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The American University in Cairo
School of Sciences and Engineering

**A cross-sectional survey study to assess
attitudes towards research misconduct among
the community of the American University in
Cairo**

A Thesis Submitted to
Biotechnology Department
in partial fulfillment of the requirements for
the degree of Master of Science

by Marwan Felaefel
under the supervision of Dr. Henry Silverman
University of Maryland, Baltimore

AUC secondary advisor: Dr. Asma Amleh
May 2015

DEDICATION

To those who gave up their lives for bread, freedom and justice, all the sweat, tears and blood that you have shed, shall never be forgotten and will never be in vain...

ACKNOWLEDGMENTS

I *would like to express my sincere* gratitude to all those who helped this work come to light I would like to namely mention my advisor Prof. Henry Silverman, for introducing me to research ethics, supporting me and guiding me through this work. Dr. Asma Amleh, for being my mentor, and her continuous support through my journey in AUC. Hillary Edwards for her efforts with the project, and the writing process. Mohamed Taha for his support with statistics and last but not least my family and friends for bearing with me throughout all the hardships.

ABSTRACT

Background: Research misconduct is on the rise globally and it is jeopardizing scientific integrity by breaching the basis of responsible scientific conduct. Available data indicates rising levels of fabrication, falsification and plagiarism that are alarming despite the presence of guidelines in many of the high-income countries. High profile cases of misconduct in low and middle income countries are on the rise as well, yet data regarding the amount of misconduct taking place remain scarce.

Objective: To assess investigators' attitudes as well as the prevalence of research misconduct in an Egyptian University and identify possible factors that might account for our results.

Methods: We performed a cross-sectional survey study at the American University in Cairo (AUC) that included undergraduates, post-graduates and faculty. The survey tool included the following sections: a) demographics, b) attitudes regarding the acceptability of certain practices in research conduct and c) frequency of observed and self-identified instances of scientific misconduct. The study was approved by the institutional review boards at AUC and at the University of Maryland, Baltimore.

Data Analysis: We used descriptive analysis and a chi-square test for bivariate analysis. We entered data by the use of SPSS software. A p value of 0.05 was considered significant

Results: We analyzed data from 191 participants 18 to 64 years of age. Of the respondents, 52.4% had received research ethics training.

Regarding attitudes toward research misconduct:

- 1) 77.3% expressed concern about the occurrence of research misconduct,
- 2) 50.0% agreed that dishonesty and misrepresentation of data are common,
- 3) 64.5% regard pressures to publish to gain promotion is a major reason for engaging in misconduct.
- 4) 71.8% of participants confirmed their awareness of regulations that govern research involving humans, animals, or laboratory practices.

Incidence of research misconduct observed at least once by participants included: plagiarism (43.8%), obtaining improper informed consents (34.6%), and eliminating data that contradicts one's hypothesis (46.9%). Self-identified incidences for the same categories were 9.1%, 10.4%, and 26.0%; respectively.

Conclusions: The results indicate that misconduct is related to level of education, work environment in addition to possible ineffectiveness of training. Results may be explained by a lack of understanding or awareness of the unethical nature of research misconducts. This study provides insights on the attitudes towards and prevalence of misconduct among researchers in the Egypt.

Limitations: This study included self-reporting of self-identified practices, which could represent an underestimate of actual practice. Also, results from a single university may not be generalizable to other universities in Egypt and to other countries in the Middle East.

Next steps: Data from other sites in Egypt and countries in the Middle-East are being gathered and will be pooled and analyzed with the data already collected. Further training in the responsible conduct of research is recommended. Further qualitative research (e.g., interview studies) is needed to further explore the reasons for our results.

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List of Acronyms

AUC	American University in Cairo
BA	Bachelor of Art
BSc	Bachelor of Science
CFR	Code of Federal Regulations
COI	Conflict of Interest
COPE	Committee On Publication Ethics
DHHS	Department of Health and Human Services
EC	Ethics Committee
F	Females
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HIV	Human Immunodeficiency Virus
ICH	International Conference on Harmonization
IRB	Institutional Review Board
M	Males
MD	Medical Doctor
MPH	Master of Public Health
MSc	Master of Science
NIH	National Institute of Health

ORI	Office of Research Integrity
OSI	Office of Scientific Integrity
OSIR	Office of Scientific Integrity Review
PhD	Doctor of Philosophy Degree
SMQ-R	Scientific Misconduct Questionnaire-Revised
SPSS	Statistical Package for the Social Sciences
US	United States
USD	United States Dollars

INTRODUCTION

Basis to Responsible Conduct

Advancement in knowledge and science is based upon the contributions of new findings to the well-established knowledge. To maintain the integrity of science, systemic methods of documentation and circulation of science has evolved over the years.

