriers when physical distancing not feasible, personal protective equipment, face coverings, ventilation, resources to maintain good hygiene practices and routine cleaning and disinfection at a workplace.[79] Various guidelines by Centers for Disease Control (CDC), World Health Organization, (WHO), state and federal governments were provided to mitigate risk of exposure to COVID-19 not only in public settings but also occupational settings.[78-83] Due to the pandemic of COVID-19, measures to mitigate risk of COVID-19 exposure were put in place in workplace settings, including academic research laboratories.[82] Previous literature on safety climate identified factors such as leadership priority for safety, supervisor commitment and co(workers) norms in relation to safety in improving safety climate and safety behaviors.[22] The COVID-19 pandemic resulted in changes to biosafety program management and safety measures in research laboratories that could have impacted leadership priority to safety, supervisor commitment and group norms. I could not find any studies that explored the impact of COVID-19 pandemic on research professionals' perceptions of safety in biological research laboratories. Hence, this study proposes to investigate the impact of changes to laboratory safety measures due

to COVID-19 pandemic on biosafety climate and biosafety perceptions in biological and biomedical research laboratories.

This study utilized the test-retest reliability method to assess whether the BSCL scores remain the same by conducting a longitudinal study over a one-year interval. CFA was also conducted to confirm the biosafety climate scale structure proposed by EFA in Chapter 2 of this dissertation. The hypothesis being tested in this study was whether COVID-19 pandemic is associated with changes in biosafety climate perceptions. The null hypothesis being tested is that COVID-19 pandemic is not associated with biosafety climate. To test this hypothesis, biosafety climate perceptions prior to COVID-19 pandemic (2019) and during COVID-19 pandemic (2020) and its impact on biosafety climate and safety perceptions of researchers at University of Louisville (UofL) biological and biomedical research laboratories were examined.

Rationale & Purpose of the Study

To test the reliability of the BSCL scale, this study proposes to assess stability of the BSCL scale items by using test-retest methods. To confirm the construct validity of the BSCL scale, CFA will be conducted utilizing a sample different from the one used in EFA in Chapter-2. This study also seeks to discover if COVID-19 pandemic impacted safety perceptions and biosafety climate in biological laboratories. By investigating the impact of COVID-19 pandemic on safety perceptions in biological laboratories, we can determine the factors that influence biosafety climate.

The University of Louisville Institutional Review Board reviewed the study design and protocols were approved to proceed (IRB 18.1220, Appendix C). All institutional policies and guidelines on participant privacy were followed.

Methods

Participant Sampling and Subject Recruitment

The study participants consisted of researcher professionals (RPs) who engaged in biological research activities at UofL. An email list of UofL researchers who were involved in past or current chemical, animal, clinical and biological research activities was provided by the biosafety administration at UofL. RPs included principal investigators, Institutional Biosafety Committee (IBC) members, research associates, students, graduate research assistants, lab personnel and equivalent positions at UofL. The subject recruitment email sent to the potential participants is shown in Appendix D. The inclusion criteria for the participants were: a) involved in biological research as researcher or biosafety administration, b) must be working with biological agents belonging to risk group (RG) 1, 2 or 3 agents at biosafety level (BSL) 1, 2 or 3 laboratories, and c) should be 18 years or older.

Survey Administration

The biosafety climate questionnaire was distributed to RPs at UofL through REDCap™ during two periods: a) RP1 study -prior to COVID-19 pandemic that is between November 19, 2019, to December 04, 2019, and b) RP2 study -during COVID-19 pandemic that is between November 02, 2020 to February 09, 2021. The survey consisted of BSCL-17 scale, questions on background information such as age, gender, education level, training, type of work conducted, and work environment. Responses to the 17 items in the BSCL scale was mandatory whereas other questions were optional. All items were positive and measured on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). The study participants were not provided with any form of compensation and their identity was kept anonymous. The survey that was utilized in both RP1 and RP2 studies were similar, except additional questions on lab design and research

perceptions during COVID-19 pandemic were added to the survey during RP2 study. The survey has been presented in Appendix E.

Data Management and Analysis

The data collected through REDCap™ was exported into Microsoft Excel for data cleaning and management. Surveys completed by RPs in RP1 and RP2 study were included in the analysis. Surveys completed by participants who identified their role as biosafety professional (BP), both BP and RP, or other role was excluded from the analysis. IBM-SPSS (version 27), IBM SPSS-AMOS (version 27) and R (R Core Team, 2021) were utilized for data analysis.

Statistical Analysis

CFA was used to assess the construct validity of the biosafety climate scale. A three factor - underlying construct model was hypothesized through EFA in a previous study.[62] Structural equations model was developed using IBM SPSS-AMOS Version 27 software to confirm biosafety climate dimensions derived from EFA. CFA was used to test for model fit and construct reliability. This study estimated model goodness of fit utilizing several fit indices as literature suggested there is no specific index to estimate model goodness of fit.[25,41,67] This study utilized Absolute Fit (Root Mean Square of Error Approximation- RMSEA), Comparative Fit Index (CFI), Incremental Fit (NFI, IFI) Tukcker-Lewis Index (TLI), and Parsimonious Fit (Chi-square/Degrees of Freedom - ChiSq/df) to test the level of model fitness. RMSEA values between 0.05 and 0.08 (ideally) or between 0.05 to 0.1, CFI >0.90, NFI $\geq$0.90, IFI >0.90, TLI >0.95, and ChiSq/df <5.0 are recommended as indicators of good fitting models.[25,41,84-91]

The Pearson's product-moment correlation[71] was computed using IBM-SPSS to quantify the degree of consistency among measurements in the RP1 and RP2 studies. Internal consistency was tested using Cronbach's alpha analysis using SPSS.[38-39,62] For continuous variables, independent

samples t-tests (for normal distribution), Wilcoxon methods (for non-normal distribution) and Fishers Exact Test for categorical variables was utilized to compare RPs responses during the two periods in the study. Differences in RPs perceptions prior to and during the pandemic was examined using the Wilcoxon rank sum test using R.

Results

Sample Size and Participant Characteristics

The biosafety climate questionnaire was shared with RPs prior to the pandemic in 2019 (RP1 survey) and during the pandemic in 2020 (RP2 survey). Two email reminders were sent to potential respondents requesting them to complete the survey. RP1 survey resulted in 228 responses. Of these 108 were incomplete and 120 were completed that consisted of 91 RPs, 4 both RP and BP, and 25 other role). RP2 survey resulted in 433 responses. Of these 209 were incomplete and 223 were completed that consisted of 120 RPs, 1 both RP and BP, 102 other). 91 RPs from RP1 study and 120 RPs from RP2 study were included in the data analysis. The characteristics of the participants in RP1 and RP2 surveys are shown in Table 6. The sample population in RP1 study was majorly male (n=48, 54.5%), aged (46.00 $\pm$14.28), had post doctorate (n=57, 64.8%), in the role of principal investigator (n=36, 39.6%) followed by professor (n=33, 36.3%), conducted research (n=89, 97.8%), worked at BSL-2 setting (n=69, 75.8%), worked with RG-1 agents (n=53, 58.2%) followed by RG-2 (n=45, 49.5%), with government funding (n=72, 79.1%), had an average team size of 6.25 and 11.68 years of experience in current role. The sample population in RP2 study was majorly male (n=61, 51.3%), aged (43.44 $\pm$14.97), had post doctorate (n=57, 47.5%), in the role of principal investigator (n=33, 27.5%) followed by research assistant (n=27, 22.5%), conducted research (n=116, 96.7%), worked at BSL-2 setting (n=81, 67.5%), worked with RG-1 agents (n=67, 55.8%) followed by

RG-2 (n=58, 48.3%), in open/shared laboratory space (n=63, 57.3%), with government funding (n=90, 75.0%), had an average team size of 7.11 and 8.71 years of experience in current role.

Confirmatory Factor Analysis

Table 7 shows the fit indices values obtained from CFA of RP2 dataset. The initial model tested the underlying three factor structure consisting of 1) management priority, communication, and participation, 2) group norms, and 3) supervisor commitment that was hypothesized using the RP1 dataset from a previous study.[62] Though $\chi 2/df$ was acceptable, the values obtained for fit indices: $\chi 2/df$=2.652, NFI=0.82, IFI=0.885, TLI=0.864, and CFI=0.884 were not within the recommended range. Hence, it was concluded that fitting the model obtained at this stage does not indicate a good fit. Literature on CFA recommends researchers to carry out post-hoc fitting.[90] So, the model was corrected for a better fitting by including five underlying factors 1) management priority, 2) communication, 3) participation, 4) group norms, and 5) supervisor commitment based on theory.[62] These modifications resulted in the modified model and the results of the fit indices improved, are shown in Table 7. The modified model showed $\chi 2/df$ as acceptable as well as the values obtained for fit indices: $\chi 2/df$=2.155, NFI=0.869, IFI=0.925, TLI=0.905, and CFI=0.924. The values of NFI =0.869 and TLI =0.905 showed an improvement but were slightly below the recommended value of >.90 and >.95 respectively. The RMSEA value improved from 0.118 in initial model to 0.099 in the modified model, however both the values were above the recommend value of 0.08, indicating that both the models were not a good fit for the data tested. However, RMSEA value between 0.08 to 0.1 provides adequate fit per few studies.[91-92] suggesting the modified model in this study could indicate a model fit of value in evaluating biosafety climate scale. The standardized and unstandardized factor loadings for the modified model with five factor confirmatory model biosafety climate for RPs is presented in Figure 3 and Figure 4 respectively. The Cronbach's alpha scores shown in Table 8 for BSCL

scale was 0.957 for RP1 study[62] and for RP2 study was 0.947 and for the underlying five factors it was greater than 0.8 in both RP1 and RP2 studies, indicating internal consistency of the scale.

Test-Retest Correlation

To assess the stability of the items in BSCL scale, a test-retest procedure was used to establish the stability of results from respondents who were asked to take the survey initially in 2019 and 12 months later in 2020. The Pearson's product-moment correlation showed that there was a significant positive correlation between the biosafety climate scores on the RP1 survey and those on the RP2 survey ($r=1$, $p=0.30$), thereby indicating that the items in the BSCL scale were effective in measuring biosafety climate over time.

Survey Analysis

Biosafety climate perceptions of RPs measured using BSCL scale,[62] is presented in Table 9. Wilcoxon rank sum test showed that there was no statistically significant change in biosafety climate perceptions of RPs prior to and during COVID-19 pandemic, ($p > 0.352$). The mean aggregate of BSCL score of RPs during 2020 (mean =72.080) slightly decreased compared to BSCL score of RPs in 2019 (mean =72.630), however this was not found to be statistically significant. Thus, we fail to reject the null hypothesis that COVID-19 pandemic is not associated with biosafety climate. Study participants perceived 11 of 17 items on BSCL scale slightly less positively during 2020 compared to 2019, though this difference was not found to be significant. Of the five factors, perceptions on supervisor commitment to safety showed an increase during 2020 compared to 2019. However, this difference was not found to be significant ($p>0.673$).

Perceptions on biosafety practices was examined prior to and during COVID-19 pandemic using Wilcoxon signed-rank test as shown in Table 10. The results did not indicate any significant

differences in biosafety climate perceptions during the two periods. A slight increase in following CDC, National Institute of Health (NIH) and OSHA guidelines during 2020 was noticed. RPs perceived concepts based on regulations and safety culture to drive university biosafety program during 2019 whereas concepts based on institutional policies and behavior-based safety during 2020. Online trainings given during both periods remained comparable (mean = 4.37 & 4.38), however a decrease in classroom and hands on training was observed. Perceptions on biosafety resources awareness such ABSA, WHO, CDC, NIH, PSDA, OSHA, Guidelines for biosafety laboratory competency and IBC guidelines decreased during 2020 compared to 2019. A decrease in biohazard exposure prevention awareness during 2020 was noticed. The number of announced lab inspections decreased during 2020 compared to 2019. Biosafety perceptions prior to and during COVID-19 pandemic of RPs at UofL was examined as shown in Table 11. No significant differences were observed in RPs biosafety perceptions during both the periods. Researchers rated biosafety practices at UofL as "can be improved" to "good" during both 2019 and 2020. Perceptions on risk level of work conducted in the lab slightly decreased during 2020 compared to 2019. A slight increase in perceptions on measures taken in lab against hazards and university's biosafety program in mitigating risks during 2020 compared to 2019 was seen.

RPs perceived biological laboratory safety perceptions during COVID-19 pandemic positively as presented in Table 12. RPs agreed that they felt safe working in labs (mean = 4.06), university prioritized COVID-19 precautions in labs (mean = 4.05), supervisor prioritized COVID-19 precautions (mean = 4.29), and peers in lab complied with lab safety precautions (mean=4.06). RPs agreed that there was good communication on changes in lab safety (mean = 3.98). However, they agreed that there were challenges imposed by COVID-19 precautions (mean =3.71).

Discussion

Based on a previous study on biosafety scale development,[62] this study aimed to further test the psychometric properties of a new instrument biosafety climate (BSCL) scale designed for measuring biosafety climate among researchers in biological and biomedical laboratories. The initial CFA model did not show a good fit; however, modified model improved the goodness of fit indices, indicating a five factor instead of three factors in BSCL scale. Kenny et al, recommended not to compute RMSEA for studies with small sample sizes as the results could falsely indicate a poor fitting model.[92] Hence, future studies with a larger sample size could be taken up to confirm a factor structure that demonstrates a good fit. However, the findings from CFA showed that a five-factor underlying structure might be more appropriate for BSCL scale, as shown in Figure 5. These factors are management priority, supervisor commitment, communication, participation, and group norms, which corresponds to factors envisaged in other studies.[22,38,44,62] The items in the BSCL scale seem to be a stable measure of biosafety climate based on the results of test-retest procedure using Pearson's product-moment correlation statistics. The results conclude that biosafety climate remained the same prior to and during COVID-19 pandemic at UofL biological research laboratories. Hence, we conclude that there is not sufficient evidence to support that COVID-19 pandemic is associated with changes in biosafety climate perceptions. This could imply that the measures taken during the pandemic were successful in maintaining safety of researchers in biological laboratories. The other explanation could be that since researchers represent a unique set of individuals who already work with infectious agents, they might have been more receptive to safety measures put in place due to the pandemic. However, further studies are advised to examine how biosafety climate might have been impacted by the pandemic in research laboratories and cross-validate the results with this study.

A key strength of this study is that it was able to compare BSCL scores from two different time periods in a similar sample to test the reliability of the scale. This study provides insights on biosafety climate perceptions, biosafety perceptions, and biosafety practices in biological research laboratories during COVID-19 pandemic. However, there are limitations to this study. Researchers from only one public university were included in the study warranting caution when generalizing the study findings to other public universities. The other limitation in using a questionnaire is that participants might lack proper understanding about questions resulting in inaccurate responses. Nevertheless, this study adds on to the literature of safety climate scale specific to biological laboratories in the USA.

The comparison of biosafety climate before and during COVID-19 provides a unique opportunity to assess the factors that affect biosafety climate. This study confirmed the structure of BSCL scale and identified underlying five factors for researchers at an academic biological laboratory. The five factors identified are in accordance with the five factors of biosafety climate identified in other studies.[21,42] Studies have demonstrated safety climate as a robust predicator of safety-related outcomes.[35,62] However, there are limited studies that explain how frequently safety climate should be assessed.[94] This study suggested that biosafety climate might be assessed periodically to verify the impact of intentional or unintentional changes to biosafety program management at an institution utilizing the BSCL scale.

Further studies could be taken up to assess the reliability of the BSCL scale in biological research laboratories across different universities in the USA. Additional studies on associations between biosafety climate and safety related outcomes are recommended. Studies on changes to biosafety climate perceptions before and during COVID-19 pandemic in different occupational settings such as manufacturing, healthcare or service industry in comparison to biosafety climate perceptions in biological laboratory settings can be conducted.

Conclusion

This study was conducted to validate the structure of BSCL scale and compare biosafety climate perceptions before and during the pandemic. The results showed evidence of test-retest reliability demonstrating the reliability of BSCL scale in evaluating biosafety climate in biological research laboratories. It suggested the construct structure of BSCL scale as having five underlying factors: university administration priority, supervisor commitment, communication, participation, and group norms. Biosafety climate prior and during the COVID-19 pandemic in biological laboratories was compared to assess the impact of changes made to research lab safety due to the pandemic. This study concluded that there was no significant difference in biosafety climate prior to and during COVID-19 pandemic in biological research laboratories.

Characteristics	UofL RP1 Prior to COVID-19 Pandemic (n=91) N (%)	UofL RP2 During COVID-19 Pandemic (n=120) N (%)	p-value[1]
Gender			0.408
Female	38(43.2)	61(51.3)	
Male	48(54.5)	57(47.9)	
Other (Non-Binary)	2(2.3)	1(0.8)	
IBC Membership			0.938
Current	7(7.9)	8(6.7)	
Past	3(3.4)	4(3.4)	
Never	79(88.8)	107(89.9)	
Role			0.371
Principal Investigator	36(39.6)	33(27.5)	
Professor	33(36.3)	25(20.8)	
Lab Manager	15(16.5)	24(20.0)	
Research Assistant	19(20.9)	27(22.5)	
GRA/GA/TA	7(7.7)	18(15)	
Student	7(7.7)	23(19.2)	
Other-Research Role	17(18.7)	16(13.3)	
Educational Background			
High School	3(3.4)	6(5)	0.069
Bachelors	12(13.6)	31(25.8)	
Masters	16(18.2)	26(21.7)	
PhD	57(64.8)	57(47.5)	
Type of Work			0.229
Research	89(97.8)	116(96.7)	
Teaching	26(28.6)	36(30)	
Diagnostics	6(6.6)	17(14.2)	
Other	1(1.1)	2(1.7)	
BSL Level			0.756
BSL-1	40(44.0)	55(45.8)	
BSL-2	69(75.8)	81(67.5)	
BSL-2+	13(14.3)	27(22.5)	
BSL-3	8(8.8)	12(10.0)	
RG Level			0.917
RG-1	53(58.2)	67(55.8)	
RG-2	45(49.5)	58(48.3)	
RG-3	9(9.9)	14(11.7)	
Research Funding			0.628
Government	72(79.1)	90(75.0)	
University	38(41.8)	54(45.0)	
Private	19(20.9)	27(22.5)	
Other	3(3.3)	4(3.3)	
Lab Design			
Open Lab	Not collected	63(57.3)	
Closed Lab	Not collected	22(20.0)	
Both	Not collected	25(22.7)	
Continuous Variable= mean (SD)	UofL RP1 Prior to COVID-19 Pandemic (n=91)	UofL RP2 During COVID-19 Pandemic (n=120)	p-value[1]
Age (years, continuous)	46.99(14.28)	43.44(14.97)	0.102
Experience in current role(years)	11.68(11.50)	8.71(9.19)	0.053
Team Size	6.25(6.803)	7.11(10.78)	0.988

Table 6: Characteristics of Study Participants in the UofL Biosafety Climate Study (n=211)

Models	$\chi 2$	DF	$\chi 2$/DF*	NFI	IFI	TLI	CFI	RMSEA
Limit			<2.0-5.0	>.90	>.90	>.95	>.90	<.08
Initial	307.589	116.000	2.652	0.828	0.885	0.864	0.884	0.118
Modified	234.888	109.000	2.155	0.869	0.925	0.905	0.924	0.099

Table 7: Goodness of fit indicators of the Biosafety Climate Scale for Research Professionals (n=120)

Biosafety Climate Scale & Proposed Factors	Number of items BSCL-17	Cronbach's Alpha	
		UofL RP1 During COVID-19 Pandemic (n-91)	UofL RP2 During COVID-19 Pandemic (n-120)
F1: Management Priority	3	0.903	0.823
F2: Supervisor Commitment	3	0.972	0.927
F3: Communication	3	0.906	0.877
F4: Participation	4	0.886	0.873
F5: Group Norms	4	0.935	0.895
Biosafety Climate Scale	17	0.957	0.947

Table 8: Cronbach's alpha coefficients of Biosafety Climate Scale and Factors

Note: The validated biosafety climate (BSCL) scale consisted of 17 items and 5 factors for research professionals (RP). Factors 1, 2, 3 ,4 and 5 are represented as F1, F2, F3, F4 and F5 respectively. Factor 1 consisted of items 1, 2 and 3. Factor 2 consisted of items 4, 5 and 6. Factor 3 consisted of items 7, 8 and 9. Factor 4 consisted of items 10, 11, 12 and 13. Factor 5 consisted of items 14, 15, 16 and 17.

Biosafety Climate Scale: Items and Factors (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	UofL RP1 Prior to COVID-19 Pandemic (n=91)		UofL RP2 During COVID-19 Pandemic (n-120)		
	Mean	Std. Dev.	Mean	Std. Dev.	p-value[1]
Biosafety Climate Score	72.630	11.534	72.080	9.606	0.352
1. The safety of research professionals is a priority for my institution.	4.418	0.716	4.408	0.655	0.713
2. University administration considers research professionals' safety to be as important as productivity.	4.198	0.909	4.142	0.873	0.486
3. University administration shows support for prevention of biological hazards and incidents through involvement and commitment.	4.231	0.895	4.275	0.686	0.781
4. In the laboratory (institution), my supervisor acts quickly to correct problems/issues that affect research professional's safety.	4.451	0.847	4.475	0.744	0.784
5. My supervisor clearly considers the safety of research professionals to be of great importance.	4.538	0.779	4.508	0.698	0.462
6. My supervisor acts decisively when a concern of a research professional's safety practices is raised.	4.462	0.821	4.508	0.767	0.840
7. There is good communication at my institution about biosafety issues which affect me.	4.187	0.953	4.225	0.727	0.663
8. Information about proper biosafety practices is always brought to my attention in my institution.	4.110	0.971	4.133	0.777	0.702
9. My contributions to resolving biosafety concerns in the institution are listened to.	4.066	0.929	3.975	0.864	0.334
10. Research professionals participate in developing best biosafety practices in my institution.	3.989	0.983	3.883	0.832	0.251
11. Research professionals are encouraged to become involved in biosafety matters.	4.110	0.960	3.942	0.910	0.128
12. At my institution, the promotion of best biosafety practices involves all levels of the organization.	3.857	1.101	3.975	0.874	0.735
13. Consultation in developing best biosafety practices involves researchers and biosafety professionals.	4.143	1.017	4.133	0.798	0.416
14. In the laboratory (institution), we discuss research professional's safety, biological hazards and incident prevention.	4.319	0.905	4.200	0.826	0.131
15. In the laboratory (institution), we care about each other's safety awareness.	4.571	0.652	4.517	0.580	0.324
16. In the laboratory (institution), we remind each other of the regulations and guidelines regarding research professional's safety.	4.418	0.776	4.292	0.738	0.128
17. In the laboratory (institution), we care about each other's safety compliance.	4.560	0.653	4.492	0.594	0.269
Factor 1: University Administration Priority	12.850	2.319	12.820	1.917	0.588
Factor 2: Supervisor Commitment	13.450	2.382	13.490	2.066	0.673
Factor 3: Communication	12.360	2.618	12.330	2.128	0.577
Factor 4: Participation	16.100	3.509	15.930	2.910	0.525
Factor 5: Group Norms	17.870	2.758	17.500	2.415	0.113

Table 9: Comparison of Biosafety Climate Prior to COVID-19 Pandemic versus During COVID-19 Pandemic in the UofL Biosafety Climate Study

Biosafety Practices at UofL	UofL RP1 Prior to COVID-19 Pandemic (n=91)			UofL RP2 During COVID-19 Pandemic (n-120)			
	N	Mean	Std. Dev.	N	Mean	Std. Dev.	p-value[1]
Regulations and guidelines Which of the following regulations and guidelines does the biosafety program follow at your institution? (Select all that apply) (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)							
CDC	84	4.643	0.831	112	4.652	0.756	0.626
NIH	88	4.602	0.917	111	4.739	0.657	0.541
OSHA BBP	88	4.750	0.777	116	4.819	0.486	0.742
Institutional Policies	85	4.812	0.500	112	4.795	0.539	0.658
Other (Formaldehyde safety, lab specific, biosafety manual, vendor waste handling)	7	2.857	1.864	19	2.632	1.862	0.826
University biosafety practices Select all that apply to your institution. (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Regulations and guidelines are strictly followed	88	4.170	0.874	119	4.210	0.700	0.870
Everyone is encouraged to know regulations and guidelines	89	4.483	0.624	119	4.504	0.595	0.869
Practical Training is given to first time researchers in lab before they begin work	88	4.318	0.953	117	4.291	0.872	0.549
Peer to Peer feedback on biosafety issues and safe practices is encouraged	89	4.034	1.027	119	4.092	0.863	0.997
Biosafety issues and safe practices are easily communicated	88	4.170	0.887	119	4.134	0.823	0.585
Senior management is involved in addressing biosafety issues and improve safe practices	88	3.920	1.096	117	4.085	0.961	0.387
Concepts that drive university's biosafety program Which of the following concepts drives the biosafety program at your institution? (Select all that apply) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Regulations (Federal & State such as OSHA, NIH, CDC, DOT and others)	89	4.607	0.633	116	4.578	0.577	0.476
Institutional Policies	88	4.443	0.676	117	4.513	0.582	0.604
Safety Culture	89	4.303	0.831	117	4.291	0.777	0.753
Behavior Based Safety	88	4.045	1.038	115	4.061	0.901	0.801

Mode of training given What mode of training is given at your institution? (Select all that apply) (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)							
Online	89	4.371	0.760	117	4.376	0.653	0.739
Classroom	88	3.511	1.039	115	3.374	1.055	0.394
Hands on by Researchers	87	3.954	0.975	114	3.851	1.050	0.553
Hands on By Biosafety	86	3.105	1.218	111	3.144	1.119	0.767
Hands on by both researchers and Biosafety professionals	85	3.306	1.102	107	3.243	1.131	0.657
Other (animal care, biological hazards, chemical hazards)	12	2.750	1.765	12	1.833	1.528	0.145
Training taken with 1 year	RP1: BBP (79(86.8%)), NIH (47(51.6%)), BS (68(74.7%)) PR2: BBP (100(83. %)), NIH (50(41.7%)), BS (89(74.2%))						
Training taken with 3 year	RP1: BBP (63(69.2%)), NIH (52(57.1%)), BS (64(70.3%)) PR2: BBP (85(70.8%)), NIH (72(60%)), BS (92(76.7%))						
Training taken with 5 year	RP1: BBP (59(65.8%)), NIH (48(52.7%)), BS (59(64.8%)) PR2: BBP (79(65.8%), NIH (65(54.2%)), BS (81(67.5%))						
Biosafety resource awareness Which of the following biosafety resources are you aware of? (Select all that apply) (1-Not at all Aware,2- Slightly Aware,3-Moderately Aware,4-Very Aware,5-Extremely Aware)							
ABSA	80	2.450	1.340	104	2.144	1.169	0.152
WHO	81	2.506	1.343	105	2.571	1.262	0.721
CDC	86	3.791	1.294	110	3.645	1.201	0.236
NIH	88	4.170	0.962	111	3.991	1.031	0.208
PSDS	81	1.901	1.319	103	1.874	1.289	0.956
OSHA	88	4.364	0.912	115	4.296	0.805	0.247
Guidelines for Biosafety Laboratory Competency	87	3.425	1.361	105	3.286	1.299	0.423
IBC	87	4.230	1.053	114	4.018	1.056	0.069
Other (IIACUC committee)	8	2.875	1.727	4	1.500	1.000	
Resources utilized for risk assessment Which of the following do you utilize to assess the risk of your research and lab activities in your lab? (Select all that apply) (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)							
Risk group of agents	83	3.831	1.333	111	3.820	1.370	0.954
Consultation with a biosafety officer	87	3.425	1.207	112	3.339	1.159	0.546
CDC	78	3.372	1.442	102	3.196	1.428	0.398
NIH	87	3.782	1.316	104	3.644	1.292	0.390
PSDS	76	1.842	1.327	98	1.776	1.145	0.914

Peer research	75	3.000	1.489	99	3.131	1.475	0.563
OSHA	88	4.148	1.099	113	4.080	1.127	0.660
IBC	85	4.318	0.929	110	4.200	1.107	0.690
Other (General peer research)	5	2.400	1.342	4	1.500	1.000	0.338
Lab inspection conducted by biosafety program administration The biosafety administration at your institution conducts _____type of laboratory inspections/assessments. (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)							
Announced	80	3.713	1.160	93	3.591	1.144	0.451
Unannounced	67	2.299	1.030	83	2.349	1.131	0.945
Both	55	2.691	1.052	62	2.903	1.289	0.380
Other	7	2.857	1.215	6	2.333	1.033	0.566
Biohazard exposure prevention awareness Are you aware of how to prevent exposure to a biological hazard if an incident involving these hazards occurs in your lab? (3-Yes,2-Not Sure,1-No)	89	2.96	0.208	119	2.92	0.308	
Incident reporting If incidents involving biohazards occurs in your lab, whom are you required to report to per incident reporting guidelines at your institution? (Select all that apply) (1-if yes, 0-if no)							
Principal investigator	91	0.890	0.314	120	0.817	0.389	0.142
Department chair	91	0.187	0.392	120	0.167	0.374	0.705
Biosafety officer	91	0.736	0.443	120	0.642	0.482	0.145
EHS	91	0.648	0.480	120	0.642	0.482	0.921
Government (NIH, CDC, FDA, DOD, OSHA, State)	91	0.055	0.229	120	0.042	0.201	0.656
Colleagues in the lab	91	0.319	0.469	120	0.358	0.482	0.549
I do not know	91	0.033	0.180	120	0.042	0.201	0.746
Other	91	0.011	0.105	120	0.025	0.157	0.464
Known biosafety incidents resulting in lab acquired infections Are you aware of any biosafety incidents resulting in Lab Acquired Infections in your lab during 2016 to 2020? (1-Yes,0-No)	89	0.045	0.208	117	0.017	0.130	0.242
Known biosafety incidents resulting in exposure to biohazards Are you aware of any biosafety incidents resulting in exposure to biological hazards in your lab during 2016 to 2020? (1-Yes,0- No)	89	0.067	0.252	116	0.017	0.131	0.067

Table 10: Biosafety Practices Prior to COVID-19 Pandemic versus During COVID-19 Pandemic in the UofL Biosafety Climate Study (n=211)

Biosafety Perceptions of Researchers at UofL	UofL RP1 Prior to COVID-19 Pandemic (n=91) N	Mean	Std. Deviation	UofL RP2 During COVID-19 Pandemic (n-120) N	Mean	Std. Deviation	p-value
Perception on university biosafety practices How do you rate biosafety practices at your university? (3-Good as is,2-Can be improved,1-Undergoing improvements)	90	2.72	0.498	118	2.75	0.43729	0.363
Perception on risk level of work conducted in the lab What do you consider the risk level of work conducted in your lab? (5-Very Low,4-Low,3-Moderate,2-High,1-Very High,0-I Don't Know)	89	3.73	0.986	118	3.91	1.062	0.144
Perception on measures taken in the lab against hazards Do you believe your lab takes strong measures to protect you from the hazards of the work conducted in your lab? (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	89	4.27	1.074	118	4.36	0.843	0.919
Perception on university's Biosafety program in mitigating risks Do you consider the biosafety program at your university to be effective in mitigating risks in your lab? (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	89	4.13	1.099	117	4.26	0.684	0.749
Perception on practices that improve adherence to safety practices & mitigate risk in lab Which of the following do you believe would improve adherence to safety practices and mitigating risks in your lab? (Select all that apply) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Regulations and guidelines are strictly followed	86	4.209	0.784	111	4.225	0.759	0.955
Everyone is encouraged to know regulations and guidelines	85	4.306	0.787	113	4.389	0.647	0.645
Practical Training is given to first time researchers in lab before they begin work	88	4.409	0.853	111	4.414	0.667	0.514
Peer to Peer feedback on biosafety issues and safe practices is encouraged	87	4.241	0.762	109	4.193	0.700	0.526
Biosafety issues and safe practices are easily communicated	89	4.281	0.723	111	4.252	0.707	0.738
Senior management is involved in addressing biosafety issues and improve safe practices	87	4.230	0.924	109	4.064	0.808	0.065
Perception on lab inspections Select the type of laboratory inspections/assessments you consider to be effective.							

(1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Announced	74	4.189	0.696	88	4.170	0.834	0.792
Unannounced	69	3.812	1.088	81	3.926	1.010	0.551
Both	66	4.121	0.832	91	4.110	0.849	0.997
Other	5	3.600	0.894	5	2.600	1.140	0.219
Perception on training format Select the following training format that you believe could improve biosafety at your institution. (Select all that apply) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Online	84	4.012	0.898	105	4.010	0.915	0.975
Classroom	80	3.825	0.808	105	3.800	0.892	0.884
Hands on by Researchers	82	4.037	0.853	101	4.208	0.828	0.151
Hands on By Biosafety	82	4.085	0.804	103	4.087	0.853	0.887
Hands on by both researchers and Biosafety professionals	81	4.160	0.798	101	4.129	0.845	0.857
Other (animal care, biological hazards, chemical hazards)	10	3.800	0.789	11	2.545	1.293	0.021
Perception on lab design Which lab design do you believe is safer: (Select appropriate response) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Open				80	3.013	1.153	
Closed				99	4.000	0.892	
Both				59	3.441	0.815	
Perception on lab design type preferred Which lab design do you prefer to work at: (Select appropriate response) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Open				76	3.39	1.223	
Closed				89	3.89	1.133	
Both				54	3.50	0.694	

Table 11: Biosafety Perceptions Prior to COVID-19 Pandemic versus During COVID-19 Pandemic in the UofL Biosafety Climate Study (n=211)

	UofL RP2 During COVID-19 Pandemic (n=120)		
Perceptions on Research Safety during COVID-19 Pandemic In relation to Covid-19 and your activity in research labs, do you feel: (Select appropriate response) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	N	Mean	Std. Deviation
Feel safe working in labs	118	4.059	0.899
University prioritizes covid-19 precautions in labs	118	4.051	0.968
Supervisor prioritizes covid-19 precautions in labs	116	4.293	0.885
Good communication on changes in lab safety	116	3.983	1.095
In lab, peers are complying with lab safety and covid-19 precautions	116	4.060	0.981
Covid-19 precautions are imposing additional challenges to lab safety	117	3.709	1.059

Table 12: Biological Laboratory Safety Perceptions During COVID-19 Pandemic in the UofL Biosafety Climate Study (n=120)

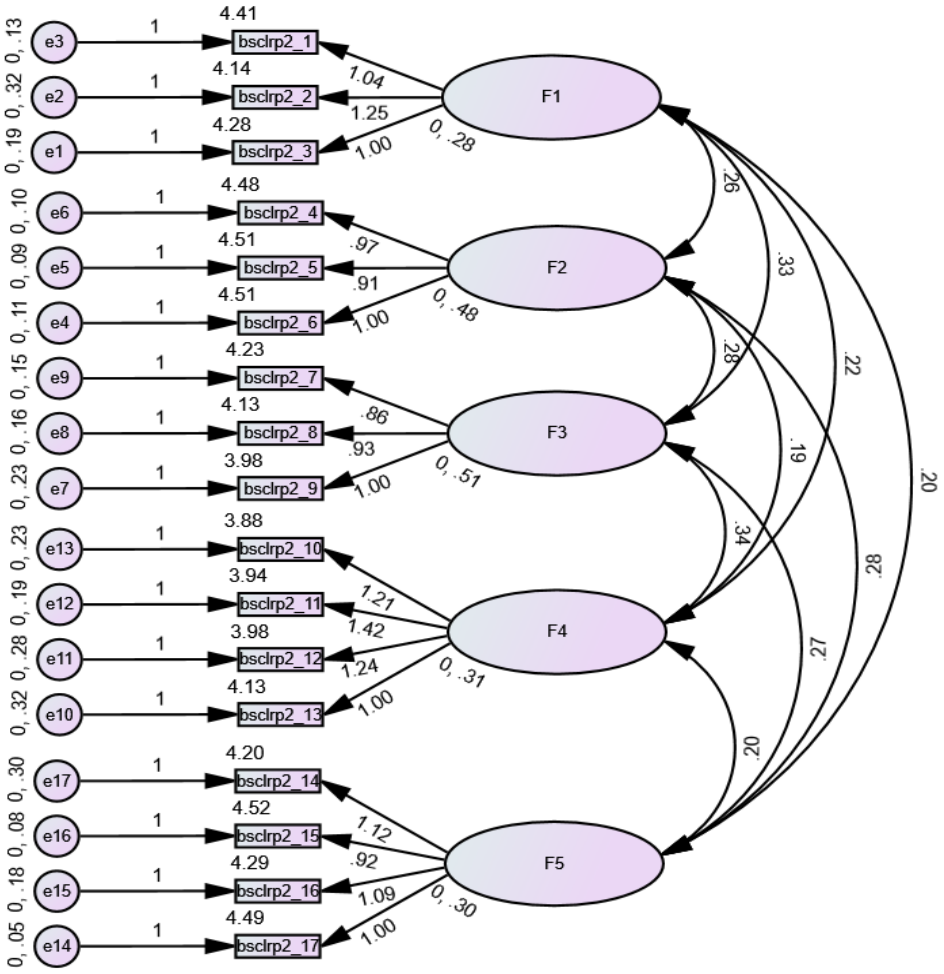


Figure 3: Confirmatory Factor Analysis of Biosafety Climate Scale for Researchers at UofL (n=120), Unstandardized Estimates of 5 Factors

Note: CFA results of unstandardized estimated of 5 factors are presented. 17 items are represented as bsclrp2_1 to bsclrp2_17 for the 17 items of Research Professionals Biosafety Climate (BSCL-17) scale. The five factors are presented as management priority (F1), communication (F2), participation (F3), group norms (F4), and supervisor commitment (F5). The variance, that is the amount of change on dependent variable is 0.28, 0.48. 0.51, 0.31 and 0.30 for the five factors. The covariance that is the amount of change in single predictor variable ranged from 0.19 to 0.34.