Today, academic publishing remains the main method of primary literature as recognized by the scientific community and acknowledged for references. New scientific concepts and methods have been introduced through methods such as peer review, scientific critique and citation. These processes of scientific contributions are well established, now aided by the advancement in communication through the internet has helped tracing back the origin of any work done. References and citations allow researchers to continue from where others have stopped.

To confirm existing knowledge, previous work done by other researchers should be reliable, reproducible, and consistent. This can be achieved through the twelve principles of responsible research conduct defined by Shamoo and Resnik (Shamoo and Resnik, 2009).

1. **Honesty:** in all aspects related to one's research reporting, including methods, contributions, conflict of interest and of course data that should be free from any misinterpretation, fabrication or falsification. This commitment does not only apply to publications but also to grant proposals, reports and other scientific communications.
2. **Objectivity:** is required or expected in (but not limited to) the design of the experiments, the analysis and interpretation of data, writing of grant proposals, personnel decision, expert testimony and peer review.
3. **Openness:** meaning being open to criticism and new ideas when sharing data, ideas, tools, results, resources and materials.
4. **Confidentiality:** includes (but not limited to) protection of subjects private information, submissions of papers or grants, and business or military secrets.
5. **Carefulness:** include keeping good records of all research activities to avoid error that are because of negligence, careful data collection, design of the research consenting of the participants are all important steps to increase competence in the scientific activity.
6. **Respect for colleagues:** regardless of their ethnicity, background, religion, gender, and their qualifications. Meaning that this should extend to students and subordinates where training, mentoring and education should be exercised.
7. **Respect for intellectual properties:** which includes abiding to copyright laws, honoring patents and similar forms of intellectual property protection laws; this also requires giving credit were appropriate and to avoid using unpublished data either results or methods without prior permission.

8. **Respect for law:** such as local laws and regulations, that may also extend to certain institution specific policies and regulations.
9. **Respect for research subjects:** human subjects when part of research activities should be treated with respect meaning that the experiments they are involved in are very well designed to maximize benefits for them and to minimize harms or possible risks, human research subjects should never be treated as means to an end studies they are involved in should well preserve their privacy, autonomy and dignity. Additionally whenever a vulnerable population (such as children) is part of human subject research special measures and precautions should be in place to ensure their well being is not affected, and to ensure the burdens and benefits of the research are fairly distributed. Animal subjects as well should be treated with respect and are required to receive proper care as living beings; they should be saved from any poorly designed or unnecessary experiments.
10. **Stewardship:** Utilizing human, financial and technological resources in the best way possible, by ensuring use of proper research sites, materials, samples and tools.
11. **Social responsibility:** take into account the social consequences of research activities to prevent unfavorable consequences by seeking proper research, expert testimony, consulting and public education.
12. **Freedom:** which should be granted by the governments and the research institutions, where freedom of thought and inquiry should be granted and not interfered with (Shamoo and Resnik, 2009).

The History of Research Misconduct and its Regulation

Over the past decades, increased evidence of lack of integrity in the scientific research process has created concerns over the reliability of available scientific literature and credibility of biomedical research (Nussenzveig and Zukanovich Funchal, 2008; Trikalinos et al, 2008; Jha, 2012). The lack of integrity in scientific work could be a consequence to many reasons, one of which is research misconduct, including fabrication, falsification and plagiarism in addition to other practices.

Evidence of research misconduct is not a new trend.. As mentioned in the book Betrayers of the Truth, authors Broad and Wade discuss evidence of misconduct in work by famous scientists such as Galileo, Newton, Mendel, and Pasteur. With the increase in public knowledge and publicity of research misconduct, international bodies began to develop of guidelines and ethical codes of conduct such as the Nuremburg code (1948), Declaration of Helsinki (1964), the Good Laboratory Practices (GLP) in the early 1970s. During the 1980s, numerous cases of academic misconduct continued, with little abatement due to poor levels of resources and training from research institutions and inadequate treatment to the whistleblowers. These concerns triggered the establishment of the Office of Scientific Integrity (OSI) and the Office of Scientific Integrity Review (OSIR) in 1989 under the National Institute of Health (NIH) by the Department of Health and Human Services (DHHS)

in the United States. Today, these offices have been reorganized to be the Office of Research Integrity (ORI), which develops policies and promotes responsible scientific conduct. In addition, the office reviews and monitors investigations related to research misconduct and provides consultations to institutes for technical issues encountered in allegations of research misconduct (Shamoo and Resnik, 2009).