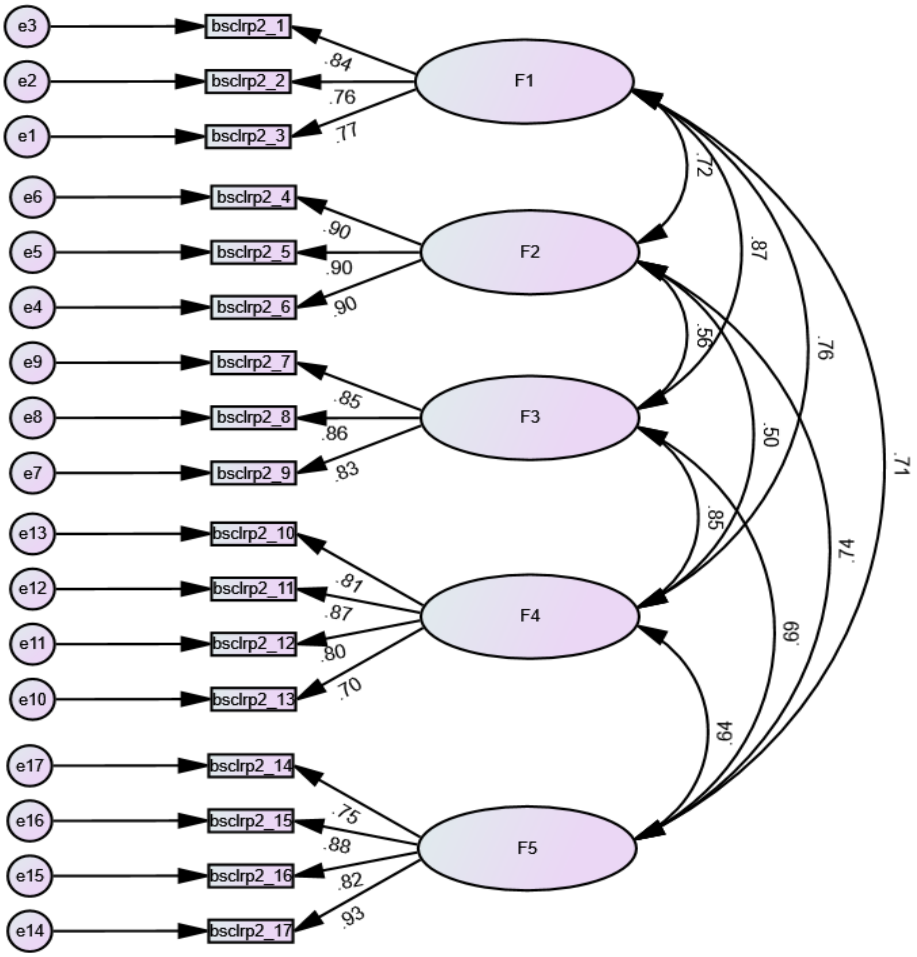


Figure 4: Confirmatory Factor Analysis of Biosafety Climate Scale for Researchers at UofL (n=120), Standardized Estimates of 5 Factors

Note: CFA results of standardized estimated of 5 factors are presented. 17 items are represented as bsclrp2_1 to bsclrp2_17 for the 17 items of Research Professionals Biosafety Climate (BSCL-17) scale. The five factors are presented as management priority (F1), communication (F2), participation (F3), group norms (F4), and supervisor commitment (F5). The factor loading estimates (higher the better) ranged from 0.70 to 0.93 and were acceptable. The correlations between the factors ranged from 0.50 to 0.87.

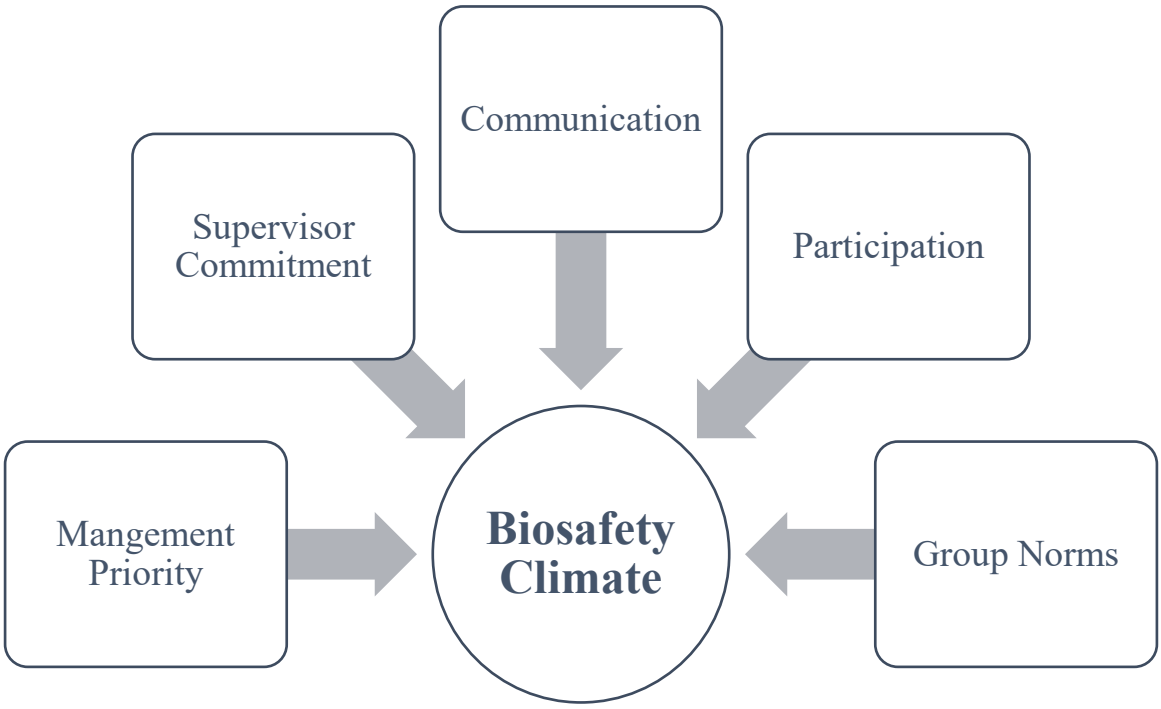


Figure 5: Five underlying factors of Biosafety Climate Scale for Researchers in Biological Laboratories.

CHAPTER 4: ASSESSMENT OF BIOSAFETY CLIMATE IN BIOLOGICAL AND BIOMEDICAL LABORATORIES AT PUBLIC UNIVERSITIES IN THE USA

Introduction

The prior chapters focused on developing, validating a Biosafety Climate (BSCL) scale, and its application in comparing biosafety climate perceptions before and during coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) at University of Louisville (UofL). The current chapter examines the status of biosafety climate and safety perceptions in research and teaching biological laboratories at public universities in the Unites States.

As the previous chapters explained, there are few studies that investigated safety climate specific to biological research laboratories. Industry specific safety climate scales rather than universal are encouraged.[18,34-35,62] Marin et al identified., a safety climate instrument specific to students conducting chemical laboratory work that could be beneficial in identifying safety gaps that inhibit proactive approaches to improve safety.[25] In their study, they advocate use of safety climate scales to understand perspectives of different groups, even those that are seldom considered to identify gaps in college laboratory safety.[25] The BSCL scale was developed and validated in Chapter 2 utilizing research professionals (RPs) from University of Louisville (UofL) and biosafety professionals (BPs) from different public universities in the US. As explained in previous chapters, there are no studies that specifically assessed biosafety climate perceptions of RPs and BPs who represent two groups with distinct roles who directly work with

potentially infectious microorganisms and hazardous biological materials in laboratories.[62] This chapter focuses on assessing biosafety climate and biosafety perceptions in biological and biomedical research laboratories at public universities in the US. In Chapter 3, confirmatory factor analysis (CFA) was utilized to confirm the BSCL scale construct using a dataset consisting of responses to BSCL survey from RPs at UofL. The CFA analysis in Chapter 3, indicated that a BSCL scale for RPs with underlying five factors might be more appropriate. Hence, this chapter further analyzed the construct validity of BSCL scale using a larger sample size to address the limitations in chapter 3.

Coronavirus disease (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was declared a pandemic in March 2020.[74-78] This resulted in guidelines from Centers for Disease Control (CDC), World Health Organization (WHO), state and federal governments on how to implement measures to mitigate risk of exposure to SARS-CoV-2 in occupational settings including academic research laboratories.[79-83] Chapter 2 explored the impact of COVID-19 pandemic on biosafety climate perception at UofL. This chapter further explores the perceptions of biosafety climate and research safety during COVID-19 pandemic in public academic and teaching biological laboratories in the US.

The purpose of this study was to perform CFA on BSCL scale of RPs and BPs and examine status of biosafety climate in biological and biomedical laboratories at public universities in the US. This study investigated whether an individual's biosafety climate perceptions depend on their role as either a research or biosafety professional. The null hypothesis being tested is that biosafety climate perceptions of research professionals and biosafety professionals are the same. To test this hypothesis, biosafety climate perceptions of research and biosafety professionals at public research and teaching laboratories in the United States were examined. This study also

considered various factors such as biosafety practices and biosafety perceptions and their impact on biosafety climate of either RPs or BPs. COVID-19 pandemic resulted in challenges to not only public safety but also occupational safety during the year 2020 - 2021. Hence, this study explored the effect of COVID-19 pandemic on perceptions of biological laboratory safety.

Rationale & Purpose of the Study

The study's purpose was to identify biosafety climate of researchers and biosafety professionals in biological and biomedical science laboratories at public universities in the USA. RPs and BPs represent two groups with distinct roles.[62] RPs directly work with potentially infectious microorganisms and hazardous biological materials utilizing biosafety practices in laboratories. In contrast, BPs facilitate implementation of biosafety practices and policies in the laboratories by providing on-site policy compliance, guidance, and administrative support. Although RPs and BPs have distinct roles, they share a common goal of ensuring safety in biological laboratories. To my knowledge, there has never been a study conducted to examine the biosafety climate perceptions of RPs and BPs. Hence, this study proposes to quantify biosafety climate perceptions of these two key players of biosafety program management in public universities. This research also proposed to investigate the impact of biosafety practices, biosafety perceptions, and COVID-19 pandemic on biosafety climate. By doing this, the factors that influence biosafety climate of researchers and biosafety professionals could be determined.

The study design and protocols were approved by University of Louisville Institutional Review Board to proceed (IRB 18.1220, Appendix B). All institutional policies and guidelines on participant privacy were followed.

Methods

Participant Sampling and Subject Recruitment

The study participants consisted of RPs and BPs who engaged in biological research utilizing risk group (RG)1, 2, and 3 agents at public research and teaching laboratories in the US. The inclusion criteria for the participants were: a) involved in biological research as either researcher or biosafety administrative personnel, b) must be working with biological agents belonging to RG 1, 2 or 3 agents at biosafety level (BSL) 1, 2 or 3 laboratories, and c) should be 18 years or older. The exclusion criteria consisted of any researchers not involved in biological research activities at private academic universities or commercial organizations. The RPs consisted of principal investigators, Institutional Biosafety Committee (IBC) members, research associates, students, graduate research assistants, lab personnel and equivalent positions. The BPs consisted of biosafety officers, assistant biosafety officer, safety training specialists, biosafety administrative personnel, and equivalent positions. Initially, the study planned to disseminate surveys to biosafety officers and/or research safety admiration at public universities requesting them to share the survey with researchers and/or biosafety administrative personnel at their respective institutions. A subject recruitment email was sent to potential participants as shown in Appendix F. However, due to a low response to survey invitations an alternative plan of directly contacting population of interest was utilized. A list of public institutions offering a bachelors or advanced (masters and doctoral) awards in biological and biomedical programs/majors was obtained from National Center for Education Statistics website.[95] The list obtained consisted of 584 universities. Email addresses of potential participants was collected by reviewing the university's website and relevant department pages. Survey invitations were sent to approximately 35,000 potential participants through email.

Survey Administration

The biosafety climate questionnaire consisting of BSCL scale,[62] background questions on age, gender, education, training, type of work conducted, and work environment was shared through REDCap™ with potential participants. The survey was administered from November 23, 2020, to April 06, 2021. Three email reminders were sent to the participants who did not respond to the survey invitation. All the questions in the survey were optional to respond except the BSCL scale consisting of 17 items. These items were positive and measured on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). No form of compensation was provided to the study participants whose identity was kept anonymous. The survey was similar to the one used in the previous chapter, presented in Appendix E.

Data Management and Analysis

Survey data collected through REDCap™ was exported to Microsoft Excel for data cleaning and management. Only the surveys that were completed by RPs and BPs were considered for data analysis. Surveys completed by participants that identified their role as both BP and RP, or other was excluded. IBM-SPSS (version 27), IBM SPSS-AMOS (version 27) and R (R Core Team, 2021) were utilized for data analysis.

Statistical Analysis

CFA was used to test for model fitness and construct relatability of BSCL scale for RPs and BPs. A three factor-underlying construct was hypothesized[62] through exploratory factor analysis (EFA) in Chapter-2. However, CFA analysis on a different data set in the study presented in Chapter-3, indicated a five factor-underlying structure for BSCL scale of RPs. Like Chapter-3, this study also utilized Absolute Fit (Root Mean Square of Error Approximation- RMSEA), Comparative

Fit Index (CFI), Incremental Fit (NFI, IFI) Tukcker-Lewis Index (TLI), and Parsimonious Fit (Chi-square/Degrees of Freedom - ChiSq/df) to test the level of model fitness. RMSEA values between 0.05 and 0.08 (ideally) or between 0.05 to 0.1, CFI >0.90, NFI >0.90, IFI >0.90, TLI >0.95 and ChiSq/df < 5.0 are recommended as indicators of good fitting models.[25,41,84-91] Maximum likelihood method was applied for model estimation. Internal consistency was tested using Cronbach's alpha analysis using SPSS[38-39,62].

For continuous variables, independent samples t-tests (for normal distribution), Wilcoxon methods (for non-normal distribution) and Fishers Exact Test for categorical variables was utilized to compare RPs and BPs responses in the study. Differences in research professionals' perceptions prior to COVID-19 pandemic and during the pandemic was examined. Logistic regression is a poplar multivariate model.[96-98] Logistic regression models,[96-102] were used to evaluate associations of biosafety climate score and items scores with the outcome of predicting RPs or BPs. The estimates are the log odds ratios. The probability of falling into a biosafety professional or a researcher profile is linked with the items scores through this logistic regression model. Assumptions of logistic regression[96-102] such as dependent variable measured on an ordinal level, continuous independent variables, ordinal/categorical variables were met in this study. Linear modelling was employed to examine associations of aggregate BSCL scores and individual item scores of RPs and BPs with different variables such as biosafety practices, biosafety perceptions, and lab safety perceptions during COVID-19 pandemic. Linear regression[103-105] was utilized to predict the aggregate BSCL scores of RPs and BPs based on different variables such as biosafety practices, biosafety perceptions, and lab safety perceptions during COVID-19 pandemic.

Results

Sample Size and Participant Characteristics

The biosafety climate questionnaire was shared with RPs and BPs. Three email reminders were sent to potential participants requesting them to complete the survey. The survey resulted in 2237 responses, out of which 1277 were incomplete and 960 were completed. Out of the 960 responses, 690 responses were from RPs, 157 responses from BPs, 36 both RP and BP and 80 others. 690 RPs and 157 RPs were included in the data analysis.

The characteristics of the participants RPs and BPs are shown in Table 13. The sample population in USA-RPs study was majorly male (n=345, 50.4%), aged (44.29 $\pm$ 13.12), had doctoral level of education (n=492, 71.6%), in the role of principal investigator (n=359, 52%) followed by professor (n=317, 45.9%), never an Institutional Biosafety Committee (IBC) member (n=577 63.3%), conducted research (n=670, 97.1%), worked at BSL-2 setting (n=446, 64.6%), worked with RG-1 agents (n=478, 69.3%) followed by RG-2 (n=320, 46.4%), primarily in open/shared lab design (n=335, 53.1%), in labs with government funding (n=569, 82.5%), had an average team size of (7.78 $\pm$ 14.45) and (9.88 $\pm$9.68) years of experience in current role.

The sample population in USA-BPs study was majorly female (n=79, 52.7%), aged (47.6 $\pm$ 11.11), had doctoral level of education (n=51, 32.7%), in the role of biosafety officer (n=90, 57.3%), current IBC member (n=109, 70.3%), conducted research (n=152, 96.8%), worked at BSL-2 setting (n=148, 94.3%), worked with RG-1 agents (n=146, 93%) followed by RG-2 (n=145, 92.4%), primarily in both open/closed lab design (n=120, 87.6%), in institutions with government funding (n=151, 96.2%), had an average team size of (3.80 $\pm$ 3.01) and (7.64 $\pm$6.50) years of experience in current role.

Confirmatory Factor Analysis

The results of CFA showing the statistical fit indices of the measurement model are shown in Table 14. Initial model tested the three-factor structure of RP-BSCL, consisting of 1) management priority, communication, and participation, 2) group norms, and 3) supervisor commitment that was hypothesized using the UofL RPs1 dataset in a previous study.[62] For BP-BSCL scale, the initial model tested the three-factor structure, consisting of 1) management priority and communication 2) group norms and research professionals participation, and 3) supervisor commitment that was hypothesized using the UofL RPs1 dataset in a previous study.[62] The modified model for both RP and BP, BSCL scale tested the five-factor structure, consisting of 1) management priority, 2) communication, 3) participation, 4) group norms, and 5) supervisor commitment based on theory.[62]

As reported in Table 14, the initial factor model that emerged from EFA presented fit indices which were below the recommended level for the measurement model for both BPs and RPs BSCL scale. For the RP-BSCL construct, initial model had $\chi 2/df = 9.49$, above the recommended value of <5.0 and the values obtained for fit indices: NFI=0.898, IFI=0.908, TLI=0.892, and CFI=0.908, and RMSEA =0.11 were not within the recommended range. However, the modified model showed improvement in fit indices of RP-BSCL construct against the initial model. The modified model had acceptable $\chi 2/df = 4.042$, NFI=0.959, IFI=0.969, TLI=0.961, CFI=0.969, and RMSEA=0.066 for the BSCL construct for researchers. The modified model for RP-BSCL construct provided additional support for the goodness of the model based on theory.[62] The standardized and unstandardized factor loadings for the modified model with five factor confirmatory model biosafety climate for RPs are presented in Figure 6 and Figure 7 respectively, which are within the acceptable range.

For the BPs BSCL construct, the initial model had acceptable $\chi 2/df = 3.27$ and the values obtained for fit indices: NFI=0.840, IFI=0.883, TLI=0.862, CFI=0.882 and RMSEA=0.12 which were not within the recommended range. The modified model for the BP-BSCL construct showed slight improvement with $\chi 2/df = 2.949$, NFI=0.864, IFI=0.906, TLI=0.881, CFI=0.905, and RMSEA=0.112 though still below the recommended values. The modified model for BPs-BSCL construct failed to provide adequate support for goodness of the model. However, as discussed in Chapter-3, Kenny et al, recommend not to compute RMSEA for studies with small sample sizes as the results could indicate a poor fitting model.[92] Hence, in this study we considered five factor structure of BSCL construct for BPs to enable comparison of RPs and BPs.

The standardized and unstandardized factor loadings for the modified model with five factor confirmatory model biosafety climate for BPs are presented in Figure 8 and Figure 9 respectively, which are within the acceptable range.

The aggregate Cronbach's alpha scores for BSCL scale were 0.953 and 0.955 for RPs and BPs respectively, as shown in Table 15. The alpha scores for the five factors were greater than 0.8 in both USA-RPs and USA-BPs studies, indicating internal consistency of the scale.

Survey Analysis

The biosafety climate perceptions of RPs and BPs measured using the BSCL scale,[62] is shown in Table 16. The aggregate biosafety climate score of RPs ranged from 17 to 85, with a mean score of 69.94 ($\pm$ 12.51) and for BPs it ranged from 17 to 85, with a mean score of 68.90 ($\pm$ 11.80). Figure 10 compares the five factor scores of RPs and BPs. Three factors of the biosafety climate construct: management priority, communication and group norms are slightly greater for RPs compared to BPs. However, supervisor commitment and participation are slightly greater for BPs compared to RPs. Perceptions on biosafety practices of RPs and BPs was examined, as shown in

Table 17. Differences in biosafety practices between RPs and BPs has been observed. RPs responded that they are most aware of NIH guidelines and least aware of Pathogen safety data sheets. BPs were most aware of CDC guidelines and least aware of WHO's guidelines for biosafety laboratory competency. Biosafety perceptions of RPs and BPs was examined, as shown Table 18. Biosafety practices were rated higher by RPs (mean =2.64) compared to BPs (mean=1.90), where 3 = good as is, 2= can be improved and 1=undergoing improvements). RPs perceived the risk of work conducted in their labs as "low" whereas BPs considered the risk of work conducted at their institutions as "moderate". RPs and BPs perceived biological laboratory safety perceptions during COVID-19 pandemic positively as shown in Table 19. Both RPs and BPs agreed that: they felt safe working in labs (mean = 4.22 & 4.18); university prioritized COVID-19 precautions in labs (mean = 4.30 & 4.43); supervisor prioritized COVID-19 precautions (mean = 4.48 & 4.47); there was good communication on changes in lab safety (mean = 4.22 & 4.26); peers in lab complied with lab safety precautions (mean=4.28 & 4.17). RPs and BPs agreed that those precautions imposed by COVID-19 caused additional challenges to lab safety (mean=3.84 & 4.01).

Logistic regression

Preliminary data exploration was conducted for exploratory purposes using Wilcoxon methods on some of the items for individual regressions. We found significant differences in some of the variables and found that logistic regression is appropriate for this data set. Logistic regression is a robust test that accounts for confounders and hence would be appropriate in this study. Logistic regression was performed on the 17 items as well as the aggregate climate score of the BSCL scale using USA-RPs and USA-BPs data sets.

Logistic regression shows how different items discriminate the two groups: RPs and BPs. The results of logistic regression are presented in Table 20. Logistic regression of BSCL score could not discriminate RPs and BPs ($p > 0.34$). However, results of logistic regression on 17 items showed some significant differences in perceptions of RPs and BPs. Significant differences were found for items 3, 8, 9, 10, 11, 12, 13, 15 and 17. The results from the model indicate that respondents who reported greater scores on items 3, 8, 10, 12, 15 and 17 were associated with RPs. The respondents who reported greater scores on items 9, 11, and 13 were associated with BPs.

Linear Modeling

Linear modeling was performed to examine the relationship between BSCL score and variables such as age, gender, education background, biosafety practices, biosafety perceptions, and biological laboratory safety perceptions during the pandemic on RPs and BPs. The results of linear regression of BSCL score of RPs and BPs are presented in Table 21. The BSCL score of RPs was positively correlated with age of RPs, significant at $p < 0.006$. However, the BSCL score of BPs did not correlate with age of BPs ($p > 0.77$). A positive correlation between the variable on biosafety practices based on safety culture -communication (Biosafety issues and safe practices are easily communicated) and BSCL score of RPs was found to be significant at $p < 0.001$. A positive correlation between the variable on biosafety practices based on safety culture -management commitment (Senior management is involved in addressing biosafety issues and improve safe practices) and BSCL score of RPs was found to be significant at $p < 0.001$. Perceptions on university's Biosafety program in mitigating risks was found to positively correlated with BSCL scores of RPs as well as BPs which found to be significant $p < 0.001$. A positive correlation between BSCL scores of RPs and their perception on COVID-19 pandemic measures (Supervisor prioritizes COVID-19 precautions in labs) was found to be significant at p

< 0.001. A positive correlation between BSCL scores of BPs and their perception on COVID-19 pandemic measures (Research labs are safe during COVID-19 pandemic) was found to be significant at $p < 0.001$.

Ordinal Regression

Ordinal regression was performed to examine the relationship between individual BSCL item scores and variables such as age, gender, education background, biosafety practices, biosafety perceptions, and biological laboratory safety perceptions during the pandemic on RPs and BPs. The results are presented in Table 22. Significant associations between variables and item scores of RPs and BPs were observed. A positive correlation between the variables of age and biosafety practices based on behavior-based safety (peer to peer feedback on biosafety issues and safe practices is encouraged) and item 1 (The safety of research professionals is a priority for my institution) for RPs was noticed. Item 5 (My supervisor clearly considers the safety of research professionals to be of great importance) positively correlated with COVID-19 precautions which emphasized on supervisor priority ($p = 0$). IBC membership negatively correlated with the item 9 (My contributions to resolving biosafety concerns in the institution are listened to) for BPs.

Discussion

The current study collected survey data from RPs and BPs at public universities in USA who were involved with biological and biomedical research activities. Initially, survey invitations were sent out to biosafety officers and equivalent officials at various public universities in the US. The assumption was that they would be able to distribute the survey to RPs and biosafety administrate personnel within their institutions. However, due to low response rate, we had to come up with alternative approaches. When designing a survey, different elements such as invitation mode, subject line, location, URL link, length of test, and survey time need to be

carefully selected.[106] Literature suggests use of different strategies to improve web survey efficiency through use of reminders.[106-108] Based on feedback from initial survey invitations and review of exiting literature on survey design, modifications were made to the survey invitation and survey design to increase response rate. Changes such as: subject line, details in the invitation, font size, font color, three reminders to complete the survey, survey invite sent directly by the research investigators to potential participants emails and so on were made, which aided in increased response.

To further understand the biosafety climate construct, this study performed CFA to test the goodness of the factor pattern previously hypothesized[62] with EFA in Chapter-2, and cross validated the model indicated through CFA in Chapter-3. The results of CFA showed a good fit for the modified model with five underlying factors of BSCL scale for RPs. These factors are management priority, supervisor commitment, communication, participation, and group norms, which corresponds to factors envisaged in other studies.[22,38,62] The underlying factors of the biosafety climate construct can also be assessed using BSCL scale for RPs. However, this study could not confirm the underlying factor structure for BP-BSCL scale and additional studies are recommended to assess the underlying factors of BSCL scale for BPs. Nevertheless, the BSCL construct with five underlying factors showed to be a better fit than three underlying factors initially hypothesized for BP-BSCL. The BSCL scale can be used to assess safety climate perceptions of RPs and BPs.

Logistic regression was conducted to analyze the data. The aggregate BSCL score was unable to distinguish RPs and BPs. However, some of the individual item scores were able to discriminate RPs and BPs. The differences in item perceptions of RPs and BPs can be justified. As explained in a previous study, RPs and BPs represent two groups with distinct roles with a shared goal of ensuring safety in biological laboratories.[62] BPs ensure administrative support and

implementation of biosafety practices to ensure safety of RPs who directly work with potentially infectious agents.[62] Consequently, differences in their perceptions of safety climate are expected.

RPs have higher perceptions than BPs for items 3, 8, 10, 12, 15 and 17. Higher perceptions on item 3 (University administration shows support for prevention of biological hazards and incidents through involvement and commitment) and item 8 (Information about proper biosafety practices is always brought to my attention in my institution) signifies that researchers recognize university administration's support in preventing hazards and communicating safety issues. However, BPs consider the university's support and communication to be lower than RPs. RPs and BPs have different responsibilities due to which their expectations on support from university administration might be different. Item 10 (Research professionals participate in developing best biosafety practices in my institution) and item 12 (At my institution, the promotion of best biosafety practices involves all levels of the organization) corresponds to participation of researchers in biosafety matters, which researchers perceive to be greater than BPs. Item 15 (In the laboratory (institution), we care about each other's safety awareness) and item 17 (In the laboratory (institution), we care about each other's safety compliance) are also perceived more positively by RPs compared to BPs. The safety climate perceptions of RPs might be more influenced by the culture within their laboratories followed by their departments and university. Whereas for BPs perceptions might be influenced by the overall culture at the university level.

RPs have lower perceptions than BPs for the items of 9, 11 and 13. Lower perceptions for RPs compared to BPs was found to be significant on item 9 (my contributions to resolving biosafety concerns in the institution are listened to); item 11 (research professionals are encouraged to become involved in biosafety matters); and 13 (Consultation in developing best biosafety practices involves researchers and biosafety professionals). Due to the nature of their work, BPs generally interact with multiple research labs and researchers within their institution. Whereas not

all RPs in a university are involved in biosafety affairs due to various reasons such as: students or junior research associates unaware of biosafety opportunities, principial investigators who are not interested in biosafety affairs, or RPs not actively working with infectious agents and therefore might not be aware of biosafety opportunities. Hence, BPs might feel that RPs have ample opportunities to participate whereas not all RPs might agree they had an opportunity to be involved in biosafety matters.

One of the important goals of occupational safety and health (OSH) is assessing and evaluating risks, as misjudging the risks posed may lead to incidents.[109-111] Risk perception consists of cognitive and emotional dimensions.[112] Cognitive dimension related to being knowledgeable and understanding of the risks involved whereas as emotional dimension related to how one feels about them.[112] Ivenksy, stated that for OSH program to be effective, a shared vision of hazards and required controls is essential.[109] Risk perceptions are subjective as it depends on a multitude of factors such as conceptions of knowledge, experience, and personalities. Response to hazards depends on risk perceptions of the hazard posed.[109,112-114] Risk in OSH is defined as, "the likelihood that a person may be harmed or suffers adverse health effects if exposed to a hazard." Risk can be further explained as actual risk (actual hazards/actual control) and perceived risk (perceived hazards/perceived control) which is influenced by individuals' perceptions and is prone to be subjective.[109-111] Studies showed that safety programs are supported when an occupational hazard is matched by a control.[109] Whereas annoyance, low support, fear, outrage with lack of safety support is reported when safety programs don't match the hazards (or perceived hazards).[109] Studies on biosafety laboratory risk assessment emphasized use of relevant knowledge and methods to identify and describe risk which is a systemic, comprehensive, and continuous process.[113-115]

This study highlighted that BPs were more aware of biosafety resources and often utilized various resources during risk assessment compared to RPs as shown in Table 17. It was observed that RPs primarily utilized IBC and risk group of agent's risk assessment whereas BPs utilized various

resources such as risk group of agents, CDC, IBC, peer research and NIH guidelines for risk assessment. Also, it was observed that the awareness on incidents leading to exposure to biohazards and lab acquired infections is greater for BPs than RPs, Table 17. This suggests that the information being applied to assess risk might be different for RPs and BPs leading to differences in risk perceptions. RPs considered the risk level of work conducted in their labs to be "low" risk whereas BPs considered the risk level to "moderate", Table 18. RPs positively rated biosafety practices compared to BPs, demonstrating differences in perceptions on practices in place to ensure biological laboratory safety, Table 18. This indicates that BPs considered the risk to be greater than RPs in biological laboratories because of which they might have perceived the biosafety practices in place less positively than RPs.

The results of linear regression in this study suggested that age positively correlated with BSCL scores of RPs. Holden et al.,[116] in their study on patient safety climate found significant differences on total safety scores based on age. The association of age and BSCL perceptions of RPs needs to be further evaluated so that the needs of specific age group can be met through specific training or information sharing. Communication and management commitment are key aspects of safety culture.[117-118] A positive correlation of total BSCL scores for both RPs and BPs with biosafety practices based on communication and management commitment aspects of safety culture was found. This suggests that a biosafety program that utilizes concepts of safety culture is associated with higher BSCL perceptions. Studies suggest that individuals' perceptions vary based on group-level safety climate(supervisor) and organizational level safety climate (top management).[119] Positive correlation of supervisor priority on COVID-19 precautions on BSCL scores of RPs might indicate that RPS perceptions are driven by supervisor commitment to safety. The negative association of IBC membership on BPs perceptions on item 9, might suggest that there are challenges in communication between RPs and BPs. Since, IBCs are usually composed of members from both biosafety administration and research community.

This study validated BSCL scale utilizing national data collected from public universities with biological and biomedical laboratories in the US. Per my knowledge, this is the first national survey that evaluated BSCL perceptions of two key players of biosafety: researchers and biosafety administrative personnel. Logistic regression was applied to avoid confounding effects[101] by analyzing the association of different item variables together to measure the relationship between item variables and BSCL perceptions of RPs and BPs. However, this study has few limitations. Only biological and biomedical laboratories at public universities in the US were represented in this study, warranting caution when generalizing the finding of this study across public, private, diagnostic, or clinical laboratories across the US or other countries. The data in this study was collected through web-based survey which has its limitations[71] such as not being able to reach the population of interest. This study directly invited only the participants whose emails were publicly available in university websites. This study relied on principal investigators or biosafety officers to share the survey with students or other research personnel in their laboratories whose emails might not be available in university websites. Another limitation of this study is the lack of quantitative data on practices, risk perceptions and hazards that could have been valuable in examining BSCL perceptions.

There are various theoretical and practical implications based on the findings of this study. The BSCL scale for RPs was not only validated but the underlying five factor structure of the BSCL scale construct was confirmed. BSCL scale can be used as a tool to assess BSCL perceptions of RPs and BPs. Safety climate literature recommends examining the perspectives of all parties involved in understanding safety gaps.[25] This study was successful in identifying gaps in safety perceptions by evaluating perceptions of researchers. This study quantified BSCL perceptions, biosafety practices, biosafety perceptions, and research safety during COVID-19 pandemic in public research and teaching biological laboratories of RPs and BPs in the US. RPs and BPs

mostly had positive perceptions on COVID-19 precautions taken to ensure lab safety during COVID-19 pandemic. Insights on the differences in perceptions of BSCL scale items of RPs and BPs was also presented through this study. As previous studies noted,[62] issues in biosafety programs can be addressed proactively by evaluating biosafety climate and safety culture within biological laboratories. The findings from this study contribute to the existing literature on safety climate specific to academic laboratories. The insights gained from this study will be greatly beneficial when developing biosafety management programs or improving existing programs. Individual institutions can utilize the BSCL scale to measure biosafety climate within their institutions and compare with national biosafety climate perceptions. The BSCL scale can be employed before and after an intervention, periodic BSCL assessments and to understand research professionals' perceptions for biosafety program improvement.

Additional studies could be taken up to compare BSCL perceptions in US with other developed and developing countries as well as with nonacademic biological research laboratories. The knowledge gained from the development, validation and BSCL scale administration process can be utilized to develop specific safety climate scale for chemical and radiation laboratories at public universities. Studies on association of biosafety climate perceptions and related safety outcomes such as decreased exposure to biological hazards, fewer lab acquired infections, increased safety participation and increased resources are advised.

Conclusion

This study was conducted to confirm the underlying structure of BSCL scale for RPs and BPs and compare their biosafety climate perceptions in biological and biomedical laboratories at public universities in the USA. The results confirmed a BSCL construct for RPs with five underlying factors: management priority, supervisor commitment, communication, participation, and group

norms. However, for BSCL construct for BPs, the scale could not confirm the underlying factor structure warranting additional studies. The overall BSCL perceptions of RPs and BPs were comparable, however some of the item scores were found to be significantly different. This study showed that there are gaps in perceptions of risk, resources awareness, resource utilization of RPs compared to BPs. This might explain the motivation behind RPs and BPs in perceiving some of items on university support, communication, participation, and group norms differently. For an effective OSH program, a shared vision of hazards and required controls is considered necessary.[109] Additional studies to comprehend the differences in perceptions of risk, practices (controls) in place, resource awareness, resource utilization of RPs and BPs should be considered. Effective biosafety programs can be developed when RPs and BPs work together with a shared vision of implementing appropriate practices (controls) based on actual risk in biological and biomedical research. The results of this study will inform the biosafety community on biosafety climate scale and its application in quantifying safety climate at biological laboratories.

	USA-RP n=690	USA-BP n=157	
Characteristics	N (%)	N (%)	p-value[1]
Gender			0.680
Female	335(48.9)	79(52.7)	
Male	345(50.4)	70(46.7)	
Other	5(0.7)	1(0.7)	
IBC Membership			<0.001
Current	70(10.2)	109(70.3)	
Past	40(5.8)	8(5.2)	
Never	577(63.3)	38(24.5)	
Role			NA
Principal Investigator	359(52)		
Professor	317(45.9)		
Lab Manager	110(15.9)		
Research Assistant	92(13.3)		
GRA/GA/TA	104(15.1)		
Student	78(11.3)		
Other-Research Role	74(10.7)		
Biosafety Officer		90(57.3)	
Assistant Biosafety Officer		18(11.5)	
Research Training Professional		9(5.7)	
Research Safety Professional		28(17.8)	
Other-Biosafety Administration role		44(28.0)	
Educational Background			<0.001
High School	4(0.6)	0	
Bachelors	120(17.5)	38(24.4)	
Masters	71(10.3)	67(42.9)	
PhD	492(71.6)	51(32.7)	
Type of Work			<0.001
Research	670(97.1)	152(96.8)	
Teaching	318(46.1)	145(92.4)	
Diagnostics	45(6.5)	90(57.3)	
Other	6(0.9)	9(5.7)	
BSL Level			<0.001
BSL-1	396(57.4)	147(93.6)	
BSL-2	446(64.6)	148(94.3)	
BSL-2+	93(13.5)	116(73.9)	
BSL-3	32(4.6)	91(58.0)	
BSL-4		2(1.3)	
RG Level			
RG-1	478(69.3)	146(93.0)	<0.001
RG-2	320(46.4)	145(92.4)	
RG-3	48(7.0)	104(66.2)	
RG-4	3(0.4)	3(1.9)	
Research Funding			<0.001
Government	569(82.5)	151(96.2)	
University	410(59.4)	147(93.6)	
Private	175(25.4)	122(77.7)	
Other	12(1.7)	3(0.3)	
Lab Design			
Open Lab	335(53.1)	8(5.8)	<0.001
Closed Lab	159(25.2)	9(6.6)	
Both	137(21.7)	120(87.6)	
Continuous Variable= mean (SD)	USA-RP n=690	USA-BP n=156	p-value[1]
Age (years, continuous)	44.29 (14.12)	47.6 (11.11)	0.005
Experience in current role(years)	9.88 (9.68)	7.644 (6.50)	0.202
Team Size	7.78 (14.45)	3.80 (3.01)	<0.001

Table 13: Characteristics of Study Participants in the USA Biosafety Climate Study (n=847)

Models	χ2	DF	χ2/DF*	NFI	IFI	TLI	CFI	RMSEA
Limit			<2.0-5.0	>.90	>.90	>.95	>.90	<.08
Biosafety Climate Scale for Researchers (n=690)								
Models	χ2	DF	χ2/DF*	NFI	IFI	TLI	CFI	RMSEA
Initial	1101.449	116	9.495	0.898	0.908	0.892	0.908	0.111
Modified	440.594	109	4.042	0.959	0.969	0.961	0.969	0.066
Biosafety Climate Scale for Biosafety Professionals (n=157)								
Models	χ2	DF	χ2/DF*	NFI	IFI	TLI	CFI	RMSEA
Initial	379.099	116.000	3.268	0.840	0.883	0.862	0.882	0.121
Modified	321.401	109	2.949	0.864	0.906	0.881	0.905	0.112

Table 14: Goodness of fit indicators of the Biosafety Climate Scale (n=847)

Biosafety Climate Scale & Proposed Factors	Number of items BSCL-17	Cronbach's Alpha USA-RP n=690	Cronbach's Alpha USA-BP n=157
F1: Management Priority	3	0.892	0.872
F2: Supervisor Commitment	3	0.935	0.927
F3: Communication	3	0.886	0.848
F4: Participation	4	0.908	0.908
F5: Group Norms	4	0.923	0.923
Biosafety Climate Scale	17	0.953	0.955

Table 15: Cronbach's Alpha Coefficients of Biosafety Climate Scale and Factors (n=847)

Note: The validated biosafety climate (BSCL) scale consisted of 17 items and 5 factors for research professionals (RP) and biosafety professionals (BP). Factors 1, 2, 3 ,4 and 5 are represented as F1, F2, F3, F4 and F5 respectively. Factor 1 consisted of items 1, 2 and 3. Factor 2 consisted of items 4, 5 and 6. Factor 3 consisted of items 7, 8 and 9. Factor 4 consisted of items 10, 11, 12 and 13. Factor 5 consisted of items 14, 15, 16 and 17.

Biosafety Climate Scale: Items and Factors (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	USA-RPs n=690		USA-BPs n=157	
	Mean	Std. Dev.	Mean	Std. Dev.
Biosafety Climate Score	69.942	12.513	68.904	11.809
1. The safety of research professionals is a priority for my institution.	4.359	0.842	4.248	0.829
2. University administration considers research professionals' safety to be as important as productivity.	4.028	1.014	3.898	0.955
3. University administration shows support for prevention of biological hazards and incidents through involvement and commitment.	4.136	0.937	3.866	0.975
4. In the laboratory (institution), my supervisor acts quickly to correct problems/issues that affect research professional's safety.	4.345	0.887	4.363	0.848
5. My supervisor clearly considers the safety of research professionals to be of great importance.	4.455	0.818	4.478	0.773
6. My supervisor acts decisively when a concern of a research professional's safety practices is raised.	4.388	0.895	4.401	0.807
7. There is good communication at my institution about biosafety issues which affect me.	3.986	1.081	3.854	0.999
8. Information about proper biosafety practices is always brought to my attention in my institution.	3.951	1.076	3.669	1.028
9. My contributions to resolving biosafety concerns in the institution are listened to.	3.961	1.024	4.076	0.971
10. Research professionals participate in developing best biosafety practices in my institution.	3.743	1.100	3.707	0.989
11. Research professionals are encouraged to become involved in biosafety matters.	3.788	1.093	4.153	0.864
12. At my institution, the promotion of best biosafety practices involves all levels of the organization.	3.639	1.137	3.471	1.089
13. Consultation in developing best biosafety practices involves researchers and biosafety professionals.	3.858	1.094	4.134	0.899
14. In the laboratory (institution), we discuss research professional's safety, biological hazards and incident prevention.	4.249	0.923	4.229	0.815
15. In the laboratory (institution), we care about each other's safety awareness.	4.490	0.776	4.204	0.799
16. In the laboratory (institution), we remind each other of the regulations and guidelines regarding research professional's safety.	4.216	0.917	4.057	0.935
17. In the laboratory (institution), we care about each other's safety compliance.	4.349	0.861	4.096	0.838
Factor 1: Management Priority	12.523	2.541	12.012	2.468
Factor 2: Supervisor Commitment	13.188	2.448	13.242	2.271
Factor 3: Communication	11.897	2.871	11.598	2.626
Factor 4: Participation	15.029	3.918	15.464	3.216
Factor 5: Group Norms	17.304	3.140	16.585	3.009

Table 16: Comparison of Biosafety Climate of Research and Biosafety Professionals in the USA Biosafety Climate Study (n=847)

Biosafety Practices of Research and Biosafety Professionals in the USA	USA-RP n=690			USA-BP n=157		
	N	Mean	Std. Dev.	N	Mean	Std. Dev.
Regulations and guidelines Which of the following regulations and guidelines does the biosafety program follow at your institution? (Select all that apply) (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)						
CDC	641	4.526	0.873	155	4.761	0.511
NIH	640	4.589	0.858	151	4.728	0.702
OSHA BBP	639	4.595	0.906	155	4.794	0.566
Institutional Policies	652	4.724	0.632	156	4.756	0.594
Other	83	3.072	1.659	33	4.455	1.201
University biosafety practices Select all that apply to your institution. (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)						
Regulations and guidelines are strictly followed	687	4.054	0.895	157	3.911	0.827
Everyone is encouraged to know regulations and guidelines	685	4.353	0.855	156	4.263	0.719
Practical Training is given to first time researchers in lab before they begin work	683	4.173	1.030	156	3.782	0.932
Peer to Peer feedback on biosafety issues and safe practices is encouraged	686	3.914	1.037	157	3.834	0.926
Biosafety issues and safe practices are easily communicated	687	4.015	1.007	154	3.909	0.924
Senior management is involved in addressing biosafety issues and improve safe practices	684	3.835	1.096	157	3.573	1.105
Concepts that drive university's biosafety program Which of the following concepts drives the biosafety program at your institution? (Select all that apply) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)						
Regulations (Federal & State such as OSHA, NIH, CDC, DOT and others)	675	4.557	0.650	156	4.596	0.577
Institutional Policies	675	4.455	0.734	157	4.331	0.737
Safety Culture	669	4.039	0.958	155	3.768	1.037
Behavior Based Safety	668	3.647	1.156	155	3.316	1.049
Mode of training given What mode of training is given at your institution? (Select all that apply) (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)						
Online	685	4.304	0.835	157	4.210	0.707
Classroom	656	3.098	1.163	153	3.366	0.901
Hands on by Researchers	667	3.898	1.039	152	3.730	0.884

Hands on By Biosafety	658	2.678	1.145	154	3.078	0.967
Hands on by both researchers and Biosafety professionals	645	2.826	1.220	146	2.911	1.076
Other (animal care, biological hazards, chemical hazards)	74	1.973	1.249	19	2.368	1.257
Training taken with 1 year	Research Professionals: BBP (346), NIH (226), BS (471) Biosafety Professionals: 131 said train bbp every year. 9 every 3 years, 12 others					
Training taken with 3 year	Research Professionals: BBP (362), NIH (313), BS (499) Biosafety Professionals:38 train NIH every year, 56 every 3 years, 5 every 3 years and 47 every other					
Training taken with 5 year	Research Professionals: BBP (341), NIH (324), BS (471) Biosafety Professionals: 68 train BS every year, 40 every 3 years, 3 every 3 years and 41 others					
Biosafety resource awareness Which of the following biosafety resources are you aware of? (Select all that apply) (1-Not at all Aware,2- Slightly Aware,3-Moderately Aware,4-Very Aware,5-Extremely Aware)						
ABSA	612	1.92	1.155	150	4.63	0.670
WHO	626	2.42	1.253	150	4.41	0.868
CDC	658	3.57	1.188	154	4.71	0.533
NIH	654	3.80	1.155	151	4.64	0.615
PSDS	611	1.43	0.953	146	4.18	1.127
OSHA	658	3.71	1.260	150	4.75	0.451
Guidelines for Biosafety Laboratory Competency	642	2.99	1.395	146	3.49	1.266
IBC	659	3.86	1.178	152	4.51	0.719
Other (packaging & shipping--IACUC committee)	35	2.94	1.662	14	4.71	0.469
Resources utilized for risk assessment Which of the following do you utilize to assess the risk of your research and lab activities in your lab? (Select all that apply) (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)						
Risk group of agents	632	3.786	1.279	149	4.624	0.692
Consultation with a biosafety officer	637	3.251	1.196	142	4.246	0.893
CDC	615	3.039	1.321	149	4.557	0.711
NIH	619	3.207	1.414	150	4.387	0.903
PSDS	588	1.320	0.860	144	3.424	1.255
Peer research	571	2.923	1.543	136	4.007	1.085
OSHA	606	3.178	1.577	145	4.352	0.804
IBC	621	3.805	1.306	146	4.493	0.824

Other (IACUC Committee and Citi training)	34	3.000	1.688	10	4.300	0.823
Lab inspection conducted by biosafety program administration The biosafety administration at your institution conducts _____type of laboratory inspections/assessments. (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)						
Announced	587	3.726	1.142	142	4.246	0.908
Unannounced	549	2.525	1.045	136	2.596	1.043
Both	422	2.962	1.187	98	3.255	1.246
Other	48	1.958	1.368	10	2.400	1.265
Biohazard exposure prevention awareness Are you aware of how to prevent exposure to a biological hazard if an incident involving these hazards occurs in your lab? (3-Yes,2-Not Sure,1-No)	686	2.92	0.306	154	2.61	0.575
Incident reporting If incidents involving biohazards occurs in your lab, whom are you required to report to per incident reporting guidelines at your institution? (Select all that apply) (1-if yes, 0-if no)						
Principal investigator	690	0.783	0.413	157	0.885	0.320
Department chair	690	0.291	0.455	157	0.312	0.465
Biosafety officer	690	0.693	0.462	157	0.822	0.384
EHS	690	0.580	0.494	157	0.771	0.422
Government (NIH, CDC, FDA, DOD, OSHA, State)	690	0.052	0.223	157	0.382	0.487
Colleagues in the lab	690	0.343	0.475	157	0.146	0.355
I do not know	690	0.048	0.214	157	0.013	0.113
Other	690	0.033	0.180	157	0.274	0.447
Known biosafety incidents resulting in lab acquired infections Are you aware of any biosafety incidents resulting in Lab Acquired Infections in your lab during 2016 to 2020? (1-Yes,0-No)	685	0.010	0.101	155	0.123	0.329
Known biosafety incidents resulting in exposure to biohazards Are you aware of any biosafety incidents resulting in exposure to biological hazards in your lab during 2016 to 2020? (1-Yes,0- No)	686	0.055	0.229	155	0.516	0.501

Table 17: Biosafety Practices of Research Professionals and Biosafety Professionals in the USA Biosafety Climate Study (n=847)

Biosafety Perceptions of Research and Biosafety Professionals in the USA	USA-RP n=690			USA-BP n=157		
	N	Mean	Std. Dev.	N	Mean	Std. Dev.
Perception on university biosafety practices How do you rate biosafety practices at your university? (3-Good as is,2-Can be improved, -Undergoing improvements)	686	2.64	0.543	156	1.90	0.592
Perception on risk level of work conducted in the lab What do you consider the risk level of work conducted in your lab? (5-Very Low,4-Low,3-Moderate,2-High,1-Very High,0-I Don't Know)	686	3.94	0.809	156	2.97	0.75305
Perception on measures taken in the lab against hazards Do you believe your lab takes strong measures to protect you from the hazards of the work conducted in your lab? (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	686	4.28	0.882	156	3.97	0.822
Perception on university's Biosafety program in mitigating risks Do you consider the biosafety program at your university to be effective in mitigating risks in your lab? (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	686	4.00	0.951	157	4.02	0.738
Perception on practices that improve adherence to safety practices & mitigate risk in lab Which of the following do you believe would improve adherence to safety practices and mitigating risks in your lab? (Select all that apply) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)						
Regulations and guidelines are strictly followed	637	4.04	0.825	139	3.99	0.691
Everyone is encouraged to know regulations and guidelines	646	4.25	0.747	142	4.24	0.673
Practical Training is given to first time researchers in lab before they begin work	646	4.38	0.822	145	4.37	0.734
Peer to Peer feedback on biosafety issues and safe practices is encouraged	648	4.12	0.876	146	4.28	0.803
Biosafety issues and safe practices are easily communicated	640	4.20	0.816	147	4.39	0.647
Senior management is involved in addressing biosafety issues and improve safe practices	641	3.90	0.988	143	4.27	0.771
Perception on lab inspections Select the type of laboratory inspections/assessments you consider to be effective. (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)						
Announced	534	4.15	0.799	122	4.07	0.773
Unannounced	528	3.92	0.968	119	4.08	0.926
Both	540	4.09	0.814	126	4.34	0.695

Other	27	2.63	1.305	11	4.45	0.688
Perception on training format Select the following training format that you believe could improve biosafety at your institution. (Select all that apply) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)						
Online	600	3.73	1.024	138	3.87	0.809
Classroom	584	3.58	1.016	139	3.91	0.751
Hands on by Researchers	589	4.01	0.934	141	4.30	0.643
Hands on By Biosafety	608	3.98	0.960	142	4.19	0.694
Hands on by both researchers and Biosafety professionals	588	3.99	0.956	145	4.37	0.633
Other (animal care, biological hazards, chemical hazards)	53	3.11	1.187	21	3.86	1.236
Perception on lab design Which lab design do you believe is safer: (Select appropriate response) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)						
Open	503	3.06	1.045	110	2.41	0.961
Closed	545	3.90	0.901	131	4.30	0.720
Both	319	3.45	0.803	84	3.29	1.001
Perception on lab design type preferred Which lab design do you prefer to work at: (Select appropriate response) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)						
Open	508	3.57	1.157	109	2.49	1.085
Closed	480	3.73	1.100	124	4.35	0.722
Both	301	3.52	0.831	81	3.26	1.034

Table 18: Biosafety Perceptions of Research Professionals and Biosafety Professionals in the USA Biosafety Climate Study (n=847)

	USA-RP n=690			USA-BP n=157		
Perceptions on Research Safety of Research and Biosafety Professionals in the USA during COVID-19 Pandemic In relation to COVID-19 and your activity in research labs, do you feel: (Select appropriate response) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	N	Mean	Std. Dev.	N	Mean	Std. Dev.
Feel safe working in labs (Research labs are safe)	674	4.22	0.853	154	4.18	0.658
University prioritizes COVID-19 precautions in labs	675	4.30	0.939	153	4.43	0.686
Supervisor prioritizes COVID-19 precautions in labs	674	4.48	0.788	151	4.47	0.671
Good communication on changes in lab safety	672	4.22	0.970	152	4.26	0.801
In lab, peers (researchers') are complying with lab safety and covid-19 precautions	670	4.28	0.866	154	4.17	0.748
COVID-19 precautions are imposing additional challenges to lab safety	671	3.84	1.144	154	4.01	0.871

Table 19: Biological Laboratory Safety of Research and Biosafety Professionals During COVID-19 Pandemic in the USA Biosafety Climate Study (n=847)

Coefficients	Estimate	Std. Dev.	z Value	p-Value
Intercept	-1.51225	0.64093	-2.359	0.018302 *
1. The safety of research professionals is a priority for my institution.	-0.17079	0.20613	-0.829	0.407334
2. University administration considers research professionals' safety to be as important as productivity.	0.29018	0.17255	1.682	0.092623.
3. University administration shows support for prevention of biological hazards and incidents through involvement and commitment.	-0.71255	0.18683	-3.814	0.000137 ***
4. In the laboratory (institution), my supervisor acts quickly to correct problems/issues that affect research professional's safety.	0.123	0.24006	0.512	0.608395
5. My supervisor clearly considers the safety of research professionals to be of great importance.	0.0539	0.26989	0.2	0.841701
6. My supervisor acts decisively when a concern of a research professional's safety practices is raised.	0.26263	0.24704	1.063	0.287723
7. There is good communication at my institution about biosafety issues which affect me.	0.07038	0.17116	0.411	0.680942
8. Information about proper biosafety practices is always brought to my attention in my institution.	-0.40404	0.16688	-2.421	0.015471 *
9. My contributions to resolving biosafety concerns in the institution are listened to.	0.49362	0.16409	3.008	0.002628 **
10. Research professionals participate in developing best biosafety practices in my institution.	-0.54617	0.16249	-3.361	0.000776 ***
11. Research professionals are encouraged to become involved in biosafety matters.	1.14721	0.1865	6.151	7.68e-10 ***
12. At my institution, the promotion of best biosafety practices involves all levels of the organization.	-0.40682	0.14817	-2.746	0.006041 **
13. Consultation in developing best biosafety practices involves researchers and biosafety professionals.	0.50184	0.14361	3.495	0.000475 ***
14. In the laboratory (institution), we discuss research professional's safety, biological hazards and incident prevention.	0.30694	0.196	1.566	0.117333
15. In the laboratory (institution), we care about each other's safety awareness.	-0.80888	0.25614	-3.158	0.001589 **
16. In the laboratory (institution), we remind each other of the regulations and guidelines regarding research professional's safety.	0.26818	0.2161	1.241	0.214599
17. In the laboratory (institution), we care about each other's safety compliance.	-0.50689	0.24848	-2.04	0.041351 *
Biosafety Climate Score	-0.006577	0.006945	-0.947	0.3436

Table 20: Logistic Regression Comparing Research and Biosafety Professionals in the USA Biosafety Climate Study (n=847)

Note: The results of fitting a logistic regression model on Biosafety Climate Survey dataset. Estimate is the logs odds ratio and Signif. codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1, .

Results from Linear Regression of Research Professionals BSCL scores and variables (n=690)			Results from Linear Regression of Biosafety Professionals BSCL scores and variables (n=157)		
Variable	Estimate	P-Value	Variable	Estimate	P-Value
Age	0.115324	0.006766	Age	0.033458	0.714025
Biosafety issues and safe practices are easily communicated	2.081987	4.02E-05	Senior management is involved in addressing biosafety issues and improve safe practices	3.10716	7.59E-04
Perception on university's Biosafety program in mitigating risks	5.828477	3.29E-30	Perception on university's Biosafety program in mitigating risks	8.657818	1.61E-07
Supervisor prioritizes COVID-19 precautions in labs	3.027694045	3.72E-05	Research labs are safe during COVID-19 pandemic	3.82946913	0.023011298

Table 21: Linear Regression of Biosafety Climate (BSCL) Scores of Research and Biosafety Professionals in the USA (n=847)

Results from Ordinal Regression of Research Professionals BSCL items scores and variables (n=690)

Variable	Item Name	Estimate	P-value
Age	Item 1: The safety of research professionals is a priority for my institution.	0.0210329	0.0017237
Peer to Peer feedback on biosafety issues and safe practices is encouraged	Item 1: The safety of research professionals is a priority for my institution.	0.7987449	0
Perception on university's Biosafety program in mitigating risks	Item 7: There is good communication at my institution about biosafety issues which affect me.	1.3429292	0
Supervisor prioritizes COVID-19 precautions in labs	Item 5: My supervisor clearly considers the safety of research professionals to be of great importance.	1.0875542	0

Results from Ordinal Regression of Biosafety Professionals BSCL items scores and variables (n=157)

Variable	Item Name	Estimate	P-value
IBC Membership	Item9: My contributions to resolving biosafety concerns in the institution are listened to.	-0.6019327	0.0267659
Research labs are safe	Item 1: The safety of research professionals is a priority for my institution.	1.0723065	0.0008514

Table 22: Ordinal Regression of Individual BSCL Scale Items of Research and Biosafety Professionals in the USA (n=847)

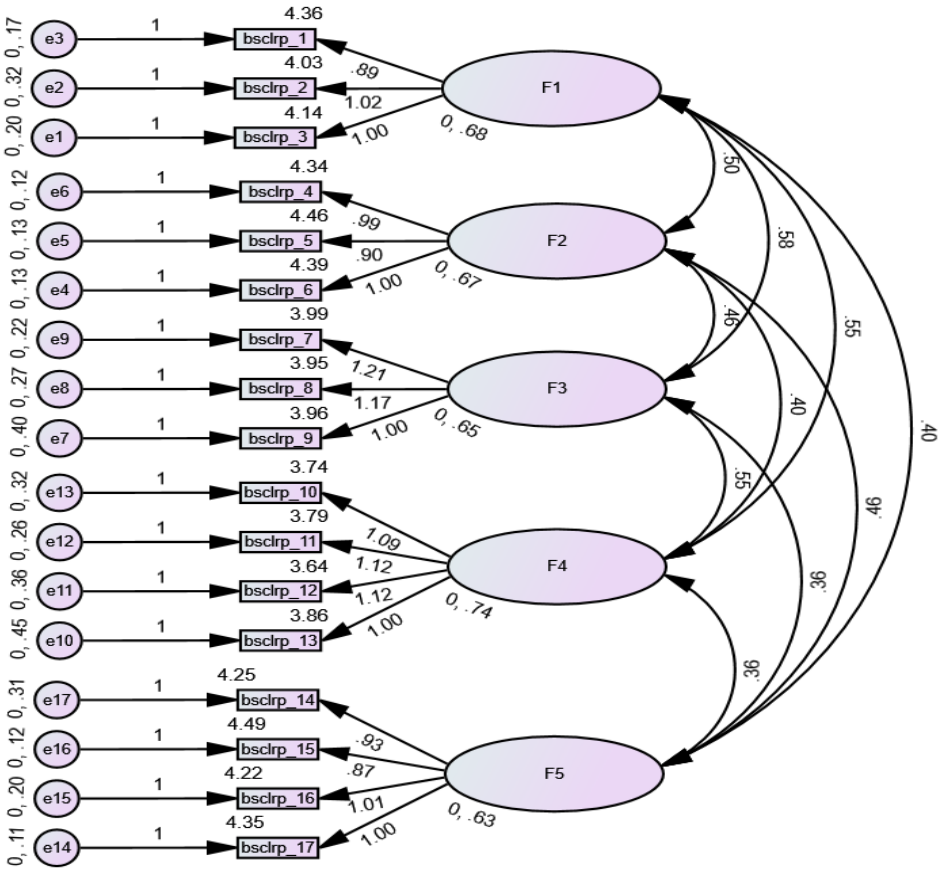


Figure 6: Confirmatory Factor Analysis of Biosafety Climate Scale for Researchers at USA(n=690), Unstandardized Estimates of 5 Factors

Note: CFA results of unstandardized estimated of 5 factors are presented. 17 items are represented as bsclrp_1 to bsclrp_17 for the 17 items of Research Professionals Biosafety Climate (BSCL-17) scale. The five factors are presented as management priority (F1), communication (F2), participation (F3), group norms (F4), and supervisor commitment (F5). The variance, that is the amount of change on dependent variable is 0.68, 0.67, 0.65, 0.74 and 0.63 for the five factors. The covariance that is the amount of change in single predictor variable ranged from 0.36 to 0.58.

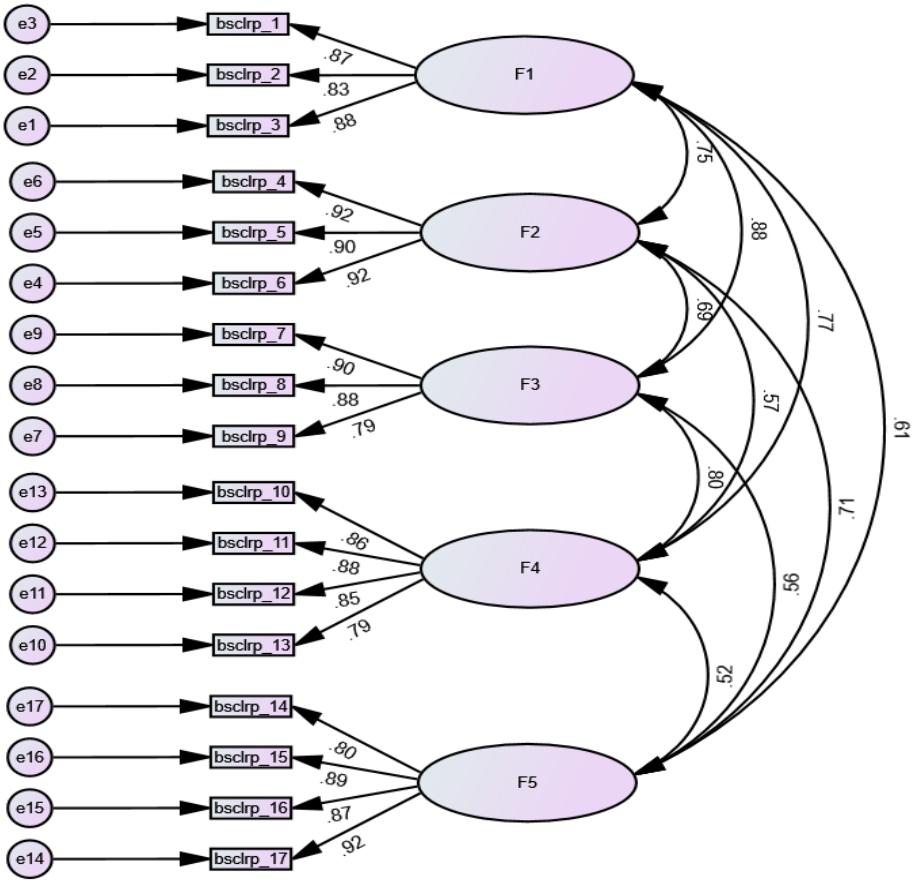


Figure 7: Confirmatory Factor Analysis of Biosafety Climate Scale for Researchers at USA(n=690), Standardized Estimates of 5 Factors

Note: CFA results of standardized estimated of 5 factors are presented. 17 items are represented as bsclrp_1 to bsclrp_17 for the 17 items of Research Professionals Biosafety Climate (BSCL-17) scale. The five factors are presented as management priority (F1), communication (F2), participation (F3), group norms (F4), and supervisor commitment (F5). The factor loading estimates (higher the better) ranged from 0.79 to 0.92 and were acceptable. The correlations between the factors ranged from 0.52 to 0.88.

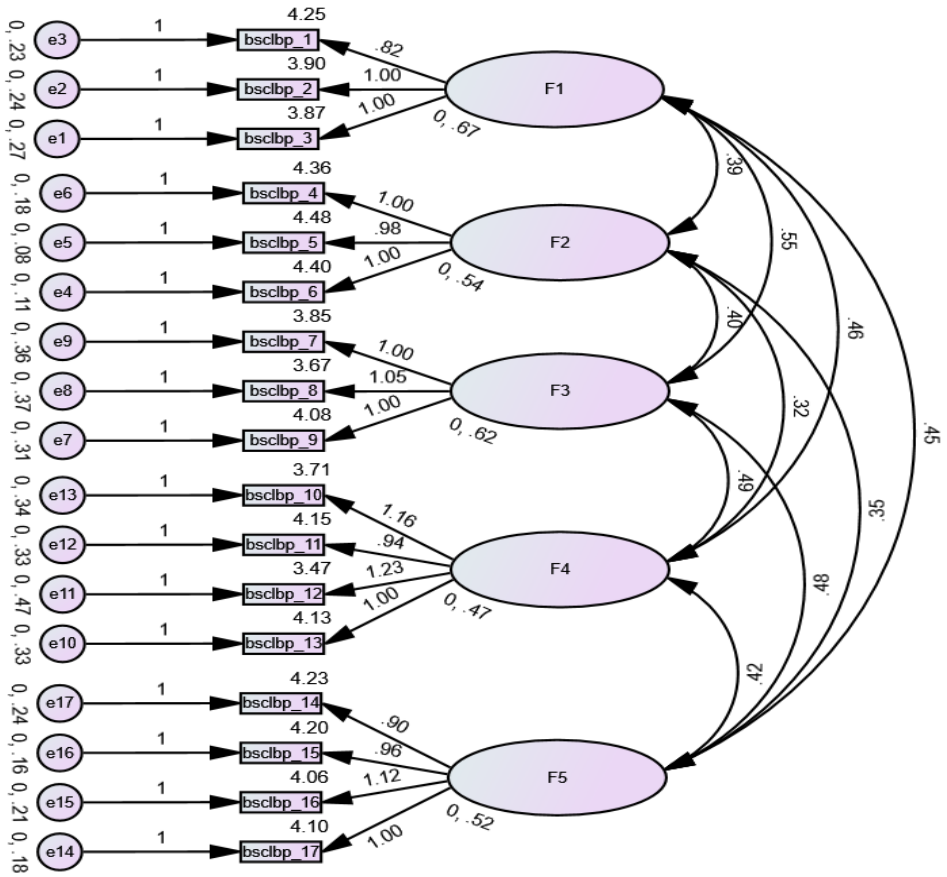


Figure 8: Confirmatory Factor Analysis of Biosafety Climate Scale for Biosafety Professionals at USA(n=157), Unstandardized Estimates of 5 Factors

Note: CFA results of unstandardized estimated of 5 factors are presented. 17 items are represented as bsclbp_1 to bsclbp_17 for the 17 items of Biosafety Professionals Biosafety Climate (BSCL-17) scale. The five factors are presented as management priority (F1), communication (F2), participation (F3), group norms (F4), and supervisor commitment (F5). The variance, that is the amount of change on dependent variable is 0.67, 0.54, 0.62, 0.47 and 0.53 for the five factors. The covariance that is the amount of change in single predictor variable ranged from 0.35 to 0.55.

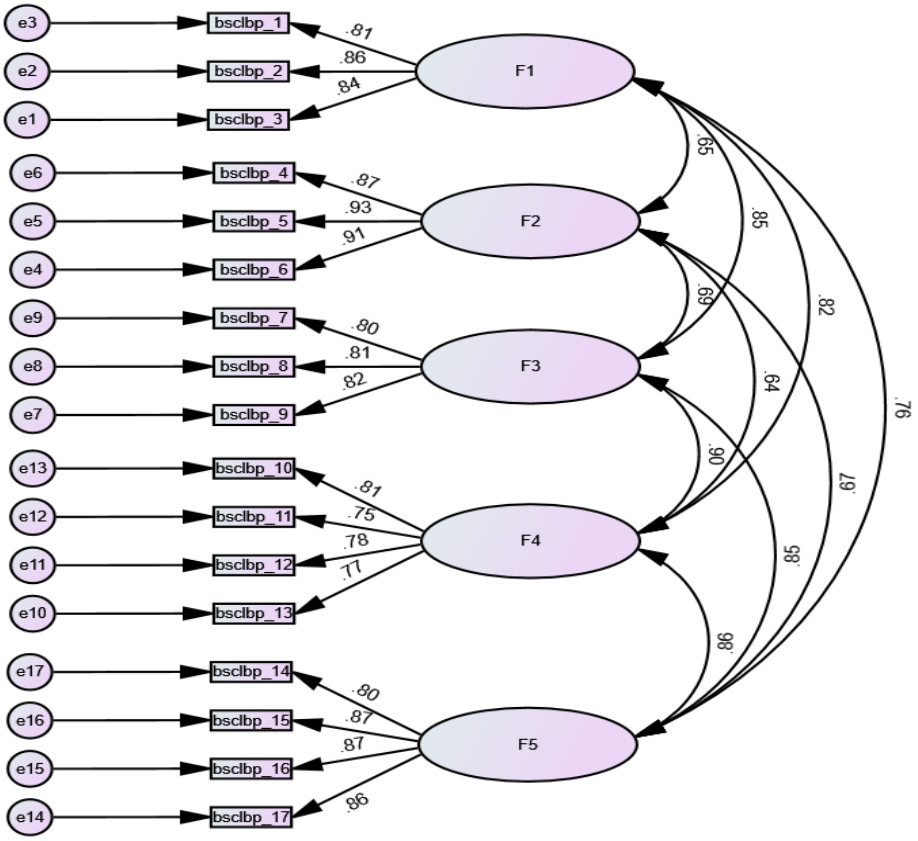


Figure 9: Confirmatory Factor Analysis of Biosafety Climate Scale for Biosafety Professionals at USA(n=157), Standardized Estimates of 5 Factors

Note: CFA results of standardized estimated of 5 factors are presented17 items are represented as bsclbp_1 to bsclbp_17 for the 17 items of Biosafety Professionals Biosafety Climate (BSCL-17) scale. The five factors are presented as management priority (F1), communication (F2), participation (F3), group norms (F4), and supervisor commitment (F5). The factor loading estimates (higher the better) ranged from 0.75 to 0.93 and were acceptable. The correlations between the factors ranged from 0.64 to 0.90.

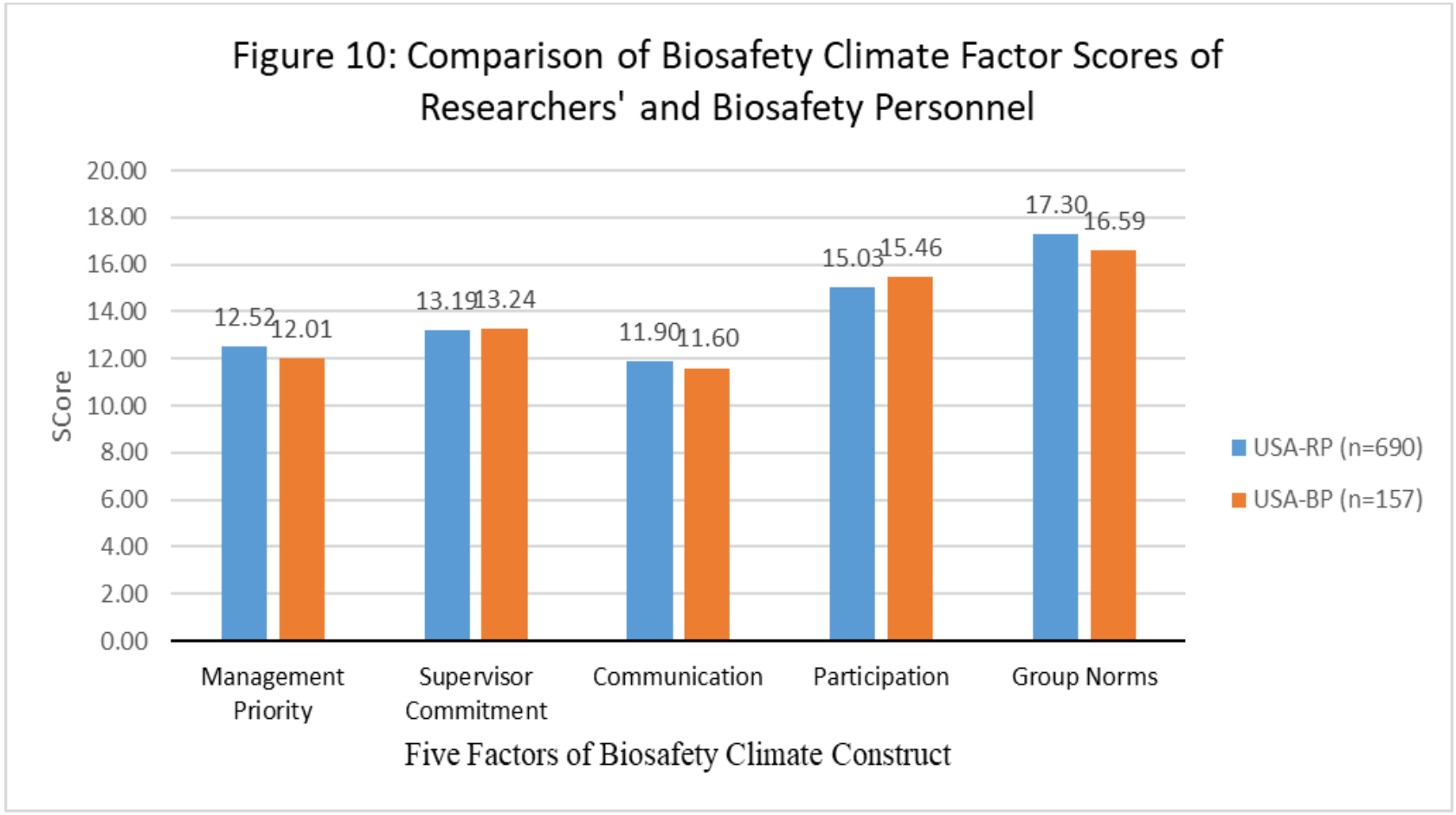


Figure 10: Comparison of Biosafety Climate Factor Scores of Researchers' and Biosafety Personnel
20.00
18.00
16.00
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
SCore
12.52
12.01
13.19
13.24
11.90
11.60
15.03
15.46
17.30
16.59
Management Priority
Supervisor Commitment
Communication
Participation
Group Norms
Five Factors of Biosafety Climate Construct
USA-RP (n=690)
USA-BP (n=157)

CHAPTER 5: IMPACT OF BIOSAFETY PROGRAM MANAGEMENT ON BIOSAFETY CLIMATE AT UNIVERSITY OF LOUISVILLE

Introduction

In the previous chapters, research on biosafety climate at academic universities in the United States of America as well as at University of Louisville (UofL) in the recent years was presented. This chapter presents my research on the impact of biosafety program management on biosafety climate over the period of 2011 to 2021 at UofL.

Literature identified aspects of management styles that play an integral role in building a safety culture that fosters trust, openness to communication on safety issues and sharing of safety information.[120] Key organizational elements such as management commitment, workforce involvement, participation, training, management, polices and communication are known to play a role in supporting safety climate in workplace.[48] A culture that has a command-and-control management style results in a rule and discipline approach that results in managers issuing orders instead of eliciting safety related information from workers.[120] Characteristics of a positive safety culture encompasses approaches that are non-disciplinary, proactive in collecting data on at-risk behaviors, safety analysis using objective data, and cooperative by engaging stakeholders within both management and labor.[120-122]

Though there are studies examining management styles and its impact on safety culture and climate, there are none to my knowledge that specifically evaluate the effect of biosafety program

management practices on biosafety climate. To address this gap, we examined biosafety program management in place and its influence on biosafety climate.

The hypothesis being tested in this study was whether changes in biosafety program management style is associated with biosafety climate perceptions. The null hypothesis being tested is that changes in biosafety program management style does not impact with biosafety climate. To test this hypothesis, the biosafety programs in place at UofL during two different periods of time and their impact on biosafety climate and safety perceptions of researchers at UofL's biological and biomedical research laboratories were examined.

This study differentiated the biosafety program management models in place at UofL based on two periods: one prior to December 31, 2014, and the second after January 01, 2016. The biosafety program in place prior to 2014 has been referred to as Biosafe-1 and the biosafety program in place since 2016 as Biosafe-2 in this study. The year 2015 was considered as a transition year in this study, during which many changes were made to the biosafety program management at UofL such as: addition of full-time employees that included a biosafety officer, training specialist and lab safety specialist, update of Biosafety manual, changes to Institutional Biosafety Committee (IBC) review process, changes to training, changes in lab assessments, and other changes in management practices. UofL went through a documented change around 2014 that resulted in a change in its biosafety program management. This change in biosafety program management at UofL presented a unique opportunity that has been utilized in this study to compare the different management styles and its impact on biosafety climate.

Rationale & purpose of the study

The study's purpose was to identify the biosafety program management model in place before December 31, 2014, and after January 01, 2016, at UofL and evaluate biosafety climate and

safety perceptions during these two periods. By examining the practices in place and their impact on safety and biosafety climate perceptions, we can determine the aspects of a biosafety program that aid in improving safety climate.

The University of Louisville Institutional Review Board reviewed the study design and protocols. The study was classified as Non-Human Subjects Research (NHSR) and was granted permission to proceed (IRB 18.1222, Appendix G). All institution policies and guidelines on participant privacy were followed.

Methods

The study being observational in nature utilized a retrospective cohort design.[123-124] Quantitative approach focuses on breadth and generalizability of a given concept whereas qualitative approach allows to understand a given issue from the perspective of the study participants.[125-126] Qualitative approaches are suited for addressing research questions like "how, and "why" to understand the context whereas questions like, "what", "when" and "how long" are better addressed by quantitative approaches.[127] For this reason, we employed both quantitative and qualitative approaches through interviews, review of past and current documents and questionnaires from UofL's Department of Environmental Health and Safety (DEHS) office which manages the UofL's Biological Safety Program.

Participant Sampling, Subject Recruitment and Enrollment

The study participants consisted of research professionals (RPs) engaged in biological research utilizing risk group (RG) 1, 2 and 3 agents at UofL laboratories. The goal was to recruit at least 12 subjects in the study. Julious, recommended a sample size of 12 per group as a rule of thumb for pilot study based on feasibility, regulatory considerations, and precision about mean and

variance.[128] The inclusion criteria for the participants were: a) involved in biological research for at least six months prior to December 31, 2014 and at least six months since January 01, 2016, b) must be working with biological agents belonging to risk group (RG) 1, 2 or 3 agents at biosafety level (BSL) 1, 2 or 3 laboratories, and c) should be 18 years or older. The RPs consisted of principal investigators, research staff and lab managers. The exclusion criteria consisted of any researchers not involved in biological research activities at UofL.

Participants were recruited by sending a subject recruitment email to everyone in the email list of UofL researchers that was provided by the biosafety personnel at DEHS. This email list consisted of past and current researchers at UofL involved in chemical, animal, clinical and biological research activities. The email was first sent on March 09, 2021, followed by two reminders. The email requested research personnel and any members from Institutional Biosafety Committee (IBC) who engaged in biological research activities at UofL to respond if interested in the study. The subject recruitment email had details on inclusion criteria, study purpose, confidentiality statement, brief details of the study and contact information of Torsten Hopp and Sivarchana Mareedu. Please see attached recruitment letter in Appendix H.

Potential study participants who responded through email or phone were provided with further details of the study, Appendix I. Details on interview and questionnaire was shared with the participants. Any questions on the study were answered through phone or email. Those who met the inclusion criteria of the study and agreed to participate in both interview and complete the survey were enrolled in the study. No compensation was provided to the study participants.

Data Collection

Quantitative and qualitative data was collected through interviews, surveys and review of biosafety program records and documents from both the periods of study.

Interviews

A semi structured interview guide was utilized to conduct interviews of study participants over Microsoft Teams or phone. The interview guide consisted of the following components. Please see attached interview guide in Appendix J.

- Confidentiality Statement: Sivarchana Mareedu read the confidentiality statement prior to the commencement of the interview. It stated that all identifying information will be removed and that the interview will be recorded if permitted.
- Study Background: A brief background on biosafety climate and the two time periods being investigated through the study was explained.
- Study Details: Details on phone/virtual interview and survey questionnaire was shared. Inclusion criteria was reiterated to ensure the participants met the criteria.
- List of Topics: The topics covered in the interview was listed, which included biosafety administration, safety practices, safety concerns, safety perceptions, and perceptions on COVID-19 pandemic precautions to ensure safety in laboratories.
- Survey Details: A link to the survey was shared with the participants at the end of the interview. They were requested to complete the survey within a week.

Sivarchana Mareedu recruited the participants, scheduled, and conducted all the interviews. All the questions in the interview were open ended. Participants were encouraged to discuss any relevant topic not listed in the guide. Mareedu took notes during the interview.

Review of Past and Current Biosafety Programs

Biosafety program records and documents at UofL such as training materials, training records, IBC protocols, IBC minutes, lab assessment and other related documents during the period of 2011 to 2021 were reviewed.

Survey Administration

A biosafety climate questionnaire was shared with study participants at the end of their interviews through REDCap. The survey was divided into four parts: a) demographic questions, b) questions based on period prior to December 31, 2014 (Biosafe-1), c) questions based on period since January 01,2016 to present (Biosafe-2), and d) current perceptions on lab safety. The questionnaire consisted of biosafety climate (BSCL) scale that was developed and validated in Chapter-2, questions on biosafety practices, biosafety perceptions, and perceptions on biological laboratory lab safety during COVID-19 pandemic at UofL. Questions on background such as age, gender, educational level, trainings, type of work conducted, and work environment were also asked. All the items in the BSCL scale were positive and measured on a five-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). All questions were optional to respond except for BSCL scales, questions on name and contact email or phone number. Survey has been shared in Appendix K.

Data Management and Analysis

The virtual interviews were recorded once the confidentiality statement was read to the participants and their permission to record was received. Only Sivarchana Mareedu had access to these recordings that were stored in a password-protected computer. Mareedu collected and summarized the interview recordings. Once the required data was collected, the recordings were erased. The survey data collected was exported from REDCap into Microsoft Excel for data cleaning and management. Data analysis was performed on only surveys that were completed. All participants were assigned a numerical identifier which was assigned to their completed surveys before sharing with Riten Mitra, who guided with data analysis.

Statistical Analysis

All analysis were conducted in R (R Core Team, 2021). For continuous variables, independent samples t-tests (for normal distribution), Wilcoxon methods (for non-normal distribution) and Fishers Exact Test for categorical variables was utilized to compare RPs responses during the two periods in the study. Differences in research professionals' perceptions during Biosafe-1 and Biosafe-2 was examined using the Wilcoxon signed-rank test.

Results

All identifying information was redacted from surveys and interview summaries before presenting the results.

Sample Size and Participant Characteristics

The subject recruitment email was sent to 4800 researchers at UofL whose emails were listed in the Listserv shared by the biosafety administration at DEHS. 45 responses were received, out of which 18 were excluded as they did not work in biological research laboratories, 6 were excluded as they did not work in biological research laboratories prior to 2014, 21 met the inclusion criteria and showed interest to participate in the study. These 21 participants were sent further details on the study out of which 15 researchers agreed to participate and 6 participants did not want to proceed citing time constraints. Interviews were scheduled with the 15 participants during the March 17 to April 13, 2021. At the end of each interview, participants were encouraged to complete the survey within a week. 15 researchers completed the survey, which met our minimum sample size requirement of 12.

The interviews lasted from 41 minutes to 1 hour 55 minutes, with an average of 72 minutes per interview. Participant characteristics are expressed as n (%) for categorical variables and mean

(SD) for continuous variables. The characteristics of the participants during the Biosafe-1 and Biosafe-2 period are shown in Table 23. The sample population during Biosafe-1 was majorly male (n=8, 53.3%), aged (45.54 years), had post doctorate (n=8, 53.3%), in the role of principal investigators (n=8, 53.3%) conducted research (n=15, 100%), worked at BSL-2 setting (n=86.7%), worked with RG-1 (n=14, 93.3%), in closed labs (n=7, 46.7%), at Health Science Campus (HSC) (n=9, 60%), with government funding (n=12, 86.7%), had an average team size of 5.8 and 11.33 years of experience in current role. The sample population during Biosafe-2 was majorly male (n=8, 53.3%), aged (51.54 years), had post doctorate (n=9, 60%), in the role of principal investigators (n=9, 60%) conducted research (n=15, 100%), worked at BSL-2 setting (n=12, 80%), worked with RG-1 and RG-2(n=11, 73.3%), in both closed and open labs (n=5, 33.3%), at Health Science Campus (HSC) (n=11, 66.7%), with government funding (n=14, 93.3%), had an average team size of 7.07 and 12.47 years of experience in current role.

Interview Summary

The topics discussed during the interview are summarized below. The same questions were asked to each of the study participants by Mareedu to keep the interview process consistent. The participants were asked to respond to each of the questions regarding Biosafe-1 and Biosafe-2.

a. Biosafety Administration

Questions were posed on biosafety program to examine the changes in program administration, accessibility of resources, changes in trainings, lab assessments, IBC review process, and perceptions on university administration's priority on biosafety over the years.

Biosafety administration was described as adversarial, less flexible, overreacting, overly fearful, combative, and confrontational prior to 2014. Since 2016, it was described as

collaborative, a partnership between researchers and administration, conducive to research and approachable.

- " Prior to 2014, it did seem a little more adversarial compared to the current administration. And I think the one shift that I have seen is more of, we are here to monitor you to more of we are here to help you."
- "Did not start off collaborative, we were to develop our own protocols and then they would tell us whether they were wrong. And then we would have to redo them. Only they wouldn't give us much feedback as to what should be changed. After 2016 we would get a set of responses back in which there would be queries about some of our protocols and then invitations to talk about them. And you know, to discuss them back and forth and so it became more collaborative."
- "Regulatory driven to almost like we're just really dotting our I's and crossing the T's because we have to have IBC in place. Culture of fear before but now gotten better. Since 2016, things have changed but feel more hands off."
- "Since 2016 dramatic change in communication and realization of actual risk involved".
- "2010-2014-hurdles much higher than other institutions I worked at. Though regulations were same, practices not appropriate for risk, unnecessary administrative burden on PI ex: biosafety protocol renewal every year."
- "My sense currently is it's more of a collaborative effort and what's best to ensure that things are done in a safe or correct way. Whereas in the past it was more about you know just, follow the rules. Here's the rules. You know, wasn't much thinking outside of that lane. Here's what we're supposed to do, we're doing it."

Trainings prior to 2014 were mostly given through in class sessions and PowerPoint presentations whereas since 2016 it has shifted towards online sessions except for initial

training. The content of the training material has been described to be similar during both periods though updates in the platforms being used, content displayed and quizzes since 2016 has been expressed. Participants noted increase in training reminders since 2016 which they considered to be a positive change. However, one participant did say that they find the trainings since 2016 to be more time consuming though not learning anything new.

- "Classroom training was always kind of a pain because it was only offered once a month or so, but I think it's gone virtual, and I really liked the changes in the training modules. They look amazing, just how they are now presented with the section. Yeah, and I don't mind the quizzes of course. I like the reminders as well."
- "Not sure, same online training but feel can reach out if I have any questions."
- “Quizzes and trainings are longer now.”
- "More online trainings-same information but different format like sway I think, and I did not like it as it got difficult but not learning anything new, just time consuming."

Participants expressed a mixed opinion on changes to accessibility of biosafety resources between the two periods. They noted that it has improved over the years as more resources are available in the DEHS website but that it could be further improved.

- "Not many repositories in UofL website, I just google. More information during 2015, but not much useful information since. Generally good but can be improved."
- “Find it easily accessible at DEHS website.”
- “I just google or ask peers.”
- “Could be improved, but I think everything is available with little effort.”
- “Not sure, I think we had access before too. Now it is more personal access.”
- “Never went to UofL website, we just use standard protocols.”

A change in lab assessments was mentioned by the participants during Biosafe-1 and Biosafe-2. Participants described a positive change regarding how lab assessments were conducted since 2016 compared to previous years. They stated an increase in lab assessments, use of self-assessment checklists and announced inspections during Biosafe-2. However, few participants noted that they were never inspected either during Biosafe-1 or 2. Few participants stated that they were not aware of lab assessments, but it could be because someone else in their lab took care of it.

- "Self-assessments now, biosafety team comes and walks together with principal investigators (PIs) or lab personnel. Prior, inspections focused on finding what's wrong and felt truly like an inspection, now it is more like find what is wrong/right and look at the process. Now it is more like let's work together."
- "Self-assessment now, I feel they are more biased, no lab will go after themselves and are conducted every 1 to 3 years and it is up to lab to request one. I never got a reminder saying you have to do one, so there is little oversight."
- "Before 2014, I don't remember lab inspections, only few if any. Now self-assessments and then Biosafety personnel comes in, knowing what to do or expect is easy."
- "Announced is collaborative whereas unannounced is presumptive or there could be no one in lab."
- "Lab assessment prior to 2014 not very routine, not sure if in place but since 2016 there are self-assessments."
- "Before 2014, don't remember. IACUC and IRB remember annual but IBC only after 2016 has been more visible. Had assessment once since 2016."
- "Lab inspections before were announced did not seem scientific but now extreme opposite is happening with no lab assessments."

The participants consisted of four current IBC members, one was a past IBC member and ten were never members of IBC. All the participants noted key changes in IBC submission processes between Biosafe-1 and Biosafe-2. They stated that prior to 2014, IBC protocols were submitted through snail mail or electronic paper copies whereas since 2016 it has moved towards use of iRIS system. The time taken to process an IBC protocol improved from 3 to 4 months during Biosafe-1 period to 1 to 2 months during Biosafe-2. However, participants noted difficulties with the current online process sometimes being challenging due to iRIS system not being user friendly.

- “You had to put together a protocol and address the various aspects of risk and so forth. But I would say that there was not as much help for the investigator in terms of what the committee was looking for. And so, I think that has improved since 2014, I think. "
- "It was not clear to investigators what exactly the committee was looking for, what people tended to do was to cut and paste material from you know, like NIH grants into the protocol they were using. But since 2016, lot clearer, no need to give proposal just tell kind of techniques and risks associated.”
- "Prior to 2014, it took forever. Yes, that is one thing that I remember very clearly. These things were a nightmare to do for us because we wait for 4-5 months before we even get an approval. I remember that certain times when there was a little bit of gap where I didn't have an approved IBC protocol for my lab. That is scary. It was a nerve-wracking experience because it's a mess and we shouldn't be continuing research, but we cannot stop work and it's a gray area. When we ask them, they say okay it's in review. iRIS is now taking much less time, maybe 1-2 months now."
- "I remember it being a frustrating process, yeah and then it was snail mail." Took up to 3 months before, now 30-45 days, much better turn around rate.
- “Prior to 2014, submit every year…but now only if there are modifications."

- Prior to 2014, “It was a huge administrative burden, and you know the problem with unnecessary administrative burden is that it leads to people not doing everything right."
- “Not much changed regarding the review process over the years, online review did add more complications. PDF was easier. Technology is hard to understand but easier to update or renew.”
- “Before if there were any problems during IBC review, it was kept hush-hush whereas now it is shared within IBC community.”
- During Biosafe-1, “IBC focused more on details not as much on risk involved”.
- “Less push back than before during IBC submission process by PIs. Some PIs don't agree but it's not escalating like before.”

On perceptions of management priority to safety, participants had mixed response. Few stated that the university’s priority has not changed between the two periods. A couple of participants noted an increase in management’s priority to biosafety over the years. However, they noted that it could be further improved. Participants expressed that the priority on biosafety was always higher within labs compared to departments or at university administration level.

- "I think the priority at the department level definitely increased over the years."
- It has always been up to the PI and nothing changed at department level but definitely gotten better at university level.”
- “They prioritize now because of NIH…it’s an evolution. So unfair to previous committees to compare as they did with what they could with the resources they had.”
- “I don't know if there is awareness at the department level at this point. My department chair is not involved. They are only involved if there is an issue, and it depends on the person's background.”

- “Too much trust in researchers, lack of priority, feels like not a high priority, it is more up to researchers.”
- “DEHS/biosafety high priority and truly concerned about safety, UofL motivation is more priority on liability or bad publicity or penalty than safety.”

b. Safety Practices

Questions were posed on safety practices to examine communication, participation, and group norms between the two periods of Biosafe-1 and Biosafe-2.

Participants expressed that communication has evolved over the years between researchers and biosafety team. Most of the participants said that they found the biosafety administration during both periods accessible and did not had any issue communicating through email or phone. Participants did mention an increase in communication during the Biosafe-2 period in the form of safety newsletters, email reminders on trainings and safety fair that was conducted as part of DEHS outreach. However, few participants noted that they do not read the newsletters and were not aware of newsletters or safety fairs.

- "There used to be one poster everywhere about IBC. That's all I remember before. Now I feel like, there is a little more. Specially electronically. Things have been much more streamlined, Communication is better, it became much more accessible."
- “Prior to 2014 don't remember. Since 2016 better communication about updates, biosafety issues around nation, good communication about changes that impact.”
- Since 2016, “See lot more emails on spills, labels, about safety and they are all informative.”

Most of the participants responded stating that their participation has been limited to within their labs. Very few participants mentioned to be part of IBC or training other research labs

within their department on biosafety matters over the years. Lack of opportunities to participate in biosafety matters at UofL was raised by a couple of participants whereas others stated that they were not interested in being involved.

- On opportunities to be involved in biological safety matters at UofL, “Not aware of any opportunities but willing to be part of.”

Group norms and behavior did not change much between Biosafe-1 and Biosafe-2. The general opinion was that some labs have better culture whereas others don’t, and it is mostly PI or lab dependent. The influence of a department on a lab’s safety culture is minimal unless it is a department that is high profile or research heavy. Participants did mention that young researchers seem to be aware of biosafety matters and are more willing to follow the guidelines.

- “People are more aware of safety now, as DEHS is more involved when things are not done right. It’s been a gradual change. Also depends on type of experiments being done. Learning and adapting based on experiments and agents being worked on.”

c. Safety Concerns

Participants stated that they do not have any major safety concerns during Biosafe-1, Biosafe-2 or COVID-19 pandemic. Few participants noted that their safety concerns which were mostly minor were fewer during Biosafe-2 compared to Biosafe-1.

- "When I first came, I had been worried that I had been doing it all wrong for years because of how strict they were being with us. You know, every little thing we were doing was putting my students at risk, even though I had been working on the same pathogens for 10 years, right? The culture was that if you don't do this in the biosafety cabinet, you know you're putting everybody at risk and they're all going to die. And as a PI, I was ultimately responsible for it. I was worried that my students were going to get sick or get exposed. And

after transition since 2016, now I'm like okay, what I learned was fine. It was just being overly cautious before 2014."

- Prior to 2014, “I felt there was no good response from biosafety, issues were brushed under the rug instead of using as an opportunity to fix.”
- “New concerns with new stuff, but I think we build up on what we know.”
- “All the labs I worked at UofL; people are pretty serious about doing things safely.”

d. Safety Perceptions

Participants noted that they had a neutral to positive opinion about biosafety practices during both Biosafe-1 and Biosafe-2. A shift in positive direction has been noted over the years which was attributed to evolution of the biosafety program over the years and building up on practices and safety awareness. Participants observed openness in biosafety discussions, consideration of actual risk during Biosafe-1. However, deficiencies continue to exist when a new PI sets up their lab or closes one at UofL.

- “University gave resources when bad things happen before. But now, it is more proactive.”
- “I have a positive opinion about the evolving biosafety.”
- “The approach that is taken currently is a good one and it balances the safety concerns, which of course have to be there with the reality of you know what it means to be a research investigator and the demands on you know time.”
- " I think before 2014, I think it was a nightmare with regulation and you did not want to talk to people because you didn't want to open up a can of worms or have them come down on you. But now they have been taking the extreme opposite side of things. I would like to see a little bit more of a safety culture and climate, not more regulations but just more presence and more availability.”

e. COVID-19 Pandemic and Biosafety

Participants said that UofL's biosafety program adapted very well during COVID-19 pandemic. Masking, six feet of social distancing, wiping high touch areas, signing up electronically for shared space or equipment usage, staggered shifts to reduce number of research personnel in a lab, flexibility on work from home, and training on specific precautions during COVID-19 were implemented. One participant highlighted having COVID-19 ambassadors who did walkthroughs to remind safety precautions as a great measure while another participant stated they found it menacing. One participant noted that they felt the precautions put in place were too restrictive as most labs already followed similar safety precautions.

- "Did a great job, early on a little shaky. But never felt unsafe, there was regular communication".
- "Felt a little menacing with covid ambassadors with non-biological background telling us what to do."
- "If there is culture of biosafety, not a big difference to add on pandemic guidelines. Precautions all there. The mindset is already there."
- "Science does suffer, we cannot do science using six feet distance, right? Because I need to train my graduate student or train new people who come to the lab and that's not possible following 6-foot distancing."
- "Safety wise it's been great; science wise it's been awful."

f. Suggestions to improve Biosafety Program Management

Participants were requested to share suggestions on improving biosafety program management at UofL.

- "Nurture good habits in the beginning and maintain them through training and inspections."

- “Have surprise visits even though there will be push back, if announced or self-assessment researchers will just select to make it look good.”
- “Prefer announced lab assessment so that we are available as we are busy with wet lab.”
- "Good change with online training modules, but I think you can only do so much with online training. And if you really want to improve safety, that comes down to direct interactions between the safety officer and the practitioners."
- "Good if outreach can involve visits to specific departments with BSL- 1 or 2 or whatever number there are and meet with them on a regular basis. They don't have to meet, they can collect survey of issues just like you're doing now but if it is something done online, that would be great."

Review of past and current documents

A summary of biosafety program records and documents during Biosafe-1 and Biosafe-2 periods that were evaluated are shown in Table 24. This review showed that training was primarily through classroom sessions during Biosafe-1 and through BioRAFT during Biosafe-2. Lab assessment and consultations were provided during both periods though self-assessment checklists were provided to laboratory personnel since 2016. Communication and outreach activities improved since 2016 compared to previous years. IBC protocol required annual submissions during Biosafe-1 whereases during Biosafe-2, IBC protocols required review only if there was a change in protocol after being approved for either 1, 3 or 5 years.

Survey Analysis

A measurement of biosafety climate perceptions of researchers at UofL biological laboratories was taken on BSCL scale as shown in Table 25, where 17 indicated low biosafety climate score

and 85 indicated high biosafety climate. A Wilcoxon signed-rank test showed that biosafety program management during Biosafe-2 elicited a statistically significant change in biosafety climate perceptions of researchers at UofL biological laboratories, ($p < 0.003$). The mean of aggregate biosafety climate score of researchers during Biosafe-2 (mean = 69.87) increased compared to Biosafe-1 (mean = 61.67). Thus, we can reject the null hypothesis that biosafety climate is not associated with biosafety program management and assume that biosafety program management in place since 2016 at UofL caused a significant increase in biosafety climate. Participants perceived all items on BSCL scale more positively during Biosafe-2 compared to Biosafe-1. However, a significant increase in perceptions was observed only in four items of 7, 8, 10 and 17. The difference in perceptions of "communication on biosafety issues at the university level" was higher during Biosafe-2 (mean = 4.20) than in Biosafe-1 (mean = 3.13), which was significant ($p < 0.011$). An increase in perceptions on "proper biosafety practices at university level" during Biosafe-2 (mean = 4.13) than in Biosafe-1 (mean = 3.13) was found to be significant ($p < 0.018$). A significant increase in perceptions on "participation of research professions in developing best biosafety practices" was observed during Biosafe-2 (mean = 4.07) compared to Biosafe-1 (mean = 2.87). The perceptions on "caring about each other's safety compliance at laboratory level" also increased during Biosafe-2 (mean=4.60) compared to Biosafe-1(mean = 4.13), significant ($p < 0.026$). An increase in all five dimensions of management priority, supervisor commitment, communication, participation, and group norms were noted during Biosafe-2 compared to Biosafe-1. However, only the dimension of communication and participation were significant. The perception on communication during Biosafe-2 (mean = 12.13) increased from that of Biosafe-1 (mean = 9.47) was found to be significant ($p < 0.012$). An increase in perceptions of participation during Biosafe-2 (mean = 15.33) compared to Biosafe-1 (mean = 12.40) was significant ($p < 0.05$).

Perceptions on biosafety practices was examined during the two periods using Wilcoxon signed-rank test are shown in Table 26. The results indicated differences in perceptions on university biosafety practices during the two time periods. An increase in perceptions of biosafety practices that are based on behavior-based safety concepts.[120,129-130] that is "Practical Training is given to first time researchers in lab before they begin work" and "Peer to Peer feedback on biosafety issues and safe practices is encouraged" was noticed during Biosafe-2 (mean = 4.00 & 4.33) compared to Biosafe-1 (mean = 3.60 & 3.13) which was significant ($p < 0.04$ & 0.013). A practice based on safety culture concepts,[120] "Biosafety issues and safe practices are easily communicated", also showed a significant ($p < 0.004$) increase during Bisoafe-2 (mean = 4.33) compared to Biosafe-1 (mean = 3.00). These findings correlated with the question on concepts that drive university's biosafety program. Participant's perceptions that concepts of institutional policies, safety culture and behavior-based safety drive the university's biosafety program increased during Biosafe-2 (mean = 4.40, 4.13 and 4.00) compared to Biosafe-1 (mean = 3.73, 3.67 and 2.87) which was found to be significant ($p < 0.019$, 0.042 and 0.006).

Biosafety perceptions prior to 2014 and since 2016 was examined are shown in Table 27. Perceptions on biosafety practices at the university showed a significant ($p < 0.042$) improvement with the rating to be slightly above "can be improved" reaching towards "good as is" (mean = 2.47) during Biosafe-2 compared to "can be improved" (mean = 2) during Biosafe-2. An increase in perception of biosafety program in mitigating risk during Bisoafe-2 (mean 4.33) compared to Biosafe-1 (mean = 3.400) was significant ($p < 0.009$). Responses on perceptions on practices to improve adherence to safety practices, lab inspections, training format, lab design preferred and considered safe was also collected from the participants. Participants showed a preference for hands on training (mean = 4.27) compared to online or classroom training (mean = 3.93). Participants preferred announced inspections (mean = 3.93) over unannounced (mean = 3.77)

inspections. The purpose of collecting this information was to utilize it in developing future intervention studies aimed at improving biosafety climate.

Participants perceived biological lab safety during COVID-19 pandemic positively as presented in Table 28. Participants agreed that they felt safe working in labs (mean = 4.40), peers complied with COVID-19 precautions (mean = 4.53) and that COVID-19 precautions were prioritized by the university (mean = 4.07) and supervisor (mean = 4.07). Communication on changes in lab safety, was considered slightly above neither agree nor disagree to agree (mean = 3.67) similar to perceptions on challenges imposed by COVID-19 precautions (mean = 3.60).

Discussion

Based on the perceptions of participants gathered through interviews, important aspects of biosafety program during Biosafe-1 and Biosafe-2 were identified at UofL, illustrated in Figure 11. The biosafety program in place prior to December 31, 2014 was described as adversarial and overreacting in approach, driven by regulations and perceived risk assessment of biological hazards, management priority to biosafety ranged from neutral to positive, training was primarily through classroom session utilizing PowerPoint presentations, lab inspections were not many and mostly announced, and IBC protocol review was mostly conducted through mail or electronic pdf/word documents with a turnaround time of 3-4 months. The biosafety program in since January 01, 2016 was described as collaborative and conducive to research in approach, driven by regulations, behavior-based safety, safety culture and actual risk assessment of biological hazards, management priority to biosafety was positive, training was given through online as well as classroom sessions, lab inspections were conducted through self-assessments and announced visits of biosafety administrative personnel, and IBC protocol review conducted through online platform of iRIS with a turnaround time of 1 to 2 months. However, it is important to consider

that biosafety program management prior to 2014 was the first of its kind at UofL that had to face challenges such as: developing a biosafety program specific to the needs of UofL, creating biosafety awareness and building a relationship between research professionals and administrative personnel. Whereas biosafety program since 2016 had the advantage of enhancing an existing biosafety program, buy in from researchers due to exposure to Biosafe-1 and additional online capabilities to run the program.

Quantitative findings through the survey corroborated qualitative data from interviews and provided consistent explanations on biosafety program management during the two periods. A significant increase in biosafety climate was observed during Biosafe-2, highlighting the importance of communication and participation dimensions on overall biosafety climate. A perceived increase in utilization of safety culture, behavior-based safety, and institutional policies and not just regulations to drive university's biosafety program during Biosafe-2 was observed. This is consistent with other studies that highlighted the importance of behavior-based safety and safety culture concepts to improve safety climate and safety outcomes.[120,131] An improvement in perceptions of biosafety practices and biosafety program in mitigating risks during Bisoafe-2 was noticed compared to Biosafe-1. Participants mostly had positive perceptions on COVID-19 precautions taken to ensure lab safety during COVID-19 pandemic.

A careful review of documents from these two periods revealed differences in biosafety program management during the two periods. Additional online resources were utilized during Biosafe-2 which boosted ease of access to biosafety resources and reduced administrative burden on researchers during IBC protocol submission. An increase in communication and outreach activities, updated forms, revised IBC bylaws, and use of self-assessments were observed since 2016.

Common themes that emerged from discussion with researchers on ways to improve biosafety program management are presented below:

1. Training: Hands on training or workshops on biological waste disposal, discarding of serological pipettes, hood use, and biosafety cabinets by floor managers or someone managing safety within department and/or biosafety administrative personnel. Specific training for custodial staff on waste pickup and actual risk.
2. Resources: A central resource on standard protocols, risk level, post exposure measures, prophylactic measures, opening and closing of labs.
3. IBC protocol submission: Continue improving iRIS platform to make it user friendly. Provide guides to navigate the website.
4. Risk assessment: Improve environmental risk assessment during research protocol review. Risk assessment should involve low risk groups and not just high-risk groups.
5. Lab inspection: Increase the frequency of lab inspections or walkthroughs to increase visibility of biosafety administration as well as their rapport with research personnel. Mimic lab inspections to NIH or EPA inspections so that researchers are prepared and meet the standards.
6. Outreach: Increase communication of safety matters through newsletters or emails with biosafety topics. Campaign about biosafety services offered so that researchers know who and how to contact for biosafety matters. Collect input on issues or suggestions to improve biosafety practices from researchers through surveys.

There are strengths and limitations of this study as is expected of any research. Using BSCL scale that was developed and validated as presented in Chapter-2 of this dissertation has been a strength. This study utilized different methods such as interviews and online survey to collect data for this study. Several studies have shown a difference in responses based on the survey

mode with positive responses by participants over telephone than mail.[132-135] However, the fact that researchers scored higher biosafety climate perceptions during Biosafe-2 comparable to the opinions expressed on change in biosafety climate perceptions during interviews is evidence that there was no bias due to survey method. Participants of the study were only from one university warranting caution when generalizing the study findings to other universities or settings. Another limitation of the study is recall bias as the participants were asked to express their perceptions from few years ago. To minimize recall bias, this study utilized review of records and documents to obtain objective data about biosafety program managements in place during the two periods. To address selection bias, this study invited all the researchers at UofL to participate in the study. Only, Sivarchana Mareedu interviewed and collected data from the participants which was deidentified before analyzing so that no one from the current biosafety program administration at UofL would influence the research design or data interpretation. Measures like carefully defining inclusion criteria, adequate sample size for a pilot test, data collected in similar way from all the participants that reduce bias,[137] were implemented.

To date, we are not aware of any study that examined the association of safety climate with biosafety program administration and practices at a public biological research university in the US. Studies suggested an increase in communication between management and employees to improve perceived occupational safety climate.[48,138] This study also showed that increased communication through newsletters, emails, safety fair and inspections during Biosafe-2 was associated with improved perceptions of biosafety climate, comparable to other studies.[22] Also, one of the suggestions by the study participants was to increase visibility of biosafety services to improve biosafety climate perceptions at UofL.

This study presented suggestions by researchers on improving biosafety climate which could be utilized to develop intervention studies aimed at improving safety climate and safety outcomes.

Additional studies that are prospective in nature could be utilized to investigate the association of biosafety climate perceptions with changes in biosafety program management.

Conclusion

The study was conducted to utilize the unique opportunity presented at UofL due to an abrupt and documented change in biosafety program procedures. This change in biosafety program management enabled us to review the impact of different biosafety program administrative models in place on biosafety climate of researchers at biological laboratories. This study was not a comparison of biosafety administrative personnel or their work during the two periods of study. The goal of the study was to identify the key aspects of biosafety program and evaluate biosafety climate prior to 2014 and since 2016. Utilizing quantitative and qualitive data collected through interviews, records review and survey, this study was able to show significant differences in biosafety program management during the two periods. Researchers perceived biosafety climate to be higher since 2016 compared to previous years. This increase in biosafety climate can be attributed to a biosafety program that is collaborative in approach and driven by actual risk, safety culture and behavior-based concepts.

	BioSafe-1 (n=15)	BioSafe-2 (n=15)	p-value[1]
Variable	N (%)	N (%)	
Female	7(46.7)	7(46.7)	
Male	8(53.3)	8(53.3)	
Role			0.848
Principal Investigator	8(53.3)	9(60)	
Professor	4(26.7)	6(40)	
Lab Manager	5(33.3)	4(26.7)	
Research Assistant	1(6.7)	1(6.7)	
Student	2(13.3)	0(0)	
Other-Research Role	1(6.7)	3(20)	
Post-Doctoral Researcher	2(13.3)	2(13.3)	
Educational Background			1.000
Bachelors	1(6.7)	1(6.7)	
Masters	3(20)	2(13.3)	
PhD	3(20)	3(20)	
Post Doctorate	8(53.3)	9(60)	
Type of Work			1.000
Research	15(100)	15(100)	
Teaching	5(33)	6(40)	
BSL Level			1.000
BSL-1	9(60)	8(53.3)	
BSL-2	13(86.7)	12(80)	
BSL-2+	3(20)	4(26.7)	
BSL-3	1(6.7)	1(6.7)	
RG Level			1.000
RG-1	14(93.3)	11(73.3)	
RG-2	10(66.7)	11(73.3)	
RG-3	2(13.3)	3(20)	
Lab Design			0.811
Open Lab	4(26.7)	5(33.3)	
Closed Lab	7(46.7)	5(33.3)	
Both	4(26.7)	5(33.3)	
Lab Location			0.284
Belknap Campus	3(20)	4(26.7)	
HSC Campus	9(60)	11(73.3)	
Both	3(20)	0(0)	
Research Funding			1.000
Government	13(86.7)	14(93.3)	
University	10(66.7)	10(66.7)	
Private	5(33.3)	6(40)	
Other	1(6.7)	1(6.7)	
Continuous Variable= mean (SD)	BioSafe-1 (n=15)	BioSafe-2 (n=15)	p-value[1]
Age (years, continuous)	45.54(11.89)	51.54(11.89)	0.000
Experience in current role(years)	11.33(8.07)	12.47(9.58)	0.575
Team Size	5.8(2.57)	7.07(4.38)	0.550

Table 23: Characteristics of Study Participants in the UofL Biosafety Program Evaluation Study (n=30)

	BioSafe-1	BioSafe-2
Institutional Biosafety Committee	IBC operating charter revised in 2013 provided general details on IBC responsibilities and membership. Committee members did not have BSL-3 experience	Bylaws of IBC approved in 2016 provided thorough details on purpose, membership, duties, terms of office and other details. Biosafety manual was created in 2017. Committee members with BSL-3 experience
Platforms Utilized	Emails, phone and electronic documents were utilized.	iRIS, an online platform for IBC protocols and BioRAFT PI platform for training and inspection was utilized.
IBC Protocol Reviews	IBC protocols were reviewed annually. IBC meeting minutes reviewed from 2014 were long and included a lot of details on proposed experiments.	IBC protocols were reviewed if there was a change in protocol. IBC protocols were approved for 1, 3 or 5 years based on risk assessment. IBC meeting minutes reviewed from 2021 were concise and appropriate.
Lab assessment	Records indicate that biosafety personnel conducted consultations and lab audits utilizing lab inspection checklists based on BSL during 2009 to 2014.	Self-assessments checklists were utilized that assessed general lab safety, chemical safety and biological safety together. Consultations with biosafety department provided.
Training	Biosafety Basics and Bloodborne Pathogens training was given through PowerPoint presentation in 2014 through classroom sessions. The slides were busy with lots of words but were appropriate.	Basic Biosafety and Bloodborne Pathogens training was given through online BioRAFT platform. The information was presented through visual aids and was interactive in nature.
Communication & Outreach Activities	Emails, phone, posters, lab consultations.	Newsletter, email reminders, phone, posters, safety fair and lab consultations.
DEHS Website	Unable to assess previous versions.	The website is updated with Biological Safety tab listing SOPS for biohazardous spills, biohazardous agents, biosafety manual, trainings, forms, documents, contact information, IBC meeting dates, waste disposal and other appropriate resources.

Table 24: Review of Biosafety Program Documents and Records in the UofL Biosafety Program Evaluation Study

	BioSafe-1 n=15		BioSafe-2 n=15		p-value[1]
Biosafety Climate Scale: Items and Factors (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	Mean	Std. Dev.	Mean	Std. Dev.	p-value[1]
Biosafety Climate Score	61.67	10.22	69.87	10.48	0.003
1. The safety of research professionals is a priority for my institution.	3.80	0.775	4.20	0.676	0.066
2. University administration considers research professionals' safety to be as important as productivity.	3.13	1.19	3.33	1.11	0.588
3. University administration shows support for prevention of biological hazards and incidents through involvement and commitment.	3.47	0.99	3.80	0.86	0.073
4. In the laboratory (institution), my supervisor acts quickly to correct problems/issues that affect research professional's safety.	4.20	1.01	4.33	0.82	0.586
5. My supervisor clearly considers the safety of research professionals to be of great importance.	4.07	1.03	4.33	0.90	0.174
6. My supervisor acts decisively when a concern of a research professional's safety practices is raised.	4.33	0.98	4.27	0.96	0.850
7. There is good communication at my institution about biosafety issues which affect me.	3.13	0.99	4.20	0.68	0.011
8. Information about proper biosafety practices is always brought to my attention in my institution.	3.13	1.06	4.13	1.06	0.018
9. My contributions to resolving biosafety concerns in the institution are listened to.	3.20	1.08	3.80	0.94	0.101
10. Research professionals participate in developing best biosafety practices in my institution.	2.87	1.13	4.07	0.88	0.003
11. Research professionals are encouraged to become involved in biosafety matters.	3.33	1.11	3.87	1.13	0.106
12. At my institution, the promotion of best biosafety practices involves all levels of the organization.	3.07	1.28	3.47	0.99	0.071
13. Consultation in developing best biosafety practices involves researchers and biosafety professionals.	3.13	1.41	3.93	1.10	0.061
14. In the laboratory (institution), we discuss research professional's safety, biological hazards and incident prevention.	4.00	1.07	4.47	0.83	0.188
15. In the laboratory (institution), we care about each other's safety awareness.	4.40	0.63	4.60	0.51	0.233
16. In the laboratory (institution), we remind each other of the regulations and guidelines regarding research professional's safety.	4.27	0.59	4.47	0.52	0.149
17. In the laboratory (institution), we care about each other's safety compliance.	4.13	0.74	4.60	0.51	0.026
Factor 1: University Administration Priority	10.40	2.44	11.33	2.29	0.061
Factor 2: Supervisor Commitment	12.60	2.87	12.93	2.63	0.586
Factor 3: Communication	9.47	2.80	12.13	2.29	0.012
Factor 4: Participation	12.40	4.01	15.33	3.79	0.005
Factor 5: Group Norms	16.80	2.76	18.13	2.10	0.078

Table 25: Comparison of Biosafety Climate Prior to 2014 versus Post 2016 in the UofL Biosafety Program Evaluation Study (n=30)

Biosafety Practices at UofL	BioSafe-1 n=15			BioSafe-2 n=15			
	N (%)	Mean	Std. Dev.	N (%)	Mean	Std. Dev.	p-value[1]
Regulations and guidelines Which of the following regulations and guidelines does the biosafety program follow at your institution? (Select all that apply) (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)							
CDC	15	4.13	0.915	15	3.93	1.033	0.463
NIH	15	4.13	1.302	15	4.27	1.100	0.892
OSHA BBP	15	4.73	0.458	15	4.73	0.458	1.000
Institutional Policies	15	4.40	0.632	15	4.53	0.640	0.572
Other	National animal care policies			Environmental and Animal care			
University biosafety practices Select all that apply to your institution. (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Regulations and guidelines are strictly followed	15	3.60	0.910	15	4.07	0.884	0.165
Everyone is encouraged to know regulations and guidelines	15	3.93	0.961	15	4.47	0.516	0.066
Practical Training is given to first time researchers in lab before they begin work	15	3.60	1.056	15	4.13	1.246	0.040
Peer to Peer feedback on biosafety issues and safe practices is encouraged	15	3.13	0.915	15	4.00	1.000	0.013
Biosafety issues and safe practices are easily communicated	15	3.00	1.134	15	4.33	0.617	0.004
Senior management is involved in addressing biosafety issues and improve safe practices	15	2.67	1.175	15	3.40	1.326	0.061
Concepts that drive university's biosafety program Which of the following concepts drives the biosafety program at your institution? (Select all that apply) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Regulations (Federal & State such as OSHA, NIH, CDC, DOT and others)	15	4.53	0.516	15	4.53	0.516	1.000
Institutional Policies	15	3.73	0.799	15	4.40	0.507	0.019
Safety Culture	15	3.67	0.617	15	4.13	0.990	0.042
Behavior Based Safety	15	2.87	1.125	15	4.00	1.069	0.006
Mode of training given What mode of training is given at your institution? (Select all that apply) (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)							

Online	15	3.33	1.234	15	4.60	0.507	0.005
Classroom	15	3.47	1.246	15	2.93	1.100	0.160
Hands on by Researchers	15	3.73	1.163	15	3.87	1.246	0.595
Hands on By Biosafety	15	2.80	1.146	15	2.67	1.234	0.666
Hands on by both researchers and Biosafety professionals	15	2.60	0.986	15	2.73	1.335	0.675
Other (animal care, biological hazards, chemical hazards)	2	2.50	2.121	1	3.00		1.000
Training taken with 1 year	BioSafe1: BBP (13), NIH (6), BS (11) Biosafe2: BBP (12), NIH (4), BS (10)						
Training taken with 3 year	BioSafe1: BBP (13), NIH (10), BS (12) Biosafe2: BBP (14), NIH (9), BS (13)						
Training taken with 5 year	BioSafe1: BBP (13), NIH (11), BS (14) Biosafe2: BBP (13), NIH (11), BS (14)						
Biosafety resource awareness Which of the following biosafety resources are you aware of? (Select all that apply) (1-Not at all Aware,2- Slightly Aware,3-Moderately Aware,4-Very Aware,5-Extremely Aware)							
ABSA	15	2.13	0.990	15	2.20	0.941	0.766
WHO	15	2.07	1.163	15	2.20	1.014	0.484
CDC	15	3.27	1.335	15	3.40	1.298	0.424
NIH	15	3.93	1.280	15	4.13	0.990	0.572
PSDS	15	2.00	1.254	15	2.20	1.207	0.345
OSHA	15	3.93	1.438	15	4.40	1.056	0.168
Guidelines for Biosafety Laboratory Competency	15	2.93	1.486	15	3.33	1.345	0.305
IBC	15	4.20	0.941	15	4.40	0.910	0.374
Other (packaging & shipping--IACUC committee)	2	2.00	1.414	2	5.00	0.000	
Resources utilized for risk assessment Which of the following do you utilize to assess the risk of your research and lab activities in your lab? (Select all that apply) (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)							
Risk group of agents	15	3.60	1.549	15	4.00	1.134	0.269
Consultation with a biosafety officer	15	2.93	1.223	15	3.47	0.915	0.066
CDC	15	2.80	1.265	15	3.00	1.254	0.299
NIH	15	3.73	1.438	15	4.00	1.309	0.608
PSDS	15	2.00	1.309	15	2.00	1.254	1.000
Peer research	14	3.07	1.492	14	3.57	1.342	0.188
OSHA	15	4.00	1.363	15	4.40	1.056	0.174
IBC	15	4.20	1.146	15	4.60	0.632	0.203
Other (IACUC Committee and Citi training)	3	2.67	1.528	2	5.00	0.000	0.500

Lab inspection conducted by biosafety program administration The biosafety administration at your institution conducts _____type of laboratory inspections/assessments. (1-Never,2-Rarely,3-Sometimes,4-Often,5-Always)							
Announced	14	3.00	1.301	14	3.14	1.512	0.679
Unannounced	14	1.50	0.650	14	1.43	0.756	0.766
Both	8	2.00	1.069	8	1.75	1.165	0.346
Biohazard exposure prevention awareness Are you aware of how to prevent exposure to a biological hazard if an incident involving these hazards occurs in your lab? (3-Yes,2-Not Sure,1-No)	15	3.00	0.000	15	3.00	0.000	NA
Incident reporting If incidents involving biohazards occurs in your lab, whom are you required to report to per incident reporting guidelines at your institution? (Select all that apply) (1-if yes, 0-if no)							
Principal investigator	15	0.73	0.458	15	0.87	0.352	0.346
Department chair	15	0.20	0.414	15	0.40	0.507	0.149
Biosafety officer	15	0.60	0.507	15	0.80	0.414	0.149
EHS	15	0.60	0.507	15	0.73	0.458	0.346
Government (NIH, CDC, FDA, DOD, OSHA, State)	15	0.13	0.352	15	0.13	0.352	NA
Colleagues in the lab	15	0.40	0.507	15	0.47	0.516	0.773
Known biosafety incidents resulting in lab acquired infections Are you aware of any biosafety incidents resulting in Lab Acquired Infections in your lab during 2016 to 2020? (1-Yes,0-No)	15	0.00	0.000	15	0.00	0.000	NA
Known biosafety incidents resulting in exposure to biohazards Are you aware of any biosafety incidents resulting in exposure to biological hazards in your lab during 2016 to 2020? (1-Yes,0- No)	15	0.13	0.352	15	0.07	0.258	0.773
Prior to 2014, 2 incidents: RNA reagents splashed in graduate student's eye and needlestick After 2016, dilute sodium azide was dumped in a sink							

Table 26: Biosafety Practices Prior to 2014 versus Post 2016 in the UofL Biosafety Program Evaluation Study (n=30)

Biosafety Perceptions of Researchers at UofL	BioSafe-1 n=15 N (%)	Mean	Std. Dev.	BioSafe-2 n=15 N (%)	Mean	Std. Dev.	p-value[1]
Perception on university biosafety practices How do you rate biosafety practices at your university? (3-Good as is,2-Can be improved,1-Undergoing improvements)	15	2.00	0.535	15	2.47	0.743	0.042
Perception on risk level of work conducted in the lab What do you consider the risk level of work conducted in your lab? (5-Very Low,4-Low,3-Moderate,2-High,1-Very High,0-I Don't Know)	15	3.53	0.640	15	3.47	0.743	0.777
Perception on measures taken in the lab against hazards Do you believe your lab takes strong measures to protect you from the hazards of the work conducted in your lab? (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	15	4.27	0.961	15	4.73	0.458	0.065
Perception on university's Biosafety program in mitigating risks Do you consider the biosafety program at your university to be effective in mitigating risks in your lab? (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	15	3.40	0.828	15	4.33	0.724	0.009
Perception on practices that improve adherence to safety practices & mitigate risk in lab Which of the following do you believe would improve adherence to safety practices and mitigating risks in your lab? (Select all that apply) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Regulations and guidelines are strictly followed				15	4.20	0.862	
Everyone is encouraged to know regulations and guidelines				15	4.47	0.640	
Practical Training is given to first time researchers in lab before they begin work				15	4.67	0.617	
Peer to Peer feedback on biosafety issues and safe practices is encouraged				15	4.33	0.488	
Biosafety issues and safe practices are easily communicated				15	4.60	0.507	
Senior management is involved in addressing biosafety issues and improve safe practices				15	4.27	0.799	
Perception on lab inspections Select the type of laboratory inspections/assessments you consider to be effective. (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)							
Announced				14	3.93	1.141	
Unannounced				13	3.77	1.166	
Both				9	3.78	0.667	

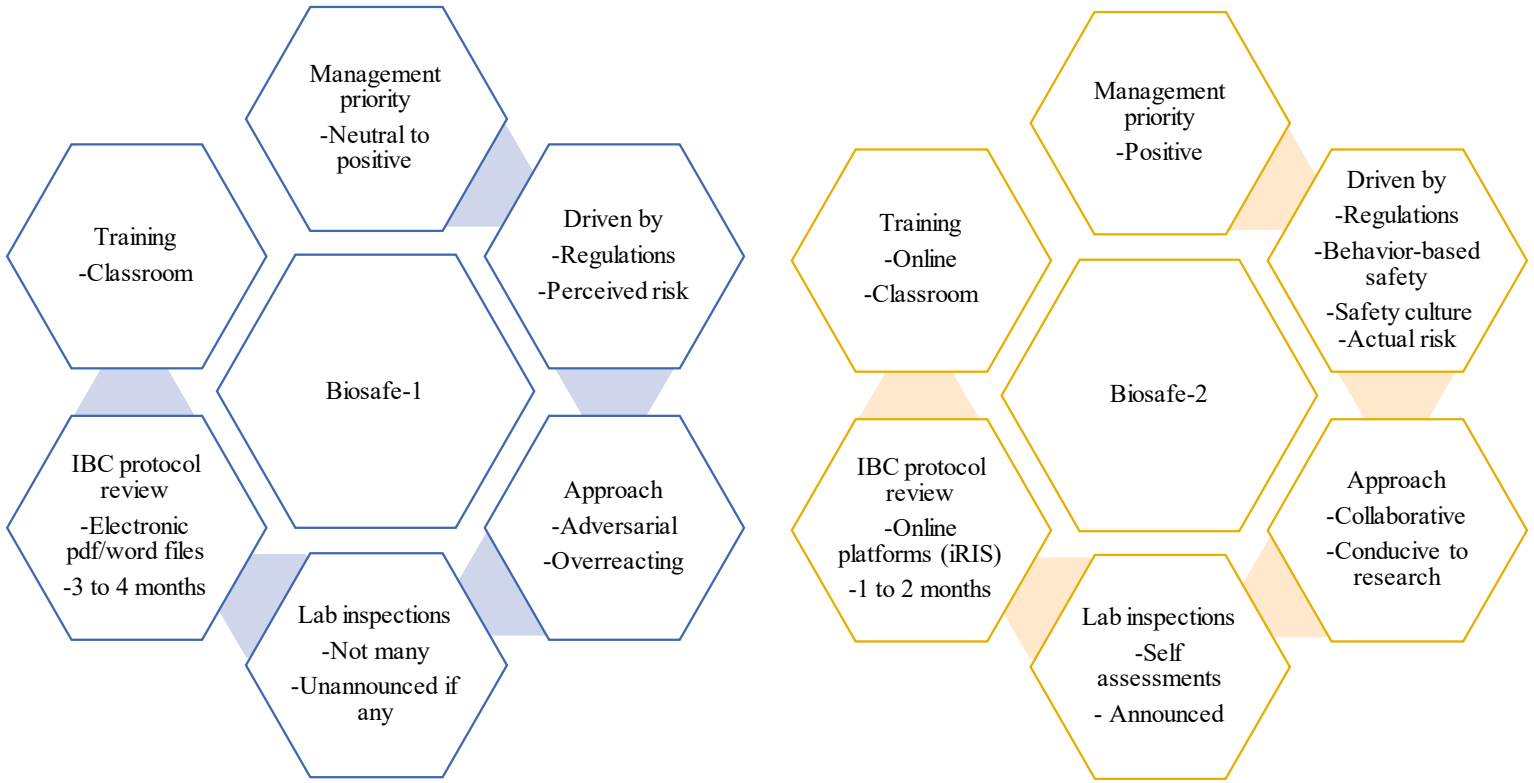
Perception on training format Select the following training format that you believe could improve biosafety at your institution. (Select all that apply) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)				
Online	15	3.93	1.163	
Classroom	14	3.93	1.072	
Hands on by Researchers	15	4.20	1.146	
Hands on By Biosafety	14	4.29	1.139	
Hands on by both researchers and Biosafety professionals	15	4.27	1.100	
Perception on lab design considered safe Which lab design do you believe is safer: (Select appropriate response) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)				
Open	14	2.86	1.167	
Closed	13	4.08	0.760	
Both	8	3.00	0.926	
Perception on lab design type preferred Which lab design do you prefer to work at: (Select appropriate response) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)				
Open	14	3.43	1.399	
Closed	12	3.83	1.193	
Both	8	3.25	1.035	

Table 27: Biosafety Perceptions Prior to 2014 versus Post 2016 in the UofL Biosafety Program Evaluation Study (n=30)

		BioSafe-2 n=15		
Perceptions on Biological Laboratory Safety during COVID-19 Pandemic In relation to COVID-19 and your activity in research labs, do you feel: (Select appropriate response) (1-Strongly Disagree,2-Disagree,3-Neither Agree nor Disagree,4-Agree,5-Strongly Agree)	N (%)		Mean	Std. Dev.
Feel safe working in labs		15	4.40	0.828
University prioritizes COVID-19 precautions in labs		15	4.07	1.033
Supervisor prioritizes COVID-19 precautions in labs		15	4.07	1.100
Good communication on changes in lab safety		15	3.67	1.113
In lab, peers are complying with lab safety and covid-19 precautions		15	4.53	0.640
COVID-19 precautions are imposing additional challenges to lab safety		15	3.60	1.183

Table 28: Biological Laboratory Safety Perceptions During COVID-19 Pandemic in the UofL Biosafety Program Evaluation Study (n=30)

Figure 11: Biosafety Program Aspects Identified During Biosafe-1 and Biosafe-2 in the UofL Biosafety Program Evaluation Study



CHAPTER 6: BIOSAFETY PROGRAM MANAGEMENT IN THE ERA OF COVID-19 AND BEYOND

Introduction

The previous chapters explored the status of biosafety climate at public universities in the United States of America to understand the current needs and challenges in ensuring safety in biological and biomedical research laboratories. Chapter 5 underscored the perspectives of research professionals in identifying opportunities to enhance a biosafety program. This chapter explored the perspectives of biosafety professionals in identifying opportunities in biosafety program management.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a new human coronavirus that caused coronavirus disease (COVID-19) was discovered in December 2019.[74-76] Not long after, it was officially declared as a global pandemic.[77-78] Approximately 597,3943 deaths and 33,292,045 cases have been attributed to COVID-19 in the US alone as of June 14, 2021.[139] Worldwide, the pandemic has resulted in 3,829,318 deaths and more than 117 million cases of COVID-19 as of June 14, 2021.[140] Given the serious threat posed by the pandemic and risk of exposure to COVID-19 pandemic at occupational settings, a multitude of measures have been put in place. Occupational Health and Safety Administration (OSHA) in USA provided guidance on implementing a workplace COVID-19 prevention program to mitigate and prevent the spread of COVID-19.[79] Centers for Disease Control (CDC), World Health Organization, (WHO), state and federal governments also provided guidance to mitigate risk of exposure to COVID-19 not only in public settings but also occupational settings.[79-83] Many changes to biosafety program

management and laboratory safety measures were made in biological and biomedical research and teaching laboratories to address the risks posed during the pandemic at public universities in the US.[82-140-142] Changes to general lab safety practices such as social distancing, remote work when feasible, sanitizing of common/shared spaces, emergency communication, procedures of cleaning, reminders on disinfection, personal hygiene, and appropriate personal protective equipment (PPE) were made.[142-144] In this chapter, we present a discussion on changes that were made to biosafety program management to meet the needs of research community during a pandemic and its implications on biosafety moving forward.

Insights from Biosafety Experts

To gain an understanding on biosafety program management, this study interviewed four biosafety subject matter experts (SMEs): Sumit Ghosh, PhD, Allen Helm, Phd, Brandy Nelson, MS and Patricia Delarosa, PhD, who were involved in biological laboratory safety at four well known public universities in the US. The biosafety professionals in this study were asked similar questions such as: explain challenges to biosafety program during the pandemic, describe changes made to meet researcher's safety, and opportunities identified for biosafety program management during the pandemic. In May 2021, they were also requested to share their opinions and suggestions to enhance biosafety program management at public universities in the US. The responses shared by these SMEs are based on their experience and views on biosafety in general and does not represent their place of work. Following is a summary from the interviews conducted with the SMEs during May 2021.

Challenges to Biosafety Program Management During the Pandemic

Federal, state, and institutional policies and guidelines were put in place that included lockdown measures to stop all non-essential work during the initial months of the pandemic, to prevent the spread of novel coronavirus.[145] This included most of the academic research laboratories unless their work contributed to help curb the pandemic noted Dr. Helm. He and other SMEs recognized that one of the challenges during the pandemic was creating a plan to return to work after a brief shutdown of laboratories so that research professionals could safely resume laboratory research activities. Finding an online platform to conduct biosafety administrative activities, meetings and trainings was recognized as another challenge by one the SMEs. Few of the SMEs noted that, conducting in person lab inspections and lab visits was difficult during the pandemic leading to decrease in frequency of lab inspections. Given the diversity in academic institutions, Ms. Nelson elaborated that, "how we make people aware of biosafety program elements, get that promulgated throughout the institution and get people on board and get buy-in", has always been a big challenge in establishing a good safety culture in biological laboratories.

Changes Made to Biosafety Program Management During the Pandemic

Biosafety professionals were assigned with the task of risk mitigation for the COVID-19, as research professionals pushed to study novel virus to understand its pathogenicity and develop countermeasures.[146] An increase in number of research professionals interested in working with the novel coronavirus was noted.[144,147] However, this soon highlighted the limitations of laboratory resources and training,[148] not only in developing countries but also in the US as recognized by the SMEs. They stated that not many institutions have biosafety laboratory level (BSL) 2+ or BSL-3 capabilities required for work with the novel coronavirus. Hence, it became a challenge to change existing capabilities of laboratories to accommodate the needs of research professionals in a short time. Also, training was developed quickly and specifically to train

research professionals who were not previously trained to work in BSL-3 settings. Meetings, orientations, and trainings were conducted online to accommodate the measures put in place due to the pandemic. As trainings were given online, existing training material was updated to make it more appealing and engaging to increase participation. Biosafety teams were assigned to conduct walkthroughs once or twice during a day to ensure COVID-19 precautions were being followed within research laboratories. Attending virtual workshops were incentivized through e-cards as means of recognition and encouragement, noted Dr. Ghosh.

The frequency of in person lab inspections decreased during the pandemic due to labs being in lockdown for few weeks and due to social distancing measures in place thereafter. To accommodate, the measures put in place to mitigate the spread of COVID-19, changes were made to lab inspections. One SME noted that their institution before pandemic conducted traditional in person lab visits but since pandemic moved to a hybrid version. The hybrid inspection consisted of two parts. The first part was a virtual inspection wherein one lab personnel and one member of the biosafety team met via zoom and reviewed training records, IBC protocol, research questions and so on. The second part of the inspection was a brief in person visit to the lab for a walkthrough to conduct visual inspection of the workspace. Another expert noted that they implemented self-assessments in place of in person laboratory inspections which seemed to work.

Opportunities for Biosafety Program Management During the Pandemic

The SMEs made an interesting observation that the use of virtual platforms for trainings and meetings during the pandemic resulted in increased attendance and participation. “We found that offering trainings and meetings through virtual platform increased attendance in our meetings, so that definitely worked in our favor”, stated Dr. Ghosh. Both Dr. Ghosh and Ms. Nelson emphasized that they observed positive response to virtual trainings and webinars. She added that the pandemic led to transition of work from traditional in person format to virtual, which proved

to be advantageous. The flexibility to schedule virtual meetings with principal investigators per their flexibility led to increased communication between research professionals and biosafety team, she noted.

During the pandemic, Ms. Nelson notes that some of her peer in the biosafety community expressed an increase in awareness to biosafety programs not only by research professionals but also the institution. The pandemic enabled people to understand and utilize the biosafety resources already available at their institutions, echoed other SMEs. Dr. Delarosa emphasized the importance of biosafety community in addressing COVID-19 pandemic. She explained that few of the many roles that biosafety community was called upon to undertake during the pandemic included: acting as public health advisers, subject matter experts in responding to scientific discussions, reaching out to public to address their risk concerns and bring an awareness to risk mitigation measures.

Biosafety during the COVID-19 era and beyond

The SMEs interviewed in this study shared their opinions on ensuring effective biosafety programs in academic laboratories. SMEs recognized collaboration with research professionals to understand their needs and being flexible as important in smooth biosafety program management. Even though the guidelines on lab safety during the initial months of the pandemic was not very clear, Dr. Helm informed that biosafety programs were able to successfully coordinate and enforce additional lab safety measures required during the pandemic. This he attributes to having a well-established communication system in place between research and biosafety professionals as well as full buy-in from university administration to implement a biosafety program. Dr. Ghosh recommends trainings that are innovative to keep people engaged and motivated to attend training sessions. Preparation is the key stated Dr. Ghosh advising biosafety programs to be prepared in the future for unexpected challenges posed by pandemic as he explains, “it has happened once it might happen again”.

To develop a good biosafety program during the COVID-19 era and beyond, it is essential to incorporate research and biosafety professionals' recommendations when creating or improving biosafety programs.

Based on the insights provided by the SME's and observations from Chapter 5. The following aspects can be summarized as important to a biosafety program from the perspective of biosafety professionals:

- Information sharing through monthly and quarterly newsletters or posters to share information on safety related topics, injuries, near misses, safety reviews, overall findings, safety regulations and guidelines.
- Trainings that are engaging and appealing when delivered through online platforms.
- Collaboration between research and biosafety professionals to work as a team to address safety concerns and mitigate risks.
- Communication between research and biosafety professional to share any safety related concerns as and when they arise.
- Buy-in/support from both management and research professionals to run a biosafety program

Chapter 3 and 5 provided details on the elements of a biosafety program that research professionals considered to be of importance. The following aspects were considered important to a biosafety program from the perspective of research professionals:

- Hands on training from both experienced research and biosafety professionals.
- Resources on standard protocols, guidelines, risk assessment, exposure prevention, post exposure measures, prophylactic measures, opening and closing labs.

- Ease of Institutional Biosafety Committee (IBC) protocol submission and review process that balances risk and appropriate control measures.
- Risk assessment based on actual risk.
- Lab inspections or visits to increase interactions between research and biosafety professionals.

The findings from previous chapters also highlighted the need to decrease gaps between research and biosafety professionals such as biosafety resources awareness, resources utilized for risk assessment, awareness on lab acquired incidents, awareness on potential exposures and risk assessment process so that research and biosafety professionals can work together as a team in establishing biological laboratory safety. Be it during COVID-19 or beyond, it is important for biosafety administration to be aware of their institutional needs and capabilities. They should be aware of:

- Number of labs (active, new, and closed)
- Type of laboratory (shared/closed/ biosafety laboratory level)
- Type of research conducted (risk groups utilized)
- Number of research professionals
- Facilities available
- Type of training platform (online/in-person) utilized versus preferred by research professionals
- Training needs (update based on findings from lab inspections and survey of researcher's feedback)
- Training platform (adaptable both online and in person)
- Resource awareness (people, facilities)
- Prioritize lab inspections (tiering labs based on hazards, type of research)

- Lab inspections - self-assessment, in person or virtual to meet the needs of the research community.

Discussion

The study identified the challenges and opportunities due to changes made to biosafety program management to accommodate the occupational safety measures put in place due to COVID-19 pandemic at biological laboratories at public universities in the US. This study identified important aspects of a biosafety program that must be considered not only during a pandemic but beyond to move biosafety in the right direction.

Dr. Delarosa reminded of the incidents that happened during 2014 that singled out federal labs for having problems with safety and biosecurity. She explained that this fundamentally shook the biosafety community, as "there was a realization that you can have all the guidance and all the regulation in place, and you still aren't safe. You still cannot guarantee the safety of your workers". She explained that this led to the publication of recommendations by the Federal Experts Security Advisory Panel (FESAP) in 2015 on changes to biosafety programs to fill in those gaps identified by the various incidences. The FESAP provides guiding principles for biosafety governance that promotes federal requirements compliance and foster culture of responsibility within research institutions,[149-150] Dr. Delarosa pointed out that this was a good way towards establishing a culture of safety in laboratories. She stated that recommendations based on nuclear regulatory safety measures[151] are now being recommended to establish a culture of responsibility to ensure safety in biological laboratories.

Dr. Ghosh states that organizations should utilize biosafety professionals' expertise in not only laboratory settings, but also other areas given their expertise and unique perspective in controlling hazards posed by infectious agents. This view was also expressed by Ms. Nelson who said that the pandemic brought increased awareness to biosafety programs at institutions. The principles of biosafety program management haven't changed before and during the pandemic stated Dr.

Helm. He explained, be it before, during or after a pandemic the three important aspects of an effective biosafety program remain the same: establishing collegiality with research professionals (improves communication), buy-in from institution and being as non-punitive as possible. “We are your colleagues, not cops”, said Dr. Helm stressing the importance of research and biosafety professionals working together as a team to establish efficient biosafety culture. In the same line of thought, Dr. Delarosa agrees that biosafety moving forward should look at understanding the systemic failures that result in biosafety accidents and incidents rather than pointing out fingers at who did that.

An important observation that Dr. Delarosa makes was the need for biosafety to transcend the confinements of a laboratory and consider its application in public health in advising on risks. Moving forward, in the era of COVID-19 pandemic and beyond it is essential to not only optimize biosafety programs in place for biological laboratories but also interface biosafety and public health practices for the health and wellbeing of everyone.

The key strength of this study is that it summarized perspectives of biosafety professionals in determining the changes made to biosafety program during the pandemic at the US academic laboratories. However, one limitation of this study is that, only SMEs at public universities in the US were interviewed. Further studies need to analyze in depth the challenges and opportunities in managing biosafety. However, the findings from this study are important in preliminary exploration on the COVID-19 pandemic’s impact on biosafety program from the perspective of biosafety professionals.

Conclusion

The findings from this chapter and previous chapters, concludes that an effective biosafety program management should incorporate elements that addresses the needs of research professionals in facilitating safe research activities while also meeting the biosafety community’s goals of risk mitigation and safety compliance. Biosafety program management should be

developed by taking into consideration the viewpoints of research professionals as the end consumers to increase their buy-in and compliance. The expertise of biosafety professionals should be considered not only in administering a biosafety program but also during risk assessment process. Research and biosafety community need to work together as a team, complementing each other's expertise in developing an effective biosafety program that protects from potential exposures to infectious agents and hazards.

The COVID-19 pandemic not only accentuated the needs for continued research on existing and emerging infectious diseases but also the need for a biosafety program to keep up with the evolving needs of microbiological and biomedical research. The insights gained from this study could help in shaping biosafety program during the COVID-19 era and beyond.

CHAPTER 7: CONCLUSION

This chapter encapsulates the overall findings, strengths, limitations, significance, and future recommendations of this dissertation.

Overall Findings

Chapter 1 presented an overview of specific aims and studies conducted as part of this dissertation. Chapter 2 presented a background on safety climate as a leading indicator of safety and its application in capturing a snapshot of safety culture at biological laboratories. A step-by-step process on scale development was provided to inform interested scholars on process involved in Biosafety Climate (BSCL) scale development. Based on survey data collected from research professionals at UofL (n=91) and biosafety professionals in the US (n=88), a biosafety climate scale with 17 items was developed and validated for research and biosafety professionals using exploratory factor analysis and reliability measures.

Chapter 3 showed that the BSCL scale was effective in measuring biosafety climate over time at University of Louisville (UofL) based on test-retest analysis. This study compared the survey data collected from research professionals at UofL (n=91) during 2019 and survey data collected from research professionals at UofL (n=120) during 2020. This study concluded that biosafety climate perceptions remained the same prior to and during COVID-19 pandemic. Confirmatory factor analysis (CFA) indicated a five-factor underlying structure for BSCL scale for research professionals.

Chapter 4 presented the results of a national survey of research and biosafety professionals at public universities in the US that worked in biological and biomedical laboratories. Survey was distributed to 584 public universities in the US, resulting in responses from research professionals (n=690) and biosafety professionals (n=157). The survey data was utilized to conduct CFA, which confirmed five underlying structure of the BSCL scale of research professionals. These five factors are: management priority, supervisor commitment, communication, participation, and group norm. This study found that the overall biosafety climate scores of research and biosafety professionals are comparable. However, some significant differences between individual item scores of the BSCL scale between research and biosafety professionals was found. This study identified the gaps in perceptions of research and biosafety professionals which suggests that the information being applied to assess risk might be different for research and biosafety professionals.

Chapter 5 found significant association between biosafety climate perceptions and biosafety program management. For this study, data was collected from research professionals (n=15) at UofL through a survey and interviews on perceptions during two different biosafety program managements in place at UofL over the period 2011 to 2021. A review of program records was also conducted as part of this study. Perspectives from research professionals on the important aspects of a biosafety program management during and beyond COVID-19 pandemic was shared in this study. A biosafety program that is collaborative in approach, driven by actual risk, safety culture and behavior-based concepts elicited better perceptions of biosafety climate from researchers.

Chapter 6 summarized the perspectives of biosafety professionals on biosafety program management in biological laboratories. Four subject matter experts were asked to share their opinions on biosafety during the pandemic. A summary of the perspectives of research professionals on biosafety program management was drawn from the previous studies. The important aspects of biosafety program management from the perspective of both biosafety and research professionals were presented in the era of COVID-19 and beyond.

Strengths

Primary data was collected for all the studies presented in this dissertation that would be of immense interest to biosafety and research community. The BSCL scale that was developed and validated can be used as a key performance indicator of biosafety programs and aid in developing targeted interventions to improve safety. The impact of COVID-19 pandemic and biosafety program management on biosafety climate perceptions was evaluated. The BSCL scale was utilized to assess the impact of two different management programs on biosafety climate at UofL, revealing valuable insights that could aid the current biosafety management to further advance biosafety. This study quantified the biosafety climate perceptions of researchers and biosafety professionals at the national level, providing a snapshot of safety status of biological research laboratories.

Limitations

This dissertation only collected data from public biological laboratories in the USA and, thus, the results should be interpreted carefully when generalizing the findings to private, diagnostic, or clinical biological laboratories. The BSCL scale for research professionals

was confirmed to have a five underlying factor structure. However, the BSCL scale for biosafety professionals was unable to confirm the underlying factor structure.

Significance

Overall, this dissertation study contributes to the field of occupational safety and fills in gaps in the literature on safety climate specific to academic biological and biomedical research laboratories in the US. BSCL scale has the potential to serve as a benchmark for evaluating biosafety climate at academic laboratories. It can serve as a tool for biosafety program management and process improvement. This dissertation utilized the BSCL scale successfully to quantify biosafety climate perceptions of research and biosafety professionals at biological laboratories. By evaluating the biosafety practices, perceptions, and impact of COVID-19 pandemic on biosafety climate perceptions at national biological laboratories, this study was able to find the gaps in differences between research and biosafety professionals. Significant differences in risk perceptions', biosafety resources awareness and utilization was observed between research and biosafety professionals. Perspectives from both research and biosafety professionals was collected as part of this dissertation, which should be considered in developing or improving biosafety programs for biological laboratories.

Future Recommendations

The association of biosafety climate and drivers of biosafety programs should be further explored. The disparities in risk assessment, utilization of biosafety guidelines, and resources between research and biosafety professionals should be evaluated. Studies should emphasize on a thorough understanding on the gaps between research and biosafety professionals in biosafety program management. Biosafety programs

management should consider the recommendations and biosafety climate perceptions of research and biosafety professionals presented in this dissertation.

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APPENDICES

APPENDIX A

Mansucript Coupright Permission

FW: Applied Biosafety Manuscript ID - APB-2021-0006.R1

Ballen, Karen <KBallen@liebertpub.com>
Tue 6/1/2021 3:26 PM
To: Mareedu,Sivarchana <sivarchana.mareedu@louisville.edu>

Dear Sivarchana:

Copyright permission is granted for the inclusion of your article, apb.2021.0006 in your dissertation.
Please give proper acknowledgement to the journal and to the publisher.

Kind regards,

Karen Ballen
Manager, Reprints, Permissions and Liebert Open Access
Mary Ann Liebert, Inc., publishers
New Rochelle, NY

From: Applied Biosafety <onbehalfof@manuscriptcentral.com>
Sent: Tuesday, June 1, 2021 11:25 AM
To: Karen Savage <Karen@absaoffice.org>
Cc: torsten.hopp@louisville.edu; ritendranath.mitra@louisville.edu; sivarchana.mareedu@louisville.edu
Subject: Applied Biosafety Manuscript ID - APB-2021-0006.R1

01-Jun-2021

Dear Ms. Savage, Barbara Johnson and Karen Byers,

Thank you for accepting our manuscript for publication in Applied Biosafety. We are grateful for the opportunity to share our work with the biosafety community.
Since this work was done as part of my Phd dissertation research, I was wondering what the process is to get copyright clearance from the published to share my work in my dissertation.
Your guidance on this matter is appreciated.

Sincerely,
Sivarchana Mareedu
Phone: (502) 718-9795

Sincerely,
Mrs. Sivarchana Mareedu

APPENDIX B

Institutional Review Board -Outcome Letter 1

UNIVERSITY OF LOUISVILLE

Human Subjects Protection Program Office
MedCenter One – Suite 200
501 E. Broadway
Louisville, KY 40202-1798

DATE:	October 29, 2020
TO:	Torsten A Hopp, Ph.D.
IRB NUMBER:	18.1220
STUDY TITLE:	Status of biosafety climate and drivers of safety culture as determined by Safety climate at US biomedical and microbiological academic laboratories.
REFERENCE #:	716865
IRB STAFF CONTACT:	Jennifer Hay 852.4535 jmhay001@louisville.edu

The amendment request has been received by the Human Subjects Protection Program Office and approved by the Chair of the Institutional Review Board (IRB) on 10/28/2020 through the expedited review procedure according to 45 CFR 46.110(B).

The following documents have been reviewed and approved:

Title	Version #	Version Date	Outcome
BiosafetyclimateSurvey	Version 4.1	10/25/2020	Approved
Preamble-Survey-10.26.2020 Version 1.4-Clean	Version 4.0	10/26/2020	Approved

The modifications include:

- Updated biosafety climate survey, email/preamble consent.
- In biosafety climate survey, question 51 for researcher' s safety survey and question 54 in biosafety professional' s survey were added.
- The email template is what we plan to share with potential survey respondents. Consent document has been changes to correct errors (such as 'me to Sivarchana Mareedu) but nothing major.
- We plan to distribute the survey:
  a. To researchers at UofL as a follow up to the survey in 2019.
  b. To researchers and biosafety professionals at US public universities that have a biomedical and microbiological program.

This change does not require participants to be re-consented.

IRB policy requires that investigators use the IRB "stamped" approved version of informed consents, assents, and other materials given to research participants. The previous versions are no longer valid. For instructions on locating the IRB stamped documents in iRIS visit:
https://louisville.edu/research/humansubjects/iRISSubmissionManual.pdf.

The committee will be advised of this action at a regularly scheduled meeting.

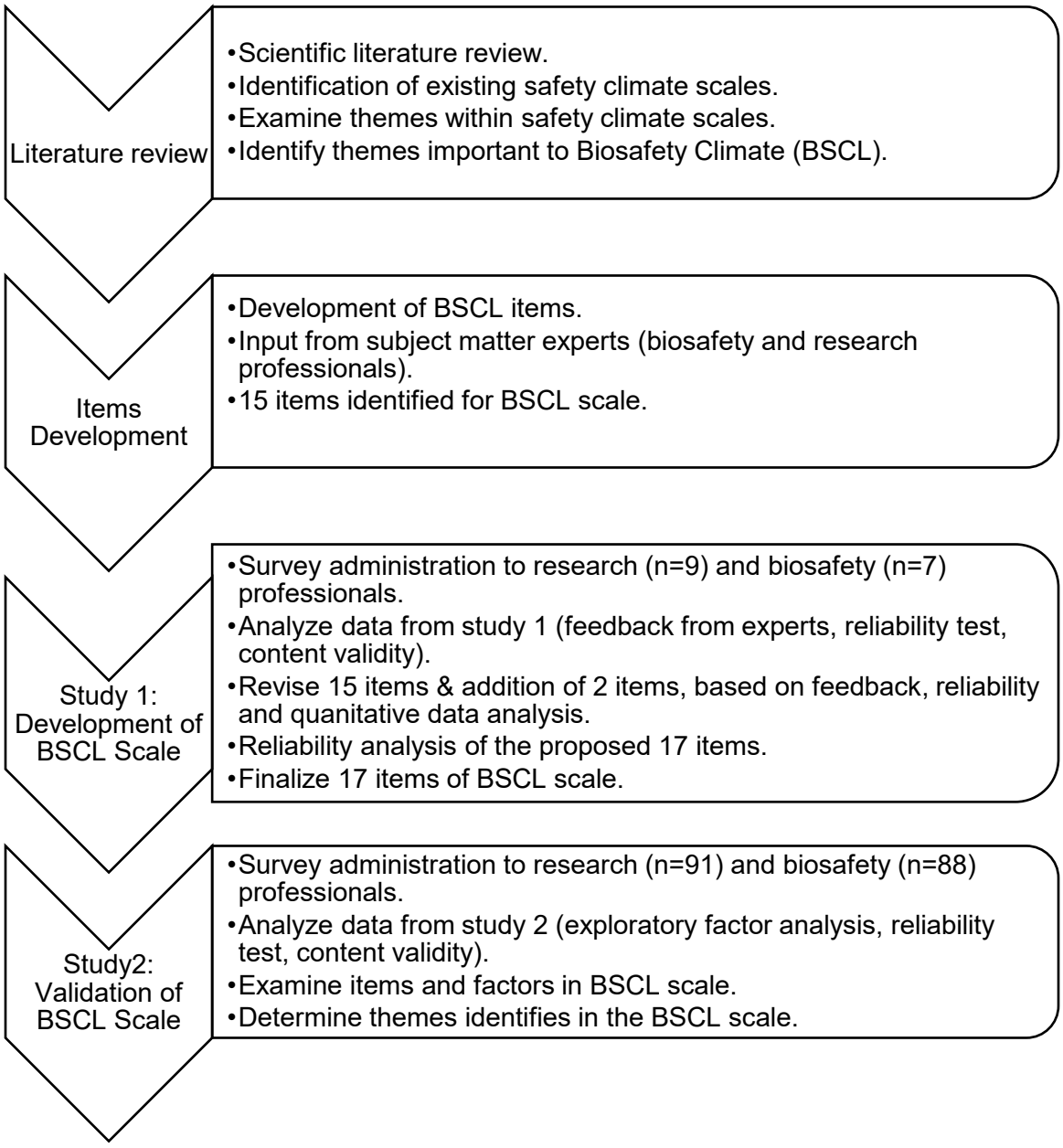
Thank you,

Laura Clark MD

Laura Clark, M.D., Chair
Biomedical Institutional Review Board
LC/jmh

APPENDIX C

Biosafety Climate (BSCL) Scale Development and Validation Process



APPENDIX D

Subject Recruitment Email

Subject title: Contribute to PhD Study | Perception of Biosafety in UofL Biological Laboratories

Greetings,

I am a Ph.D. candidate at University of Louisville. As part of my dissertation thesis, I am investigating biosafety climate and perceptions of both biosafety and research professionals at US academic laboratories under the guidance of Dr. Torsten Hopp, Biosafety Officer at UofL.

You are requested to participate in the study if you are a student, researcher and/or biosafety professional at an academic university performing microbiological and biomedical research activities utilizing risk group 1, 2 or 3 agents at BSL-1 and/or 2 laboratories.

Please contribute to our study by participating and sharing the Biosafety Climate Survey at UofL by clicking here URL LINK from REDCap. This is a public link that can be shared with others whereas the link at the bottom of this email is specific to you.

Your input will enable us to gain insights on the status of biosafety climate and understand the factors that lead to safer biological laboratories.

Your participation is essential for the success of our study and any confidential information will be strictly safeguarded. It will take you about 20 minutes to complete the survey.

Our study on Biosafety Climate in the USA (IRB #: 18.1220) has been approved by the University of Louisville's Institutional Review Board on 07/22/2019.

For further details, please respond to this email or call Sivarchana Mareedu at (502) 718-9795

Sincerely,

Sivarchana Mareedu, MS

Doctoral Candidate, School of Public Health, and Information Sciences

UofL COVID-19 Contact Tracing Advisor/Analyst

Campus Health Services and Department of Environmental Health and Safety

University of Louisville

AND

Torsten A. Hopp, PhD, RBP

University Biosafety Officer / Responsible Official

Adjunct Assistant Professor, School of Public Health and Information Sciences

Department of Environmental Health and Safety

University of Louisville

APPENDIX E

Biosafety Climate Survey: USA

Confidential

Biosafety Climate Survey at UofL

Greetings,

You are invited to participate in a research study by answering questions on a Biosafety Climate Survey! This research project is being conducted by Sivarchana Mareedu, a student at University of Louisville as part of her dissertation towards her doctoral studies in Public Health-Environmental Health Sciences. It should take approximately 20 minutes or less to complete this survey.

PARTICIPATION
Your participation in this survey is voluntary. You may refuse to take part in the research or exit the survey at any time without penalty. You are free to decline any question you do not wish to answer for any reason.

BENEFITS
You will receive no direct benefits from participating in this research study. However, your responses may help us to learn more about biosafety climate and biosafety perceptions in academic universities in US.

RISKS
There are no foreseeable risks involved in participating in this study.

CONFIDENTIALITY
Your survey answers will be sent to REDCap where data will be stored in a password protected electronic format. All directly and indirectly identifying information we collect such as your name, email, university or institution name, or IP address will be kept confidential. Confidentiality safeguarding procedures will be employed to prevent persons other than the primary and co-investigators of the study from being able to identify your answers or know whether you participated in the study.

CONTACT
If you have any questions at any time about the study of the procedure, you may contact my research supervisor. Dr. Torsten Hopp via phone at (502)-852-2959 or via email at torsten.hopp@louisville.edu . You can also contact Sivarchana Mareedu via phone at (502)718-9795 or via email at sivarchana.mareedu@louisville.edu

If you feel you have not been treated according to the descriptions in this form, or that your rights as a participant in research have not been honored during the course of this project, or you have any questions, concerns, or complaints that you wish to address to someone other than the investigator, you may contact the University of Louisville's Institutional Review Board at 501 E. Broadway , Louisville, Kentucky 40202 or email at hsppofc@louisville.edu

IRB APROVAL
Our study on Biosafety Climate in the USA (IRB #: 18.1220) has been approved by the University of Louisville's Institutional Review on 07/22/2019.

ELECTRONIC CONSENT:
You may print a copy of this consent form for your records. Continuing the survey indicates that:
☐ You have read the above information
☐ You voluntarily agree to participate

A I am 18 years or older.

◯ Yes
◯ No

B	I am a _____ at an academic university that works with Risk Group 1, 2 or 3 agents at BSL 1 or 2.	◯ Research Professional ◯ Biosafety Professional ◯ Research and Biosafety Professional ◯ Other (Note1. Research Professional refers to primary investigator, lab manager, research associate, student, graduate research assistant, lab personnel and equivalent positions. 2. Biosafety Professional refers to biosafety officer, assistant biosafety officer, training specialist or equivalent positions with responsibilities in biosafety administration.Risk GroupRG1 - Are not associated with disease in healthy adult humans or animals RG2 - Are associated with disease which is rarely serious and for which preventative or therapeutics is often available RG3 - Are associated with serious or lethal human disease for which preventative or therapeutics may be available RG4 - Are associated with lethal human disease for which preventative or therapeutics are not readily available.)

Please choose either 'Research Professional' or 'Biosafety Professional' to indicate your current role at your institution or university.

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In the Biosafety Climate Survey questionnaire, please note that:

1. Biosafety refers to safety in relation to biological research activities in a laboratory.

2. Research Professional refers to primary investigator, lab manager, research associate, student, graduate research assistant, lab personnel and equivalent positions.

3. Biosafety Professional refers to biosafety officer, assistant biosafety officer, training specialist or equivalent positions with responsibilities in biosafety administration.

4. Supervisor refers to primary investigator, research supervisor, Dean, Department Chair, EHS director, Vice President of Research Compliance, or equivalent positions.

5. University administration refers to higher management in the university who oversees research compliance and safety.

		Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
1	The safety of research professionals is a priority for my institution.	○	○	○	○	○
2	University administration considers research professionals' safety to be as important as productivity.	○	○	○	○	○
3	University administration shows support for prevention of biological hazards and incidents through involvement and commitment.	○	○	○	○	○
4	In the laboratory, my supervisor acts quickly to correct problems/issues that affect research professional's safety.	○	○	○	○	○
5	My supervisor clearly considers the safety of research professionals to be of great importance.	○	○	○	○	○
6	My supervisor acts decisively when a concern of a research professional's safety practices is raised.	○	○	○	○	○
7	There is good communication at my institution about biosafety issues which affect me.	○	○	○	○	○
8	Information about proper biosafety practices is always brought to my attention in my institution.	○	○	○	○	○
9	My contributions to resolving biosafety concerns in the institution are listened to.	○	○	○	○	○
10	Research professionals participate in developing the best biosafety practices in my institution.	○	○	○	○	○
11	Research professionals are encouraged to become involved in biosafety matters.	○	○	○	○	○
12						

	At my institution, the promotion of the best biosafety practices involves all levels of the organization.	○	○	○	○	○
13	Consultation in developing the best biosafety practices involves researchers and biosafety professionals.	○	○	○	○	○
14	In the laboratory, we discuss research professional's safety, biological hazards and incident prevention.	○	○	○	○	○
15	In the laboratory, we care about each other's safety awareness.	○	○	○	○	○
16	In the laboratory, we remind each other of the regulations and guidelines regarding research professional's safety.	○	○	○	○	○
17	In the laboratory, we care about each other's safety compliance.	○	○	○	○	○
1	The safety of research professionals is a priority for my institution.	○	○	○	○	○
2	University administration considers research professionals' safety to be as important as productivity.	○	○	○	○	○
3	University administration shows support for prevention of biological hazards and incidents through involvement and commitment.	○	○	○	○	○
4	At my institution, my supervisor acts quickly to correct problems/issues that affect research professional's safety.	○	○	○	○	○
5	My supervisor clearly considers the safety of research professionals to be of great importance.	○	○	○	○	○
6	My supervisor acts decisively when a concern of a research professional's safety practices is raised.	○	○	○	○	○
7						

	There is good communication at my institution about biosafety issues which affect research professionals.	○	○	○	○	○
8	Information about proper biosafety practices is always brought to my attention in my institution.	○	○	○	○	○
9	My contributions to resolving biosafety concerns in the institution are listened to.	○	○	○	○	○
10	Research professionals participate in developing the best biosafety practices in my institution.	○	○	○	○	○
11	Research professionals are encouraged to become involved in biosafety matters.	○	○	○	○	○
12	At my institution, the promotion of the best biosafety practices involves all levels of the organization.	○	○	○	○	○
13	Consultation in developing the best biosafety practices involves researchers and biosafety professionals.	○	○	○	○	○
14	At my institution, we discuss research professional's safety, biological hazards and incident prevention.	○	○	○	○	○
15	At my institution, we care about each other's safety awareness.	○	○	○	○	○
16	At my institution, we remind each other of regulations and guidelines regarding research professional's safety.	○	○	○	○	○
17	At my institution, we care about each other's safety compliance.	○	○	○	○	○

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18 Please enter the name of your institution or university:

_____

19 Please enter your age:

_____

20 Please indicate your gender:

- ◯ Female
- ◯ Male
- ◯ Prefer to self describe (optional)

20.1

_____
(Please indicate your gender.)

21 Select all that apply to your role:

- ☐ Primary Investigator
- ☐ Professor
- ☐ Lab Manager
- ☐ Research Assistant
- ☐ GRA/GA/TA
- ☐ Student
- ☐ Other (specify below)

21.1

_____
(Please specify your role.)

22 Are you a current member of the IBC committee at your institution?

- ◯ Yes
- ◯ No
- ◯ I was a IBC member in the past

23 Please indicate number of years in your current role:

_____

24 Indicate your educational background:

- ◯ High School
- ◯ Bachelors
- ◯ Masters
- ◯ PhD

25 Select the type of work conducted in your lab:
(Select all that apply)

- ☐ Research
- ☐ Teaching
- ☐ Diagnostics
- ☐ Other(specify below)

25.1

_____
(Please specify the type of work conducted in your lab.)

26 Select the Biosafety level of your lab:
(Select all that apply)

- ☐ BSL-1
- ☐ BSL-2
- ☐ BSL-2+
- ☐ BSL-3
- ☐ BSL-4

27 Select the risk group of the organism used in your lab:
(Select all that apply)

- ☐ RG-1
- ☐ RG-2
- ☐ RG-3
- ☐ RG-4

28 Who funds your research project in 2018-2021? (Select all that apply)

- ☐ Government (NIH, NSF, FDA, DOD, OSHA, State and so on)
- ☐ University
- ☐ Private
- ☐ Other (specify below)

28.1

_____
(Please specify who funds your research project for 2018-2020?)

29 How many members are included in your research team including you?

_____

Progress Bar
18%

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30

Which of the following regulations and guidelines does the biosafety program follow at your institution? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
30.1 Center for Disease Control and Prevention Biosafety in Microbiological and Biomedical Laboratories (BMBL) BMBL provides guidelines that became the code of practice for biosafety-the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.	○	○	○	○	○
30.2 NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules Guidelines specify the biosafety practices and containment principles for constructing and handling: (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules.	○	○	○	○	○
30.3 OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) as amended pursuant to the Needlestick Safety and Prevention Act of 2000, prescribes safeguards to protect workers against the health hazards caused by bloodborne pathogens.	○	○	○	○	○
30.4 Institutional Policies	○	○	○	○	○
30.5 All of the Above	○	○	○	○	○

30.6

Other (specify below)	○	○	○	○	○

30.6.1

_____
(Please specify other regulations and guidelines followed by the biosafety program at you institution.)

Progress Bar
25%

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31 Select all that apply to your institution.

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
31.1 Regulations and guidelines are strictly followed in our institution.	○	○	○	○	○
31.2 Everyone is encouraged to know the regulations and guidelines and follow them.	○	○	○	○	○
31.3 Practical training is given to first time researchers in lab before they begin their work.	○	○	○	○	○
31.4 Peer to peer feedback on biosafety issues and safe practices is encouraged.	○	○	○	○	○
31.5 Biosafety issues and safe practices are easily communicated between lab personnel and/or biosafety professionals.	○	○	○	○	○
31.6 Senior management is involved in addressing biosafety issues and improving safe practices.	○	○	○	○	○

Progress Bar
32%

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32 Which of the following concepts drives the biosafety program at your institution? (Select all that apply)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
32.1 Regulations Federal and State such as regulations by OSHA, NIH, CDC, DOD, DOT and others.	○	○	○	○	○
32.2 Institutional PoliciesPolicies developed and administered at University or institution.	○	○	○	○	○
32.3 Safety Culture A safety approach that requires organization's commitment, style, behavioral patterns, attitudes, values and competencies.	○	○	○	○	○
32.4 Behavior-Based SafetyA safety approach where interventions are promoted by observing daily safe behavior, cooperation between people be it management or workers, feedback on safe behavior, coaching and mentoring is done constantly. Data gathered through observation is reviewed, safety goals are set and reached to reinforce safe behaviors.	○	○	○	○	○

Progress Bar
38%

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33 What mode of training is given at your institution? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
33.1 Online	○	○	○	○	○
33.2 Classroom	○	○	○	○	○
33.3 Hands On: By Researchers	○	○	○	○	○
33.4 Hands On: By Biosafety Professionals	○	○	○	○	○
33.5 Hands On: By Research and Biosafety Professionals	○	○	○	○	○
33.6 Other (specify below)	○	○	○	○	○

33.6.1 _____

(Please specify the mode of training given at your institution.)

Progress Bar
44%

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Training Taken

		Blood Borne Pathogen	NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	Biosafety	I do not remember	Other (specify below)
34	Select all the training you have taken in the past 1 year:	☐	☐	☐	☐	☐
35	Select all the training you have taken in the past 3 years:	☐	☐	☐	☐	☐
36	Select all the training you have taken in the past 5 years:	☐	☐	☐	☐	☐

34.1

_____
(Please specify the training you have taken in the past 1 year.)

34.2

_____
(Please specify the training you have taken in the past 3 years.)

34.3

_____
(Please specify the training you have taken in the past 5 years.)

Progress Bar
50%

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37 The biosafety administration at your institution conducts _____type of laboratory inspections/assessments.

	Never	Rarely	Sometimes	Often	Always
37.1 Announced	○	○	○	○	○
37.2 Unannounced	○	○	○	○	○
37.3 Both	○	○	○	○	○
37.4 Other(specify below)	○	○	○	○	○

37.4.1

_____
(Please specify the type of laboratory inspections/assessments conducted by biosafety administration at your institution.)

Progress Bar
56%

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38 Are you aware of how to prevent exposure to a biological hazard if an incident involving these hazards occurs in your lab?

- ◯ Yes
- ◯ Not Sure
- ◯ No

39 If incidents involving bio-hazards occurs in your lab, whom are you required to report to per incident reporting guidelines at your institution? (Select all that apply)

- ☐ Primary Investigator of The Study
- ☐ Department Chair
- ☐ Biosafety Officer
- ☐ Environmental Health and Safety
- ☐ Government (NIH, NSF, FDA, DOD, OSHA, State and so on)
- ☐ Colleagues in the Lab
- ☐ I Do Not Know
- ☐ Other (specify below)

39.1

_____

(Please specify who you are required to report to per incident reporting guidelines at your institution if incidents involving bio-hazards occurs in your lab.)

40 Are you aware of any biosafety incidents resulting in Lab Acquired Infections in your lab during 2016 to 2020?

- ◯ Yes
- ◯ No

40.1

_____

(Please provide additional details about the incident/s (OPTIONAL).)

41 Are you aware of any biosafety incidents resulting in exposure to biological hazards in your lab during 2016 to 2020?

- ◯ Yes
- ◯ No

41.1

_____

(Please provide additional details about the incident/s (OPTIONAL).)

Progress Bar
62%

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42 Select the following training format that you believe could improve biosafety at your institution. (Select all that apply)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
42.1 Online	○	○	○	○	○
42.2 Classroom	○	○	○	○	○
42.3 Hands On: By Research Professionals	○	○	○	○	○
42.4 Hands On: By Biosafety Professionals	○	○	○	○	○
42.5 Hands On: By Research and Biosafety Professionals	○	○	○	○	○
42.6 Other (specify below)	○	○	○	○	○

42.6.1

_____

(Please specify the training format that you believe could improve biosafety at your institution.)

Progress Bar
68%

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43	How do you rate biosafety practices at your lab?	◯ Good as is ◯ Can be improved ◯ Undergoing improvements
44	What do you consider the risk level of work conducted in your lab?	◯ Very Low risk ◯ Low Risk ◯ Moderate Risk ◯ High Risk ◯ Very High Risk ◯ I Don't Know
45	Do you believe your lab takes strong measures to protect you from the hazards of the work conducted in your lab?	◯ Strongly Disagree ◯ Disagree ◯ Neither Agree or Disagree ◯ Agree ◯ Strongly Agree
46	Do you consider the biosafety program at your institution to be effective in mitigating risks in your lab?	◯ Strongly Disagree ◯ Disagree ◯ Neither Agree or Disagree ◯ Agree ◯ Strongly Agree

Progress Bar
75%

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47 Which of the following do you believe would improve adherence to safety practices and mitigating risks in your lab? (Select all that apply)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
47.1 Regulations and guidelines are strictly followed in our institution.	○	○	○	○	○
47.2 Everyone is encouraged to know the regulations and guidelines and follow them.	○	○	○	○	○
47.3 Practical training is given to first time researchers in lab before they begin their work.	○	○	○	○	○
47.4 Peer to peer feedback on biosafety issues and safe practices is encouraged.	○	○	○	○	○
47.5 Biosafety issues and safe practices are easily communicated between lab personnel and/or biosafety professionals.	○	○	○	○	○
47.6 Senior management is involved in addressing biosafety issues and improving safe practices.	○	○	○	○	○

Progress Bar
80%

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48 Select the type of laboratory inspections/assessments you consider to be effective.

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
48.1 Announced	○	○	○	○	○
48.2 Unannounced	○	○	○	○	○
48.3 Both	○	○	○	○	○
48.4 Other (specify below)	○	○	○	○	○

48.4.1

_____
(Please specify the type of laboratory inspections/assessments you consider to be effective.)

Progress Bar
88%

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49 Which of the following biosafety resources are you aware of? (Select all that apply)

	Not at all Aware	Slightly Aware	Moderately Aware	Very Aware	Extremely Aware
49.1 American Biological Safety Association (ABSA)	○	○	○	○	○
49.2 WHO -Laboratory Biosafety Manual	○	○	○	○	○
49.3 Center for Disease Control and Prevention - Biosafety in Microbiological and Biomedical Laboratories (BMBL)	○	○	○	○	○
49.4 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	○	○	○	○	○
49.5 Canada-Pathogen Safety Data Sheet (PSDS)	○	○	○	○	○
49.6 OSHA-Bloodborne Pathogens	○	○	○	○	○
49.7 Guidelines for Biosafety Laboratory Competency	○	○	○	○	○
49.8 Institutional Biosafety Policies and Guidelines (IBC Committee)	○	○	○	○	○
49.9 Other (specify below)	○	○	○	○	○

49.9.1 _____

(Please specify any other biosafety resources that you are aware of.)

Progress Bar
92%

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50 Which of the following do you utilize to assess the risk of your research and lab activities in your lab? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
50.1 Risk Group of Agents	○	○	○	○	○
50.2 Consultation with a Biosafety officer	○	○	○	○	○
50.3 Center for Disease Control and Prevention - Biosafety in Microbiological and Biomedical Laboratories (BMBL)	○	○	○	○	○
50.4 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	○	○	○	○	○
50.5 Canadian Pathogen Safety Data Sheet (PSDS)	○	○	○	○	○
50.6 If using novel/rare agents -utilize peer research	○	○	○	○	○
50.7 OSHA-Bloodborne Pathogens	○	○	○	○	○
50.8 Institutional Biosafety Policies and Guidelines (IBC Committee)	○	○	○	○	○
50.9 Other (specify below)	○	○	○	○	○

50.9.1 _____

(Please specify any other resources that you utilize to assess the risk of your research and lab activities.)

Progress Bar
94%

51 In relation to Covid-19 and your activity in research labs, do you feel: (Select appropriate response)

	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
51.1 Safe working in research labs	○	○	○	○	○
51.2 Your institution prioritizes Covid-19 precautions in research labs	○	○	○	○	○
51.3 Your supervisor prioritizes Covid-19 precautions in research labs	○	○	○	○	○
51.4 There is good communication on changes in research lab safety due to Covid-19	○	○	○	○	○
51.5 In the laboratory, peers are complying with lab safety and Covid-19 precautions	○	○	○	○	○
51.6 Covid-19 precautions are imposing additional challenges in lab safety	○	○	○	○	○

Progress Bar
96%

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52 Select the type of laboratory design you work at

- ◯ Open laboratory design
- ◯ Closed laboratory design
- ◯ Both

(Note1. In open lab design, researchers share one or more of the following: space, equipment bench space and support staff. It allows communication, collaboration, and team-based work.2.In closed lab design, the principal investigator and/or researcher does not share the equipment or space with other researchers.)

53 Which lab design do you believe is safer: (Select appropriate response)

	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
53.1 Open lab	◯	◯	◯	◯	◯
53.2 Closed lab	◯	◯	◯	◯	◯
53.4 Both	◯	◯	◯	◯	◯

54 Which lab design do you prefer to work at: (Select appropriate response)

	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
54.1 Open Lab	◯	◯	◯	◯	◯
54.2 Closed Lab	◯	◯	◯	◯	◯
54.3 Both	◯	◯	◯	◯	◯

Progress Bar
99%

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18 Please enter the name of your institution or university:

_____

19 Please enter your age:

_____

20 Please indicate your gender:

- ◯ Female
- ◯ Male
- ◯ Prefer to self describe (optional)

20.1

_____
(Please indicate your gender.)

21 Select all that apply to your role:

- ☐ Biosafety Officer
- ☐ Assistant Biosafety Officer
- ☐ Research Training Professional or Equivalent
- ☐ Research Safety Professional or Equivalent
- ☐ Other (specify below)

21.1 _____
(Please specify your role.)

22 Are you a current member of the IBC committee at your institution?
- ◯ Yes
- ◯ No
- ◯ I was a IBC member in the past

23 Please indicate number of years in your current role: _____

24 Indicate your educational background:
- ◯ High School
- ◯ Bachelors
- ◯ Masters
- ◯ PhD

Progress Bar
16%

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25 Select the type of work conducted at your institution:
(Select all that apply)

- ☐ Research
- ☐ Teaching
- ☐ Diagnostics
- ☐ Other(specify below)

25.1

_____
(Please specify the type of work conducted at your institution.)

26 Select the Biosafety level of labs at your institution:
(Select all that apply)

- ☐ BSL-1
- ☐ BSL-2
- ☐ BSL-2+
- ☐ BSL-3
- ☐ BSL-4

27 Select the risk group of the organisms used at your institution:
(Select all that apply)

- ☐ RG-1
- ☐ RG-2
- ☐ RG-3
- ☐ RG-4

28 Who funds research at your institution in 2018- 2021?

(Select all that apply)

- ☐ Government (NIH, NSF, FDA, DOD, OSHA, State and so on)
- ☐ University
- ☐ Private
- ☐ Other (specify below)

28.1

_____
(Please specify who funds the research for 2018-2020 at your institution?)

Progress Bar
22%

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29 What is the budget of your biosafety team for this year (2020-2021)?

_____
((OPTIONAL))

30 How many members are included in your biosafety team including you?

_____

31 Please select the members on your biosafety team: (Select all that apply)

☐ Biosafety Officer
☐ Assistant Biosafety Officer
☐ Research Training Professional or Equivalent
☐ Research Safety Professional or Equivalent
☐ Other (specify below)

31.1

_____
(Please specify the members on your biosafety team.)

32 To whom does the biosafety department report at your institution:

◯ Environmental, Health and Safety Director or Equivalent
◯ Vice President of Research Compliance or Equivalent
◯ Other (specify below)

32.1

_____
(Please specify to whom does the biosafety department reports to at your institution.)

Progress Bar
28%

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33 Which of the following regulations and guidelines does the biosafety program follow at your institution? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
33.1 Center for Disease Control and Prevention Biosafety in Microbiological and Biomedical Laboratories (BMBL) BMBL provides guidelines that became the code of practice for biosafety-the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.	○	○	○	○	○
33.2 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules Guidelines specify the biosafety practices and containment principles for constructing and handling: (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules.	○	○	○	○	○
33.3 OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) as amended pursuant to the Needle stick Safety and Prevention Act of 2000, prescribes safeguards to protect workers against the health hazards caused by bloodborne pathogens.	○	○	○	○	○
33.4 Institutional Policies	○	○	○	○	○
33.5 All of the Above	○	○	○	○	○
33.6 Other (specify below)	○	○	○	○	○

33.6.1

_____
(Please specify other regulations and guidelines followed by the biosafety program at you institution.)

Progress Bar
33%

.

34 Select all that apply to your institution.

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
34.1 Regulations and guidelines are strictly followed in our institution.	○	○	○	○	○
34.2 Everyone is encouraged to know the regulations and guidelines and follow them.	○	○	○	○	○
34.3 Practical training is given to first time researchers in lab before they begin their work.	○	○	○	○	○
34.4 Peer to peer feedback on biosafety issues and safe practices is encouraged.	○	○	○	○	○
34.5 Biosafety issues and safe practices are easily communicated between lab personnel and/or biosafety professionals.	○	○	○	○	○
34.6 Senior management is involved in addressing biosafety issues and improving safe practices.	○	○	○	○	○

Progress Bar
38%

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35 Which of the following concepts drives the biosafety program at your institution? (Select all that apply)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
35.1 Regulations Federal, State Regulations by OSHA, NIH, CDC, DOD, DOT and others.	○	○	○	○	○
35.2 Institutional Policies Policies developed and administered at University or institution.	○	○	○	○	○
35.3 Safety Culture A safety approach that requires organization's commitment, style, behavioral patterns, attitudes, values and competencies.	○	○	○	○	○
35.4 Behavior-Based Safety A safety approach where interventions are promoted by observing daily safe behavior, cooperation between people be it management or workers, feedback on safe behavior, coaching and mentoring is done constantly. Data gathered through observation is reviewed, safety goals are set and reached to reinforce safe behaviors.	○	○	○	○	○

Progress Bar
44%

.

36 What mode of training is given at your institution? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
36.1 Online	○	○	○	○	○
36.2 Classroom	○	○	○	○	○
36.3 Hands On: By Researchers	○	○	○	○	○
36.4 Hands On: Biosafety Professionals	○	○	○	○	○
36.5 Hands On: By Research and Biosafety Professionals	○	○	○	○	○
36.6 Other (specify below)	○	○	○	○	○

36.6.1 _____

(Please specify other mode of training given at your institution.)

Progress Bar
50%

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Training Given

37 How often is biosafety training given to the researchers?

- ◯ Every Year
- ◯ Every Three Years
- ◯ Every Five Years
- ◯ Other (specify below)

37.1

_____
(Please specify how often biosafety training is given to researchers.)

38 How often is NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules training given to the researchers?

- ◯ Every Year
- ◯ Every Three Years
- ◯ Every Five Years
- ◯ Other (specify below)

38.1

_____
(Please specify how often NIH training is given to researchers.)

39 How often is the bloodborne pathogen training given to the researchers?

- ◯ Every Year
- ◯ Every Three Years
- ◯ Every Five Years
- ◯ Other (specify below)

39.1

_____
(Please specify how often blood-borne pathogen training is given to researchers.)

Progress Bar
55%

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40 The biosafety administration at your institution conducts _____type of laboratory inspections/assessments.

	Never	Rarely	Sometimes	Often	Always
40.1 Announced	○	○	○	○	○
40.2 Unannounced	○	○	○	○	○
40.3 Both	○	○	○	○	○
40.4 Other (specify below)	○	○	○	○	○

40.4.1

_____
(Please specify the type of laboratory inspections/assessments conducted by biosafety administration at your institution.)

Progress Bar
60%

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41 Are all the researchers at your university aware on how to prevent exposure to a biological hazard if an incident involving these hazards occurs?

- ◯ Yes
- ◯ Not Sure
- ◯ No

42 If incidents involving biohazards occurs at your institution, to whom all is it required to be reported per the incident reporting guidelines at your institution. (Select all that apply)

- ☐ Primary Investigator of The Study
- ☐ Department Chair
- ☐ Biosafety Officer
- ☐ Environmental Health and Safety
- ☐ Government (NIH, NSF, FDA, DOD, OSHA, State and so on)
- ☐ Colleagues in the Lab
- ☐ I Do Not Know
- ☐ Other (specify below)

42.1

_____

(Please specify who you are required to report to per incident reporting guidelines at your institution if incidents involving bio-hazards occurs in your lab.)

43 Are you aware of any biosafety incidents resulting in Lab Acquired Infections in your institution during 2016 to 2020?

- ◯ Yes
- ◯ No

43.1

_____

(Please provide additional details about the incident/s (OPTIONAL).)

44 Are you aware of any biosafety incidents resulting in exposure to biological hazards in your institution during 2016 to 2020?

- ◯ Yes
- ◯ No

44.1

_____

(Please provide additional details about the incident/s (OPTIONAL).)

Progress Bar
66%

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45 Select the following training format that you believe could improve biosafety at your institution.(Select all that apply)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
45.1 Online	○	○	○	○	○
45.2 Classroom	○	○	○	○	○
45.3 Hands On: By Researchers	○	○	○	○	○
44.1 Hands On: By Biosafety Professionals	○	○	○	○	○
45.5 Hands On: Research and Biosafety Professionals	○	○	○	○	○
45.6 Other (specify below)	○	○	○	○	○

45.6.1

_____

(Please specify the training format that you believe could improve biosafety at your institution.)

Progress Bar
72%

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46 How do you rate biosafety practices at your institution?

- ◯ Good as is
- ◯ Can be improved
- ◯ Undergoing improvements

47 What do you consider the risk level of work conducted in your institution?

- ◯ Very Low risk
- ◯ Low Risk
- ◯ Moderate Risk
- ◯ High Risk
- ◯ Very High Risk
- ◯ I Don't Know

48 Do you believe your institution takes strong measures to protect everyone from the hazards of the work conducted at your institution?

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neither Agree or Disagree
- ◯ Agree
- ◯ Strongly Agree

49 Do you consider the biosafety program at your institution to be effective in mitigating risks at your institution?

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neither Agree or Disagree
- ◯ Agree
- ◯ Strongly Agree

Progress Bar
77%

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50 Which of the following do you believe would improve adherence to safety practices and mitigating risks at your institution? (Select all that apply)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
50.1 Regulations and guidelines are strictly followed in our institution.	○	○	○	○	○
50.2 Everyone is encouraged to know the regulations and guidelines and follow them.	○	○	○	○	○
50.3 Practical training is given to first time researchers in lab before they begin their work.	○	○	○	○	○
50.4 Peer to peer feedback on biosafety issues and safe practices is encouraged.	○	○	○	○	○
50.5 Biosafety issues and safe practices are easily communicated between lab personnel and/or biosafety professionals.	○	○	○	○	○
50.6 Senior management is involved in addressing biosafety issues and improving safe practices.	○	○	○	○	○

Progress Bar
82%

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51 Select the type of laboratory inspections/assessments you consider to be effective.

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
51.1 Announced	○	○	○	○	○
51.2 Unannounced	○	○	○	○	○
51.3 Both	○	○	○	○	○
51.4 Other (specify below)	○	○	○	○	○

51.4.1

_____
(Please specify the type of laboratory inspections/assessments you consider to be effective.)

Progress Bar
88%

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52 Which of the following biosafety resources are you aware of? (Select all that apply)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
52.1 American Biological Safety Association (ABSA)	○	○	○	○	○
52.2 WHO -Laboratory Biosafety Manual	○	○	○	○	○
52.3 Center for Disease Control and Prevention - Biosafety in Microbiological and Biomedical Laboratories (BMBL)	○	○	○	○	○
52.4 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	○	○	○	○	○
52.5 Canada-Pathogen Safety Data Sheet (PSDS)	○	○	○	○	○
52.5 OSHA-Bloodborne Pathogens	○	○	○	○	○
52.7 Guidelines for Biosafety Laboratory Competency	○	○	○	○	○
52.8 Institutional Biosafety Policies and Guidelines(IBC Committee)	○	○	○	○	○
52.9 Other (specify below)	○	○	○	○	○

52.9.1

_____

(Please specify any other biosafety resources that you are aware of.)

Progress Bar
95%

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53 Which of the following do you utilize to assess the risk of research and lab activities at your institution? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
53.1 Risk Group of Agents	○	○	○	○	○
53.2 Consultation with a Biosafety officer	○	○	○	○	○
53.3 Center for Disease Control and Prevention - Biosafety in Microbiological and Biomedical Laboratories (BMBL)	○	○	○	○	○
53.4 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	○	○	○	○	○
53.5 Canadian Pathogen Safety Data Sheet (PSDS)	○	○	○	○	○
53.6 If using novel/rare agents -utilize peer research	○	○	○	○	○
53.7 Osha-Bloodborne Pathogens	○	○	○	○	○
53.8 Institutional Biosafety Policies and Guidelines(IBC Committee)	○	○	○	○	○
53.9 Other (specify below)	○	○	○	○	○

53.9.1

_____

(Please specify any other resources that you utilize to assess the risk of your research and lab activities.)

Progress Bar
94%

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54 In relation to Covid-19 and research labs at your institution, do you feel: (Select appropriate response)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
54.1 Research labs are safe	○	○	○	○	○
54.2 Your institution prioritizes Covid-19 precautions in research labs	○	○	○	○	○
54.3 Your supervisor prioritizes Covid-19 precautions in research labs	○	○	○	○	○
54.4 There is good communication on changes in research lab safety due to Covid-19	○	○	○	○	○
54.5 In the laboratory, research professionals are complying with lab safety and Covid-19 precautions	○	○	○	○	○
54.6 Covid-19 precautions are imposing additional challenges in lab safety	○	○	○	○	○

Progress Bar
96%

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55 Select the type of laboratory design at your institution

- ◯ Open laboratory design
- ◯ Closed laboratory design
- ◯ Both

(Note1. In open lab design, researchers share one or more of the following: space, equipment bench space and support staff. It allows communication, collaboration, and team-based work.2.In closed lab design, the principal investigator and/or researcher does not share the equipment or space with other researchers.)

56 Which lab design do you believe is safer: (Select appropriate response)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
56.1 Open lab	◯	◯	◯	◯	◯
56.2 Closed lab	◯	◯	◯	◯	◯
56.3 Both	◯	◯	◯	◯	◯

57 Which lab design do you prefer at your instituion: (Select appropriate response)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
57.1 Open lab	◯	◯	◯	◯	◯
57.2 Closed lab	◯	◯	◯	◯	◯
57.3 Both	◯	◯	◯	◯	◯

Progress Bar
99%

.

APPENDIX F

Subject Recruitment Email

Subject title: PhD Study| Perception of Safety in US Biological Laboratories

Greetings,

We are writing this message requesting your participation in our study. If you already completed this survey, kindly ignore this message. However, we humbly request you to share this survey with your peers and acquaintances.

We appreciate your time and attention.

You are requested to participate in the study if you are at an academic university in the USA performing microbiological and biomedical research activities utilizing risk group 1, 2 or 3 agents at BSL-1 and/or 2 laboratories in one of the following roles:

- Student
- Researcher
- Biosafety professional

Please contribute to our study by participating and sharing our survey on safety practices in biological laboratory settings by clicking here URL LINK from REDCap. You can either click on this public link URL LINK from REDCap that can be shared with others or click on the link at the bottom of this email that is specific to you to complete the survey

Your input will enable us to gain insights on the status of biosafety climate, compare perceptions of researchers and biosafety professionals and understand the factors that lead to safer biological laboratories.

Your participation is essential for the success of our study and any confidential information will be strictly safeguarded. It will take you about 10 to 15 minutes to complete the survey.

Our study on Biosafety Climate in the USA (IRB #: 18.1220) has been approved by the University of Louisville's Institutional Review Board on 07/22/2019.

For further details, please respond to this email or call Sivarchana Mareedu at (502) 718-9795

NOTE: You will receive 3 emails requesting your participation in this study. Please, ignore these requests if you do not want to participate or respond 'Remove' to stop receiving these email requests. Thank you!

Sincerely,

Sivarchana Mareedu, MS

Doctoral Candidate, School of Public Health, and Information Sciences

Department of Environmental and Occupational Health Sciences

University of Louisville

AND

Torsten A. Hopp, PhD, RBP

University Biosafety Officer / Responsible Official

Adjunct Assistant Professor, School of Public Health, and Information Sciences

Department of Environmental Health and Safety

University of Louisville

APPENDIX G

Institutional Review Board -Outcome Letter 2

UNIVERSITY OF LOUISVILLE

Human Subjects Protection Program Office
MedCenter One – Suite 200
501 E. Broadway
Louisville, KY 40202-1798

DATE:	January 19, 2021
TO:	Torsten A Hopp, Ph.D.
FROM:	The University of Louisville Institutional Review Board
IRB NUMBER:	18.1222
STUDY TITLE:	Comparison of Biosafety Program before December 31, 2014 and after January 01, 2015 and its effect on Biosafety Climate at University of Louisville.
REFERENCE #:	719514
DATE OF REVIEW:	01/15/2021
IRB STAFF CONTACT:	Jennifer Hay 852.4535 jmhay001@louisville.edu

An IRB Vice-Chair has reviewed your submission. The project described does not meet the "Common Rule" definition of human subjects' research. The IRB has classified this project as Non-Human Subjects Research (NHSR). The project can proceed.

This submission has been determined to be program evaluation and not human subjects research, based on the goal(s) stated in the protocol.

Institutional policies and guidelines on participant privacy must be followed. If you are using protected health information, the HIPAA Privacy rules still apply.

Any changes to this project or the focus of the investigation must be submitted to the IRB to ensure that the IRB determination above still applies.

Amendments for personnel changes are not required.

Thank you,

Paula Radmacher, Ph.D., Vice Chair
Biomedical Institutional Review Board
PR/jmh

We value your feedback; let us know how we are doing: https://www.surveymonkey.com/r/CCLHXRP

APPENDIX H

Subject Recruitment Email

Are you involved in biological research at University of Louisville?

We are enrolling volunteers for a research study to compare biosafety climate at University of Louisville's biological research laboratories prior to December 31, 2014 and after January 01, 2015.

Qualified participants must be:

1. 18 years or older.
2. Involved in research/work at UofL biological research laboratories that utilize risk group 1, 2 or 3 agents at biosafety level 1, 2 or 3 laboratories.
3. Have worked for at least 6 months or more prior to January 01, 2015 at UofL biological research laboratories.

The study involves participation in an online survey and phone/virtual interview. Your identity will be kept strictly confidential. There is no compensation for participation in the study. But your valuable experience and input will be greatly appreciated.

If you are interested, please contact us for more details:

Sivarchana Mareedu, MS

Doctoral Candidate, School of Public Health, and Information Sciences

Department of Environmental and Occupational Health Sciences

University of Louisville

OR

Torsten A. Hopp, PhD, RBP

University Biosafety Officer / Responsible Official

Adjunct Assistant Professor, School of Public Health, and Information Sciences

Department of Environmental Health and Safety

University of Louisville

APPENDIX I

Study Details Email

Subject title: Study Details | Biosafety Climate at UofL: Now & Then

Greetings,

Thank you for expressing your interest in our study.

You are requested to participate in the study if you have been involved in biological research or biological safety related work at University of Louisville for at least 6 months or longer prior to December 31, 2014.

The study involves the following activities:

1. Questionnaires: A Biosafety climate survey that will take approximately 20 minutes to complete.
2. Phone/Virtual interview: This interview will take about 45 minutes or longer and will involve a structured interview with open and close ended questions.

To participate in the survey please click here URL LINK from REDCap . This is a public link that can be shared with others whereas the link at the bottom of this email is specific to you.

Your input will enable us to gain insights on the status of biosafety climate prior to 12/31/2014 (Then) and after 01/01/2015 (Now) at UofL and understand the factors that lead to safer

biological laboratories at academic research institutions.

Your participation is essential for the success of our study and any confidential information will be strictly safeguarded. For questions, please respond to this email or call Sivarchana Mareedu.

If you already received this email earlier, kindly ignore this message. We appreciate your time and attention.

Sincerely,

Sivarchana Mareedu, MS

Doctoral Candidate, School of Public Health, and Information Sciences

Department of Environmental and Occupational Health Sciences

University of Louisville

AND

Torsten A. Hopp, PhD, RBP

University Biosafety Officer / Responsible Official

Adjunct Assistant Professor, School of Public Health, and Information Sciences

Department of Environmental Health and Safety

University of Louisville

APPENDIX J

Interview Guide

Confidentiality Statement

- Any identifying information will be removed from the data collected.
- Only the principal investigators will have access to the information.
    - Sivarchana Mareedu
    - Dr. Torsten Hopp
- With your permission, the interview will be recorded for data collection.
- The recording will be deleted once the study is completed.

Study Details

The study involves the following activities:

- Phone/virtual interview: This interview will take approximately 60 to 90 minutes.

  Semi structured interview approach to ensure same general areas of information are collected from each interview. Includes open and close ended questions.
- Questionnaire: A Biosafety climate survey that will take approximately 40 to 60 minutes to complete. A link to the survey will be shared at the end of the interview.

In today's interview, we will be discussing about the topics listed here. It consists of 5 topics on biosafety and your thoughts on biosafety. I will email the survey link at the end of the study. This is a semi structured interview, so please feel free to discuss on any topic not mentioned here.

Biosafety Administration

A. Biosafety program in place

1. Discuss any changes in the biosafety program over the years?
2. How have trainings related to biological safety changed over the years?
3. Describe accessibility for resources on biosafety guidelines at UofL?
4. Discuss how lab assessment are conducted.

B. Institutional Biosafety Committee

1. Were you ever a member of IBC?
2. Did you ever apply for a research protocol approval through IBC?
3. Tell me about the research protocol submission process?
4. Discuss if you find the process efficient?

C. Management priority to safety

1. How would you describe the management priority on biosafety practices?
2. Discuss any changes in management priority regarding biosafety over the years at university level and at department level.

<u>Safety Practices</u>

A. Communication

1. Do you feel there is open & easy communication with biosafety officer/staff? Please explain.
2. Describe how you communicate with biosafety office for any biosafety related matters or concerns?
3. Discuss if you find the biosafety office approachable?
4. What type of communication about biosafety related matters did you receive?
5. Explain how communication about biosafety related matters has changed over the years?

B. Participation and involvement

1. Describe your involvement in biological safety matters at UofL over the years?

2. Are there opportunities to be involved? Explain.

C. Group norms and behavior

1. Explain changes in group norms and behavior in relation to biosafety over the years?
2. Discuss the awareness and participation levels of your peers/research personnel in the laboratory about biosafety matters?
3. Describe how often do you discuss biosafety matters with peers/research personnel and administration (UofL & Department)

Safety Concerns

Please discuss:

A. Any safety concerns?
B. Rate safety concerns?
C. If different over years?

Note: Respond in relation to 3 time periods:12/31/2014 or prior, 01/01/2016 to 02/29/2020 and Since 03/01/2021 (during COVID-19)

Safety Perceptions

A. Discuss if you have a positive or negative opinion on biosafety practices at UofL?
B. Describe your observation on changes in lab safety over the years?

Note: Respond in relation to 3 time periods:12/31/2014 or prior, 01/01/2016 to 02/29/2020 and Since 03/01/2021 (during COVID-19)

COVID-19 and Biosafety

A. What additional challenges to lab safety did you notice?
B. Discuss how UofL biosafety program adapted to ensure lab safety during COVID-19?

Final Thoughts

A. Any suggestions to ensure efficient lab safety practices, moving forward?
B. Discuss Biosafety over the years.
C. Your opinion on biosafety practices at UofL

Biosafety Climate Survey

I will email the link to you by the end of the day.

The online survey will take 40 to 60 minutes approximately. You can pause and resume the survey as needed. Just save your code or reach out to me. Survey consists of 6 parts:

1. Consent information
2. Inclusion criteria
3. Demographics
4. Questionnaire 12/31/2014 or prior
5. Questionnaire 01/01/2016 or later if applicable
6. Current safety perceptions

Questions or Comments.

Thank you for your participation.

APPENDIX K

Biosafety Climate Survey at UofL: Program Evaluation

Confidential

Biosafety Climate Survey at UofL -Retrospective Study

Please contact Sivarchana Mareedu at (502)718-9795 or sivarchana.mareedu@louisville.edu for any questions or concerns.

Greetings,

You are invited to participate in our research study on Biosafety Program at University of Louisville prior to December 12/31/2014 and since January 01, 2016. As part of this study, you will be participating in 1. Phone/virtual interview and 2.Biosafety survey. This research project is being conducted by Sivarchana Mareedu, a student at University of Louisville as part of her dissertation towards her doctoral studies in Public Health-Environmental Health Sciences under the guidance of Torsten Hopp, Biosafety Officer at UofL. It might take approximately 40 to 60 minutes to complete the current survey.

PARTICIPATION

Your participation in this study is voluntary. You may refuse to take part in the research or exit the survey at any time without penalty. You are free to decline any question you do not wish to answer for any reason. By answering submitting the survey questions, you agree to participate in the study.

BENEFITS

You will receive no direct benefits from participating in this research study. However, your responses may help us to learn more about different biosafety programs in place, biosafety perceptions, and their effect on biosafety climate in an academic research university.

RISKS

There are no foreseeable risks involved in participating in this study.

CONFIDENTIALITY

Your survey answers will be sent to REDCap where data will be stored in a password protected electronic format. All directly and indirectly identifying information we collect such as your name, email, university or institution name, or IP address will be kept confidential. Confidentiality safeguarding procedures will be employed to prevent persons other than the principal and co-investigator of the study from being able to identify your answers or know whether you participated in the study.

CONTACT

If you have questions at any time about the study or the procedure, you may contact Dr. Torsten Hopp via phone at (502)-852-2959 or via email at torsten.hopp@louisville@edu . You can also contact Sivarchana Mareedu via phone at (502)718-9795 or via email at sivarchana.mareedu@louisville.edu
If you feel you have not been treated according to the descriptions in this form, or that your rights as a participant in research have not been honored during the course of this project, or if you have any questions, concerns, or complaints that you wish to address to someone other than the investigator, you may contact the University of Louisville's Institutional Review Board at 501 E. Broadway , Louisville, Kentucky 40202 or email at hsppofc@louisville.edu

ELECTRONIC CONSENT:

You may print a copy of this consent form for your records. Continuing the survey indicates that:
☐ You have read the above information
☐ You voluntarily agree to participate

In the Biosafety Climate Survey questionnaire, please note that:

1. Biosafety refers to safety in relation to biological research activities in a laboratory.

2. Research Professional refers to principal investigator, lab manager, research associate, student, graduate research assistant, lab personnel and equivalent positions.

3. Biosafety Professional refers to biosafety officer, assistant biosafety officer, training specialist or equivalent positions with responsibilities in biosafety administration.

4. Supervisor refers to primary investigator, research supervisor, Dean, Department Chair, EHS director, Vice President of Research Compliance, or equivalent positions.

5. University administration refers to higher management in the university who oversees research compliance and safety.

A Are you 18 years or older?

◯ Yes
◯ No

B Have you worked for at least 6 months or more prior to December 31, 2014 at University of Louisville's biological research laboratories that utilize risk group 1, 2 or 3 agents at biosafety level 1, 2 or 3 laboratories? (Note1.Risk GroupRG-1 are not associated with disease in healthy adult humans or animals RG-2 are associated with disease which is rarely serious and for which preventative or therapeutics is often available RG- 3 are associated with serious or lethal human disease for which preventative or therapeutics may be available RG-4 are associated with lethal human disease for which preventative or therapeutics are not readily available.2. Biosafety LevelsBSL-1 labs are used to study infectious agents or toxins not known to consistently cause disease in healthy adults.BSL-2 laboratories are used to study moderate-risk infectious agents or toxins that pose a risk if accidentally inhaled, swallowed, or exposed to the skin.BSL-3 laboratories are used to study infectious agents or toxins that may be transmitted through the air and cause potentially lethal infection through inhalation exposure. BSL-4 laboratories are used to study infectious agents or toxins that pose a high risk of aerosol-transmitted laboratory infections and life-threatening disease for which no vaccine or therapy is available.)

◯ Yes
◯ No

C Have you worked for at least 6 months or more since January 01, 2016 at University of Louisville biological research laboratories that utilize risk group 1, 2 or 3 agents at biosafety level 1, 2 or 3 laboratories?

◯ Yes
◯ No

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Part 1

Please answer the following questions on demographics.

1	Please enter your name:	_____
2	Please enter your email and/or phone number:	_____
3	Please enter the name of your university:	_____
3.1	Please enter the name of your current department:	_____
4	Please enter your age:	_____
5	Please indicate your gender:	◯ Female ◯ Male ◯ Prefer to self describe (optional)
5.1		_____ (Please indicate your gender.)
6	Are you a current member of the IBC committee at your institution?	◯ Yes ◯ No ◯ I was a IBC member in the past
6.1	Please indicate the dates during which you are/were a IBC member:	_____ (Ex: Jan 2014 to Dec 2016, 01/2014 to present)

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Part 2

Please answer the following questions based on your perceptions of biosafety practices during the time period of December 2008 to December 2014 at University of Louisville's biological research laboratories.

Please answer based on the time period of December 2014 or prior.

7 Select all that apply to your role:

- ☐ Principal Investigator
- ☐ Professor
- ☐ Lab Manager
- ☐ Research Assistant
- ☐ GRA/GA/TA
- ☐ Student
- ☐ Other (specify below)
- ☐ Post Doctoral Researcher

(As of December 2014 or prior.)

7.1 _____
(Please specify your role.)

8 Please indicate number of years in the role you choose above: _____
(As of December 2014 or prior.)

9 Please indicate your educational background:

- ◯ High School
- ◯ Bachelors
- ◯ Masters
- ◯ PhD
- ◯ Post Doctorate

(As of December 2014 or prior.)

10 Select the type of work that was conducted in your lab:
(Select all that apply)

- ☐ Research
- ☐ Teaching
- ☐ Diagnostics
- ☐ Other(specify below)

(As of December 2014 or prior.)

10.1 _____
(Please specify the type of work conducted in your lab.)

11 Select the Biosafety level of your lab:
(Select all that apply)

- ☐ BSL-1
- ☐ BSL-2
- ☐ BSL-2+
- ☐ BSL-3
- ☐ BSL-4

(As of December 2014 or prior.)

11.1 Select the risk group of the organisms that were used in your lab:
(Select all that apply)

- ☐ RG-1
- ☐ RG-2
- ☐ RG-3
- ☐ RG-4

(As of December 2014 or prior.)

12 Select the type of laboratory design you worked at:

◯ Open laboratory design
◯ Closed laboratory design
◯ Both
(As of December 2014 or prior. Note1. In open lab design, researchers share one or more of the following: space, equipment bench space and support staff. It allows communication, collaboration, and team-based work.2.In closed lab design, the principal investigator and/or researcher does not share the equipment or space with other researchers.)

12.1 Select the location of the laboratory you worked at:

◯ Belknap campus
◯ HSC campus
◯ Both

13 Who funded your research project?
(Select all that apply)

☐ Government (NIH, NSF, FDA, DOD, OSHA, State and so on)
☐ University
☐ Private
☐ Other (specify below)
(As of December 2014 or prior.)

13.1 _____
(Please specify who funds your research project?)

14 How many members were included in your research team including you? _____
(As of December 2014 or prior.)

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17%

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15. Biosafety Climate at University of Louisville prior to December 31, 2014.

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
15.1 The safety of research professionals is a priority for my institution.	○	○	○	○	○
15.2 University administration considers research professionals' safety to be as important as productivity.	○	○	○	○	○
15.3 University administration shows support for prevention of biological hazards and incidents through involvement and commitment.	○	○	○	○	○
15.4 In the laboratory, my supervisor acts quickly to correct problems/issues that affect research professional's safety.	○	○	○	○	○
15.5 My supervisor clearly considers the safety of research professionals to be of great importance.	○	○	○	○	○
15.6 My supervisor acts decisively when a concern of a research professional's safety practices is raised.	○	○	○	○	○
15.7 There is good communication at my institution about biosafety issues which affect me.	○	○	○	○	○
15.8 Information about proper biosafety practices is always brought to my attention in my institution.	○	○	○	○	○
15.9 My contributions to resolving biosafety concerns in the institution are listened to.	○	○	○	○	○
15.10 Research professionals participate in developing the best biosafety practices in my institution.	○	○	○	○	○

15.11

Research professionals are encouraged to become involved in biosafety matters.	○	○	○	○	○
15.12 At my institution, the promotion of the best biosafety practices involves all levels of the organization.	○	○	○	○	○
15.13 Consultation in developing the best biosafety practices involves researchers and biosafety professionals.	○	○	○	○	○
15.14 In the laboratory, we discuss research professional's safety, biological hazards and incident prevention.	○	○	○	○	○
15.15 In the laboratory, we care about each other's safety awareness.	○	○	○	○	○
15.16 In the laboratory, we remind each other of the regulations and guidelines regarding research professional's safety.	○	○	○	○	○
15.17 In the laboratory, we care about each other's safety compliance.	○	○	○	○	○

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27%

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Please answer based on the time period of December 2008 to December 2014 .

16 Which of the following regulations and guidelines did the biosafety program follow at your institution? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
16.1 Center for Disease Control and Prevention Biosafety in Microbiological and Biomedical Laboratories (BMBL) BMBL provides guidelines that became the code of practice for biosafety-the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.	○	○	○	○	○
16.2 NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules Guidelines specify the biosafety practices and containment principles for constructing and handling: (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules.	○	○	○	○	○
16.3 OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) as amended pursuant to the Needlestick Safety and Prevention Act of 2000, prescribes safeguards to protect workers against the health hazards caused by bloodborne pathogens.	○	○	○	○	○
16.4					

Institutional Policies	○	○	○	○	○
16.5 All of the Above	○	○	○	○	○
16.6 Other (specify below)	○	○	○	○	○

16.6.1 _____

(Please specify other regulations and guidelines followed by the biosafety program at you institution.)

17 Select all that apply to your institution.

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
17.1 Regulations and guidelines are strictly followed in our institution.	○	○	○	○	○
17.2 Everyone is encouraged to know the regulations and guidelines and follow them.	○	○	○	○	○
17.3 Practical training is given to first time researchers in lab before they begin their work.	○	○	○	○	○
17.4 Peer to peer feedback on biosafety issues and safe practices is encouraged.	○	○	○	○	○
17.5 Biosafety issues and safe practices are easily communicated between lab personnel and/or biosafety professionals.	○	○	○	○	○
17.6 Senior management is involved in addressing biosafety issues and improving safe practices.	○	○	○	○	○

18 Which of the following concepts drove the biosafety program at your institution? (Select all that apply)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
18.1 Regulations Federal and State such as regulations by OSHA, NIH, CDC, DOD, DOT and others.	○	○	○	○	○
18.2 Institutional PoliciesPolicies developed and administered at University or institution.	○	○	○	○	○
18.3 Safety Culture A safety approach that requires organization's commitment, style, behavioral patterns, attitudes, values and competencies.	○	○	○	○	○
18.4 Behavior-Based SafetyA safety approach where interventions are promoted by observing daily safe behavior, cooperation between people be it management or workers, feedback on safe behavior, coaching and mentoring is done constantly. Data gathered through observation is reviewed, safety goals are set and reached to reinforce safe behaviors.	○	○	○	○	○

Progress Bar
33%

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Please answer based on the time period of December 2008 to December 2014 .

19 What modes of training were given at your institution?
(Select all that apply)

	Never	Rarely	Sometimes	Often	Always
19.1 Online	○	○	○	○	○
19.2 Classroom	○	○	○	○	○
19.3 Hands On: By Researchers	○	○	○	○	○
19.4 Hands On: By Biosafety Professionals	○	○	○	○	○
19.5 Hands On: By Research and Biosafety Professionals	○	○	○	○	○
19.6 Other (specify below)	○	○	○	○	○

19.6.1 _____
(Please specify the mode of training given at your institution.)

20 Training Taken

	Blood Borne Pathogen	NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	Biosafety	I do not remember	Other (specify below)
20.1 Select all the training you have taken in the past 1 year:	☐	☐	☐	☐	☐
20.2 Select all the training you have taken in the past 3 years:	☐	☐	☐	☐	☐
20.3 Select all the training you have taken in the past 5 years:	☐	☐	☐	☐	☐

20.1.1 _____
(Please specify the training you have taken in the past 1 year.)

20.2.1 _____
(Please specify the training you have taken in the past 3 years.)

20.3.1 _____
(Please specify the training you have taken in the past 5 years.)

21 Which of the following biosafety resources were you aware of? (Select all that apply)

	Not at all Aware	Slightly Aware	Moderately Aware	Very Aware	Extremely Aware
21.1 American Biological Safety Association (ABSA)	○	○	○	○	○
21.2 WHO -Laboratory Biosafety Manual	○	○	○	○	○
21.3 Center for Disease Control and Prevention - Biosafety in Microbiological and Biomedical Laboratories (BMBL)	○	○	○	○	○
21.4 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	○	○	○	○	○
21.5 Canada-Pathogen Safety Data Sheet (PSDS)	○	○	○	○	○
21.6 OSHA-Bloodborne Pathogens	○	○	○	○	○
21.7 Guidelines for Biosafety Laboratory Competency	○	○	○	○	○
21.8 Institutional Biosafety Policies and Guidelines (IBC Committee)	○	○	○	○	○
21.9 Other (specify below)	○	○	○	○	○

21.9.1 _____

(Please specify any other biosafety resources that you are aware of.)

22 Which of the following did you utilize to assess the risk of your research and lab activities in your lab? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
22.1 Risk Group of Agents	○	○	○	○	○
22.2 Consultation with a Biosafety officer	○	○	○	○	○
22.3 Center for Disease Control and Prevention - Biosafety in Microbiological and Biomedical Laboratories (BMBL)	○	○	○	○	○
22.4 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	○	○	○	○	○
22.5 Canadian Pathogen Safety Data Sheet (PSDS)	○	○	○	○	○
22.6 If using novel/rare agents -utilize peer research	○	○	○	○	○
22.7 OSHA-Bloodborne Pathogens	○	○	○	○	○
22.8 Institutional Biosafety Policies and Guidelines (IBC Committee)	○	○	○	○	○

22.9

Other (specify below)	○	○	○	○	○

22.9.1 _____

(Please specify any other resources that you utilize to assess the risk of your research and lab activities.)

Progress Bar
39%

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Please answer based on the time period of December 2008 to December 2014.

23 The biosafety administration at your institution conducted _____type of laboratory inspections/assessments.

	Never	Rarely	Sometimes	Often	Always
23.1 Announced	○	○	○	○	○
23.2 Unannounced	○	○	○	○	○
23.3 Both	○	○	○	○	○
23.4 Other(specify below)	○	○	○	○	○

23.4.1 _____
(Please specify the type of laboratory inspections/assessments conducted by biosafety administration at your institution.)

24 Were you aware of how to prevent exposure to a biological hazard if an incident involving these hazards occurred in your lab?
- ○ Yes
- ○ Not Sure
- ○ No

25 If incidents involving bio-hazards occurred in your lab, whom were you required to report to per incident reporting guidelines at your institution? (Select all that apply)
- ☐ Primary Investigator of The Study
- ☐ Department Chair
- ☐ Biosafety Officer
- ☐ Environmental Health and Safety
- ☐ Government (NIH, NSF, FDA, DOD, OSHA, State and so on)
- ☐ Colleagues in the Lab
- ☐ I Do Not Know
- ☐ Other (specify below)

25.1 _____
(Please specify who you are required to report to per incident reporting guidelines at your institution if incidents involving bio-hazards occurs in your lab.)

26 Were you aware of any biosafety incidents resulting in lab acquired infections in your lab during 2014 or earlier?
- ○ Yes
- ○ No

26.1 _____
(Please provide additional details about the incident/s (OPTIONAL).)

27 Were you aware of any biosafety incidents resulting in exposure to biological hazards in your lab during 2014 or earlier?
- ○ Yes
- ○ No

27.1 _____
(Please provide additional details about the incident/s (OPTIONAL).)

28 How did you rate biosafety practices at your university?
- ○ Good as is
- ○ Can be improved
- ○ Undergoing improvements

(As of December 2014 or prior.)

29 What did you consider the risk level of work conducted in your lab?

- ◯ Very Low risk
- ◯ Low Risk
- ◯ Moderate Risk
- ◯ High Risk
- ◯ Very High Risk
- ◯ I Don't Know

(As of December 2014 or prior.)

30 Did you believe your lab took strong measures to protect you from the hazards of the work conducted in your lab?

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neither Agree or Disagree
- ◯ Agree
- ◯ Strongly Agree

(As of December 2014 or prior.)

31 Did you consider the biosafety program at your university to be effective in mitigating risks in your lab?

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neither Agree or Disagree
- ◯ Agree
- ◯ Strongly Agree

(As of December 2014 or prior.)

Progress Bar
45%

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Part 3

Please answer the following questions based on your perceptions of biosafety practices during the time period of January 2016 to present at University of Louisville's biological research laboratories.

Please answer based on the time period of January 2016 to present.

7 Select all that apply to your role:

- ☐ Principal Investigator
- ☐ Professor
- ☐ Lab Manager
- ☐ Research Assistant
- ☐ GRA/GA/TA
- ☐ Student
- ☐ Other (specify below)
- ☐ Post Doctoral Researcher

(As of December 2014 or prior.)

7.1 _____

(Please specify your role.)

8 Please indicate number of years in the role you choose above: _____

(As of December 2014 or prior.)

9 Please indicate your educational background:

- ◯ High School
- ◯ Bachelors
- ◯ Masters
- ◯ PhD
- ◯ Post Doctorate

(As of December 2014 or prior.)

10 Select the type of work conducted in your lab:
(Select all that apply)

- ☐ Research
- ☐ Teaching
- ☐ Diagnostics
- ☐ Other(specify below)

(As of December 2014 or prior.)

10.1 _____

(Please specify the type of work conducted in your lab.)

11 Select the Biosafety level of your lab:
(Select all that apply)

- ☐ BSL-1
- ☐ BSL-2
- ☐ BSL-2+
- ☐ BSL-3
- ☐ BSL-4

(As of December 2014 or prior.)

11.1 Select the risk group of the organisms used in your lab:
(Select all that apply)

- ☐ RG-1
- ☐ RG-2
- ☐ RG-3
- ☐ RG-4

(As of December 2014 or prior.)

12 Select the type of laboratory design you work at:

◯ Open laboratory design
◯ Closed laboratory design
◯ Both
(As of December 2014 or prior. Note1. In open lab design, researchers share one or more of the following: space, equipment bench space and support staff. It allows communication, collaboration, and team-based work.2.In closed lab design, the principal investigator and/or researcher does not share the equipment or space with other researchers.)

12.1 Select the location of the laboratory you worked at:

◯ Belknap campus
◯ HSC campus
◯ Both

13 Who funds your research project?
(Select all that apply)

☐ Government (NIH, NSF, FDA, DOD, OSHA, State and so on)
☐ University
☐ Private
☐ Other (specify below)
(As of December 2014 or prior.)

13.1 _____
(Please specify who funds your research project?)

14 How many members are included in your research team including you? _____
(As of December 2014 or prior.)

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52%

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15. Biosafety Climate at University of Louisville since January 01, 2016.

	Strongly Disagree	Disgaree	Neither Disagree or Agree	Agree	Strongly Agree
15.1 The safety of research professionals is a priority for my institution.	○	○	○	○	○
15.2 University administration considers research professionals' safety to be as important as productivity.	○	○	○	○	○
15.3 University administration shows support for prevention of biological hazards and incidents through involvement and commitment.	○	○	○	○	○
15.4 In the laboratory, my supervisor acts quickly to correct problems/issues that affect research professional's safety.	○	○	○	○	○
15.5 My supervisor clearly considers the safety of research professionals to be of great importance.	○	○	○	○	○
15.6 My supervisor acts decisively when a concern of a research professional's safety practices is raised.	○	○	○	○	○
15.7 There is good communication at my institution about biosafety issues which affect me.	○	○	○	○	○
15.7 Information about proper biosafety practices is always brought to my attention in my institution.	○	○	○	○	○
15.8 My contributions to resolving biosafety concerns in the institution are listened to.	○	○	○	○	○
15.9 Research professionals participate in developing the best biosafety practices in my institution.	○	○	○	○	○
15.10					

	Research professionals are encouraged to become involved in biosafety matters.	○	○	○	○	○
15.11	At my institution, the promotion of the best biosafety practices involves all levels of the organization.	○	○	○	○	○
15.12	Consultation in developing the best biosafety practices involves researchers and biosafety professionals.	○	○	○	○	○
15.13	In the laboratory, we discuss research professional's safety, biological hazards and incident prevention.	○	○	○	○	○
15.14	In the laboratory, we care about each other's safety awareness.	○	○	○	○	○
15.16	In the laboratory, we remind each other of the regulations and guidelines regarding research professional's safety.	○	○	○	○	○
15.17	In the laboratory, we care about each other's safety compliance.	○	○	○	○	○

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62%

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Please answer based on the time period of January 2016 to present.

16 Which of the following regulations and guidelines does the biosafety program follow at your institution? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
Center for Disease Control and Prevention Biosafety in Microbiological and Biomedical Laboratories (BMBL) BMBL provides guidelines that became the code of practice for biosafety-the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.	○	○	○	○	○
NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules Guidelines specify the biosafety practices and containment principles for constructing and handling: (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules.	○	○	○	○	○
OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) as amended pursuant to the Needlestick Safety and Prevention Act of 2000, prescribes safeguards to protect workers against the health hazards caused by bloodborne pathogens.	○	○	○	○	○

Institutional Policies	○	○	○	○	○
All of the Above	○	○	○	○	○
Other (specify below)	○	○	○	○	○

16.6.1 _____

(Please specify other regulations and guidelines followed by the biosafety program at you institution.)

17 Select all that apply to your institution.

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
17.1 Regulations and guidelines are strictly followed in our institution.	○	○	○	○	○
17.2 Everyone is encouraged to know the regulations and guidelines and follow them.	○	○	○	○	○
17.3 Practical training is given to first time researchers in lab before they begin their work.	○	○	○	○	○
17.4 Peer to peer feedback on biosafety issues and safe practices is encouraged.	○	○	○	○	○
17.5 Biosafety issues and safe practices are easily communicated between lab personnel and/or biosafety professionals.	○	○	○	○	○
17.6 Senior management is involved in addressing biosafety issues and improving safe practices.	○	○	○	○	○

18 Which of the following concepts drives the biosafety program at your institution? (Select all that apply)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
18.1 Regulations Federal and State such as regulations by OSHA, NIH, CDC, DOD, DOT and others.	○	○	○	○	○
18.2 Institutional PoliciesPolicies developed and administered at University or institution.	○	○	○	○	○
18.3 Safety Culture A safety approach that requires organization's commitment, style, behavioral patterns, attitudes, values and competencies.	○	○	○	○	○
18.4 Behavior-Based SafetyA safety approach where interventions are promoted by observing daily safe behavior, cooperation between people be it management or workers, feedback on safe behavior, coaching and mentoring is done constantly. Data gathered through observation is reviewed, safety goals are set and reached to reinforce safe behaviors.	○	○	○	○	○

Progress Bar
68%

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Please answer based on the time period of January 2016 to present.

19 What mode of training is given at your institution?
(Select all that apply)

	Never	Rarely	Sometimes	Often	Always
19.1 Online	○	○	○	○	○
19.2 Classroom	○	○	○	○	○
19.3 Hands On: By Researchers	○	○	○	○	○
19.4 Hands On: By Biosafety Professionals	○	○	○	○	○
19.5 Hands On: By Biosafety Professionals	○	○	○	○	○
19.6 Other (specify below)	○	○	○	○	○

19.6.1 _____
(Please specify the mode of training given at your institution.)

20 Training Taken

	Blood Borne Pathogen	NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	Biosafety	I do not remember	Other (specify below)
20.1 Select all the training you have taken in the past 1 year:	☐	☐	☐	☐	☐
20.2 Select all the training you have taken in the past 3 years:	☐	☐	☐	☐	☐
20.3 Select all the training you have taken in the past 5 years:	☐	☐	☐	☐	☐

20.1.1 _____
(Please specify the training you have taken in the past 1 year.)

20.2.1 _____
(Please specify the training you have taken in the past 3 years.)

20.3.1 _____
(Please specify the training you have taken in the past 5 years.)

21 Which of the following biosafety resources are you aware of? (Select all that apply)

	Not at all Aware	Slightly Aware	Moderately Aware	Very Aware	Extremely Aware
21.1 American Biological Safety Association (ABSA)	○	○	○	○	○
21.2 WHO -Laboratory Biosafety Manual	○	○	○	○	○
21.3 Center for Disease Control and Prevention - Biosafety in Microbiological and Biomedical Laboratories (BMBL)	○	○	○	○	○
21.4 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	○	○	○	○	○
21.5 Canada-Pathogen Safety Data Sheet (PSDS)	○	○	○	○	○
21.6 OSHA-Bloodborne Pathogens	○	○	○	○	○
21.7 Guidelines for Biosafety Laboratory Competency	○	○	○	○	○
21.8 Institutional Biosafety Policies and Guidelines (IBC Committee)	○	○	○	○	○
21.9 Other (specify below)	○	○	○	○	○

21.9.1 _____

(Please specify any other biosafety resources that you are aware of.)

22 Which of the following do you utilize to assess the risk of your research and lab activities in your lab? (Select all that apply)

	Never	Rarely	Sometimes	Often	Always
22.1 Risk Group of Agents	○	○	○	○	○
22.2 Consultation with a Biosafety officer	○	○	○	○	○
22.3 Center for Disease Control and Prevention - Biosafety in Microbiological and Biomedical Laboratories (BMBL)	○	○	○	○	○
22.4 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	○	○	○	○	○
22.5 Canadian Pathogen Safety Data Sheet (PSDS)	○	○	○	○	○
22.6 If using novel/rare agents -utilize peer research	○	○	○	○	○
22.7 OSHA-Bloodborne Pathogens	○	○	○	○	○
22.8 Institutional Biosafety Policies and Guidelines (IBC Committee)	○	○	○	○	○

22.9

Other (specify below)	○	○	○	○	○

22.9.1 _____

(Please specify any other resources that you utilize to assess the risk of your research and lab activities.)

Progress Bar
74%

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Please answer based on the time period of January 2016 to present.

23 The biosafety administration at your institution conducts _____type of laboratory inspections/assessments.

	Never	Rarely	Sometimes	Often	Always
23.1 Announced	○	○	○	○	○
23.2 Unannounced	○	○	○	○	○
23.3 Both	○	○	○	○	○
23.4 Other (specify below)	○	○	○	○	○

23.4.1 _____
(Please specify the type of laboratory inspections/assessments conducted by biosafety administration at your institution.)

24 Are you aware of how to prevent exposure to a biological hazard if an incident involving these hazards occurs in your lab?
- ○ Yes
- ○ Not Sure
- ○ No

25 If incidents involving bio-hazards occurs in your lab, whom are you required to report to per incident reporting guidelines at your institution? (Select all that apply)
- ☐ Primary Investigator of The Study
- ☐ Department Chair
- ☐ Biosafety Officer
- ☐ Environmental Health and Safety
- ☐ Government (NIH, NSF, FDA, DOD, OSHA, State and so on)
- ☐ Colleagues in the Lab
- ☐ I Do Not Know
- ☐ Other (specify below)

25.1 _____
(Please specify who you are required to report to per incident reporting guidelines at your institution if incidents involving bio-hazards occurs in your lab.)

26 Are you aware of any biosafety incidents resulting in Lab Acquired Infections in your lab during 2016 to 2020?
- ○ Yes
- ○ No

26.1 _____
(Please provide additional details about the incident/s (OPTIONAL).)

27 Are you aware of any biosafety incidents resulting in exposure to biological hazards in your lab during 2016 to 2020?
- ○ Yes
- ○ No

27.1 _____
(Please provide additional details about the incident/s (OPTIONAL).)

28 How do you rate biosafety practices at your university?
- ○ Good as is
- ○ Can be improved
- ○ Undergoing improvements
(As of December 2014 or prior.)

29 What do you consider the risk level of work conducted in your lab?

- ◯ Very Low risk
- ◯ Low Risk
- ◯ Moderate Risk
- ◯ High Risk
- ◯ Very High Risk
- ◯ I Don't Know

(As of December 2014 or prior.)

30 Do you believe your lab takes strong measures to protect you from the hazards of the work conducted in your lab?

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neither Agree or Disagree
- ◯ Agree
- ◯ Strongly Agree

(As of December 2014 or prior.)

31 Do you consider the biosafety program at your university to be effective in mitigating risks in your lab?

- ◯ Strongly Disagree
- ◯ Disagree
- ◯ Neither Agree or Disagree
- ◯ Agree
- ◯ Strongly Agree

(As of December 2014 or prior.)

Progress Bar
80%

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Part 4

Please answer the following questions based on your current perceptions of biosafety practices.

32 Which of the following do you believe would improve adherence to safety practices and mitigating risks in your lab? (Select all that apply)

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
32.1 Regulations and guidelines are strictly followed in our institution.	○	○	○	○	○
32.2 Everyone is encouraged to know the regulations and guidelines and follow them.	○	○	○	○	○
32.3 Practical training is given to first time researchers in lab before they begin their work.	○	○	○	○	○
32.4 Peer to peer feedback on biosafety issues and safe practices is encouraged.	○	○	○	○	○
32.5 Biosafety issues and safe practices are easily communicated between lab personnel and/or biosafety professionals.	○	○	○	○	○
32.6 Senior management is involved in addressing biosafety issues and improving safe practices.	○	○	○	○	○

33 Select the type of laboratory inspections/assessments you consider to be effective.

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
33.1 Announced	○	○	○	○	○
33.2 Unannounced	○	○	○	○	○
33.3 Both	○	○	○	○	○
33.4 Other (specify below)	○	○	○	○	○

33.4.1 _____

(Please specify the type of laboratory inspections/assessments you consider to be effective.)

34 Which lab design do you believe is safer:
(Select appropriate response)

	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
34.1 Open Lab	○	○	○	○	○
34.2 Closed Lab	○	○	○	○	○
34.3 Both	○	○	○	○	○

35 Which lab design do you prefer to work at:
(Select appropriate response)

	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
35.1 Open Lab	○	○	○	○	○
35.2 Closed Lab	○	○	○	○	○
35.3 Both	○	○	○	○	○

36 Select the following training format that you believe could improve biosafety at your institution.
(Select all that apply)

	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
36.1 Online	○	○	○	○	○
36.2 Classroom	○	○	○	○	○
36.3 Hands On: By Research Professionals	○	○	○	○	○
36.4 Hands on: By Biosafety Professionals	○	○	○	○	○
36.7 Hands on: By Research and Biosafety Professionals	○	○	○	○	○
36.8 Other (specify below)	○	○	○	○	○

36.4.1 _____

(Please specify the type of laboratory inspections/assessments you consider to be effective.)

37 In relation to Covid-19 and your activity in research labs, do you feel:
(Select appropriate response)

	Strongly Agree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
37.1 Safe working in research labs	○	○	○	○	○
37.2 The university prioritizes Covid-19 precautions in research labs	○	○	○	○	○
37.3 Your supervisor prioritizes Covid-19 precautions in research labs	○	○	○	○	○
37.4 There is good communication on changes in research lab safety due to Covid-19	○	○	○	○	○
37.5 In the laboratory, peers are complying with lab safety and Covid-19 precautions	○	○	○	○	○
37.6 Covid-19 precautions are imposing additional challenges in lab safety	○	○	○	○	○

38 Please enter any additional comments you like to share:

_____

Progress Bar
99%

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Please click on the submit button to complete survey. Thank you for your time and patience.

CURRICULUM VITAE

Sivarchana Mareedu Boada

485 East Gary Street
Louisville, KY 40202
Email: msivarchana@gmail.com

EDUCATION

Doctor of Philosophy in Public Health Sciences -Environmental Health, August 2021
University of Louisville, Kentucky, USA

- Dissertation: Development and validation of biosafety climate scale and survey-based analyses of safety perceptions in biological research and teaching laboratories at public universities in the USA

Master of Science in Environmental, Safety and Health Management, December 2012
University of Findlay, Ohio, USA

- Thesis: Trend analysis of occupational injuries in manufacturing sector from 1926 to 2011 and benefits of implementing a lock-out/tag-out program in compliance with federal OSHA in a manufacturing company

Post Graduate Diploma in Bioinformatics, June 2010
Osmania University, India

- Thesis: Molecular Modeling and Docking Studies of RXR Antagonists based on Diepinylbenzoic Acid Structure

Bachelor of Science in Chemistry, Biotechnology and Biochemistry, June 2009
St. Mary's College, Osmania University, India

- Project: Isolation, Immobilization, and assay of enzyme amylase from different sources.

PROFESSIONAL EXPERIENCE

COVID-19 Contact Tracing Lead/Analyst, August 2020 to December 2020
University of Louisville, Louisville, Kentucky

- Established contact tracing program, data management and analysis.

- Trained and supervised 12 student workers and 2 full time employees.
- Supervised a 12-member team.
- Responsible for weekly reports on trends that was shared with University's management and Louisville Health Department for Public Health and Wellness.

COVID-19 Communicable Disease Investigator, June 2020 to July 2020

Kindred Health / Lacuna Health, Louisville, Kentucky

Client: Louisville Metro Department of Public Health and Wellness

- Assist in diseases investigation, contact tracing, completing assessment forms, communicate with patients or next of kin, identify epi link and clusters, issue isolation/quarantine orders, provide resources, document non-compliance, escalate to local health department as needed.

Case Investigator Volunteer, April 2020 to June 202

Louisville Metro Department of Public Health and Wellness, Louisville, Kentucky

- Assist Covid-19 Response group with contacting cases, completing assessment forms, daily disposition for hospitalized patients, review Electronic Health Record (EHR), communicate with patients or next of kin, identify epi link, inform administrative assistant about isolation/quarantine orders, document non-compliance, communicate with Lead Epi, Epi Director and Director of Nursing, and close cases.

Patient Registration Representative, July 2019 to July 2020

Norton Healthcare, Louisville, Kentucky

- Register patients of all ages by filling out all the required documentation, patient verification, insurance verification and provide resources to patients and their families or friends during their visit to the emergency room.

Sales Associate, November 2018 to July 2019

Coach Outlet Shoppes of the Bluegrass, Simpsonville, Kentucky

- Work at the cash register and assist multiple customers simultaneously as needed.
- Discuss product features with clients.
- Replenish inventory on sales floor as needed.
- Processes shipments as needed.
- Use company's tools and resources to be up to date with product knowledge.

Graduate Research/Teaching Assistant, August 2015 to August 2020

University of Louisville, Louisville, Kentucky

Summary: I worked with University of Louisville's, School of Public Health, and Information Sciences, EHOS department. I assisted the faculty's research on lead exposure in children exposed to cigarette smoke, nano particle exposure on mice and DEHS's biosafety related activities. I also assisted with teaching undergraduate and graduate courses.

Lab Rotation I, August 2015 to December 2015.

Assist the faculty in department's research and teaching assistant for graduate classes: Introduction to Environmental & Occupational Health, and Occupational Health and Safety.

- Assist in grading of tests and assignments.
- Attend lectures and participate in class discussions.
- Prepare grading rubrics to be used in the current and future courses.

Lab Rotation II, January 2016 to May 2016.

Assist the faculty in department's research: Lead exposure in children exposed to cigarette smoke.

- Data entry and analysis in SPSS and R studio.
- Conduct protein estimation and Western blot experiments.
- Write summary reports on assigned readings.
- Write and edit manuscript on exposure to lead in children.
- Assist and guide undergraduate students in research.
- Assist in experiments and lab maintenance under the guidance of a senior doctoral candidate student.
- Attend weekly lab meetings.
- Attend seminars by various departments in the university.
- Take required trainings to work in the lab: HIPPA, OSHA, Blood borne pathogen safety, Lab safety.

Lab Rotation III, June 2016 to December 2016.

Assist the faculty in department's research: Effects of nano particle exposure on mice.

- Assist during mouse harvesting experiments.
- Prepare materials needed prior to experiments.
- Maintain the laboratory.
- Guide Graduate visiting student from China.
- Read current literature on nano particle pollution and exposure to humans.
- Embed mouse tissues and organs in paraffin cassette and label them for storage.
- Conduct basic molecular biology and protein purifications tasks.
- Data analysis and documentation.

Lab Rotation IV, January 2017 to December 2020.

Assist DEHS's Biosafety staff in biosafety related activities and research.

- Assist in Institutional Biosafety Committee meetings.
- Assist in preparation of meeting agenda and meeting minutes.
- Attend seminars, meetings, and trainings.
- Update and periodically review the research protocols in iRIS system to follow the regulations.
- Read current literature on safety topics.

Graduate Teaching Assistant, August 2017 to August 2020.

- Assisted in undergraduate courses:
    - PHUN-550 Public Health and Our Environment
    - PHUN 550 Public Health Nutrition
    - PHUN-440 Biology for Population Health
- Develop teaching material, quizzes, and test material.
- Facilitated class discussions and lectures.
- Assisted students with questions and concerns.
- Proctored examinations and graded exams.

Environmental, Health and Occupational Safety Intern, January 2012 to June 2012

Okamoto Sandusky Manufacturing LLC, Sandusky, Ohio

- Developed 250 Lock-Out/Tag-Out procedures for all the controlled equipment to provide a safe environment for the employees and comply with OSHA.
- Incorporate a safety culture by making the employees aware of healthy and safe practices by actively observing fellow employee's work practices and making recommendations to enhance safety.
- Communicated with different employees like team leaders, operators, maintenance, and other employees at management level to gather required information to establish Lock-Out/Tag-Out program at the facility.
- Assisted the EHS manager in safety training, incident investigation, development of new and review of current training programs to ensure safe working conditions at the facility.
- Created HIMS labels, assisted in the preparation of OSHA 300 logs and incidents that occurred at the facility.

Student Assistant, August 2011 to December 2011

University of Findlay, Findlay, Ohio

- Developed and strategically implemented the project for the Self Study Report to submit to The National Environmental Health Science & Protection Accreditation Council (EHAC) for review and accreditation.
- Assisted in the accreditation renew process of the undergraduate Environmental Safety and Occupational Health Management (ESOH) program.
- Collected information on all the courses offered for the past six years by interacting with faculty and staff in various departments.
- Organized gathered information into databases for analysis.
- Analyzed the past enrollment trends and predicted the future enrollment trends in the undergraduate ESOH program.

VOLUNTEER EXPERIENCE

Library Volunteer, June 2015 to July 2015

Centerville Public Library, Centerville, Indiana

- Developed an emergency preparedness plan for the library.
- Assisted library staff with organizing events and programs for the community.
- Organized the books in the shelves.

Hospital Volunteer, January 2013 to March 2014

Reid Hospital and Health Care Services, Richmond, Indiana

- Assist in documentation of monthly environmental and safety surveys collected from various departments.
- Track the missing or misplaced surveys and keep the information up to date.
- Organize the documents for the Hospital's Incident Command System, Emergency Management Plan, and Safety Committee reports.
- Retrieve patient information and provide appropriate information in person or over the phone to patients and family/visitors, accessing current and confidential information of the patients in the hospital.

SKILLS

- Language: English, Telugu, Hindi, French (beginner level)
- Lab: Western blot analysis, PCR, Formalin-Fixed Paraffin-Embedded Experiments, Inventory maintenance, Cell culture mouse cell lines, Harvest cells and culture medium.
- Computer: Microsoft Office, MS Project office, SPSS, SAS, R, Brady graphical writing software, Programming, Web designing, Html, sybyl, video/photo editing tools, MS

Visio, Software Testing tools: QTP, Selenium, Social Media Management: Blogging and networking.

- Soft: Excellent verbal, written, analytical, interpersonal, organizational and communication skills, detail oriented, goal oriented, resourceful, flexible, accountable, innovative, enthusiastic, self-motivated, quick learner, efficient in time management, efficient team leader, team player, and possess strong work ethics.

CERTIFICATIONS

- Dental Public Health Certification (2019, non-credit)
- 30 Hours OSHA General Compliance (#23-900251577)
- ISTQB-AT: International Software Testing Quality Board-Foundation level Agile Tester

HONORS

- Phi Kappa Phi

PROFESSIONAL MEMBERSHIP

- 2018-2019: Graduate Student Council Representative for EHOS at university of Louisville
- 2017-Present: Midwest Area Biosafety Network (MABiON)
- 2016-Present: The Association for Biosafety and Biosecurity (ABSA)
- 2020-Present: The American Public Health Association (APHA)

PUBLICATIONS / MANUSCRIPTS IN PREPARATION

1. Sivarchana Mareedu-Boada, Torsten Alwin Hopp, and Riten Mitra. Development and validation of biosafety climate scale for biological and biomedical science laboratories in the United States. Applied Biosafety. Ahead of print. http://doi.org/10.1089/apb.2021.0006

2. Sivarchana Mareedu-Boada, Riten Mitra and Torsten Alwin Hopp. Biosafety Climate in biological and biomedical laboratories at public universities in the USA. In preparation

3. Sivarchana Mareedu-Boada, Riten Mitra and Torsten Alwin Hopp. Impact of COVID-19 on biosafety climate at university of Louisville. In preparation.

4. Sivarchana Mareedu-Boada, Riten Mitra, David Tollerud and Torsten Alwin Hopp. Impact of biosafety program management on biosafety climate at university of Louisville. In preparation.

5. Sivarchana Mareedu-Boada, Riten Mitra and Torsten Alwin Hopp. Biosafety program management in the era of COVID-19 and beyond. In preparation

PRESENTATIONS & CONFERENCES

1. Ensuring Biosafety in Academic Research Institutions: Biosafety Survey and Program Development

Midwest Area Biosafety Network, August 2018

2. Development and Implementation of a safety Intervention at Academic Biological Laboratories

Midwest Area Biosafety Network, August 2019

3. Development and Validation of Biosafety Climate Scale for US Biomedical and Microbiological Research Universities

Midwest Area Biosafety Network, August 2020

4. Evaluation of Biosafety Climate (BSCL) in Biological and Biomedical Laboratories at Public Universities in the USA

Midwest Area Biosafety Network, August 2021 (Scheduled to be presented)

5. Evaluation of biosafety program administration and SARS-CoV2 on Biosafety Climate at a Midwestern Public University in the USA

Annual Biosafety and Biosecurity Conference, October 2021 (Scheduled to be presented)

REFERENCES

- Torsten Hopp, PhD, RBP

  Biological Safety Officer / Responsible Official

  Adjunct Assistant Professor, School of Public Health, and Information Sciences

  Department of Environmental Health and Safety

  University of Louisville

  1800 Arthur Street,

  Louisville KY 40208

  Office: (502) 852-2959 Torsten.hopp@louisville.edu

  Relationship: PhD Dissertation Committee chair and mentor

- Gary Hoyle, PhD

  Professor

  University of Louisville, School of Public Health, and Information Sciences

  485 E. Gray, Room 205

  319 Abraham Flexner Way, Room 701 HSC-A

  Louisville, KY 40202

Office: (502) 852-3007; (502) 852-7345Gary.hoyle@louisville.edu

Relationship: PhD Dissertation Committee Co-chair and mentor

- Riten Mitra, PhD

  Associate Professor, School of Public Health, and Information Sciences

  Department of Bioinformatics and Biostatistics

  University of Louisville

  485 E. Gray, Room 122

  Louisville KY 40208

  Office: (502) 852-3986 r0mitr01@louisville.edu

  Relationship: PhD Dissertation Committee member and mentor

- Leslie A Wolf, PhD, HCLD(ABB)

  Laboratory Director

  Division of Infectious Diseases, University of Louisville

  Louisville Metro Department of Public Health and Wellness

  Adjunct Assistant Professor, School of Public Health, and Information Sciences

  University of Louisville

  485 E Gray Street

  Louisville KY 40202

  Office: (919) 628-7444 leslie.wolf@louisville.edu

  Relationship: Professor who I assisted in delivering undergraduate course