Similar national bodies to the ORI have evolved in developed countries such as Denmark, Great Britain, Australia, Germany, Norway, Finland, Canada and Japan. Low- and middle- income countries are also seeing an increase in regulation for research, such as in Poland, China and India (Council of Science Editors, n.d.). One such example in the UK is the Committee On Publication Ethics (COPE). Established in 1997 by a group of medical journal editors, COPE now enlists over 9000 editors from different academic and scientific fields. COPE offers a code of conduct and guidelines for best practices to be adapted by member journals, guidelines from COPE are available on issues such as retractions and flowcharts on handling of ethical problems that are commonly encountered. (About COPE, n.d.).

According to the US code of Federal Regulations Title 42 part 93, research misconduct is defined as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” The federal regulations have specific definitions for each of these misconducts as follows:

- "(a) Fabrication is making up data or results and recording or reporting them.
 - (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
 - (d) Research misconduct does not include honest error or differences of opinion."
- (ECFR, n.d.)

Moreover, research misconduct extends to other activities that we encounter in our daily lives and severely affects the scientific progress. Research misconduct is the failure to meet one or more of the twelve principles of responsible conduct and results in the negative impact the credibility of the scientific work. In addition to the misconducts defined by federal regulations for researches that involve human or animal subjects, namely falsification, fabrication and plagiarism, other issues concern authorship disputes, which are increasing, as well as conflicts of interest that affect the credibility and objectivity of researchers. All of these concerns will be discussed.

A. Misconduct related to Research Ethics and Practices:

Research involving human subjects:

Human subject research is defined as per the code of federal regulations to be “...a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.” Over the years human research subjects were ill-treated, abused and often extremely harmed due to participation in research activities that did not take into considerations their basic rights as human beings. Several scandalous cases in the last century have went high profile and received public attention that resulted

in development and advancement of the guidelines and regulations concerned with human subject research. The most notorious were the Nazi experiments in concentration camps during World War II, that conducted fatal inhumane tests on prisoners against their will, that lead to the ten commandments like memorandum referred to as the Nuremburg code, that was later on the basis to the Declaration of Helsinki, the corner stone of current regulations related to ethics of human research (Tyebkhan, 2003).

Another major abuse in participant rights occurred with the Tuskegee syphilis experiment that took place in Tuskegee, Alabama. It lasted for 40 years during which poor African Americans were enrolled in a study that purposely left them untreated, even though during the course of the trial penicillin has proven to be an effective treatment to their condition, nobody received penicillin or any other treatment. The infamous study lead to congressional hearing that stopped the unjustifiable study after being featured in media. The study led to the development of the Belmont Report, the document regarded to be the moral framework upon which the US federal regulations related to human subject research can be understood.

The Belmont Report, summarizes three main principles upon which all human subject research guidelines can be related namely Respect for person, Beneficence and Justice. Efforts to harmonize and standardize ethical standards related to conduct of clinical trials have been addressed in the International Conference of Harmonization under efficacy 6, Good Clinical Practice (GCP) which aims to ensure quality data that is consistent and applicable anywhere in the world combined with ethical conduct to safeguard participants. All the ethical codes and guidelines mentioned mandate that research involving human subjects to be:

- a. Scientifically sound based on solid results from preclinical experiments (in cases of clinical trials) and conducted by qualified individuals.
- b. Any foreseeable risks, should be minimized and justified by potential benefits, subjects safety and well being should prevail all other interests.
- c. Subjects' privacy and confidentiality should be respected, and gathering of any personal information should be after obtaining their consent appropriately. Informed consent should be voluntarily, without any coercion or undue inducement, and subjects should always have the right to withdraw their consent without losing any benefits that they are entitled to otherwise.
- d. Studies should be ethically conducted, meaning that it should undergo ethics review by an ethics committee or an institutional review board. Where all the previously mentioned items are validated by an independent committee that also monitor the progress of the trial and intervenes when necessary. The committee as well ensures protection of vulnerable subjects such as minors, prisoners or mentally challenged individuals when they are research subjects.

Research involving animals

The guiding principles for the ethical use of animals in testing were set forth by Russel and Burch in 1959 by what is commonly known as The Three Rs (3Rs) principle. The first R refers to Replacement, referring to the preference of non-animal methods over using animals whenever possible, to achieve the same objective. The second R refers to Reduction, where the number of animals used to obtain the information should be as low as possible. The third

R refers to Refinement, where it is required to minimize potential pain or suffering by animals as much as possible (Russel and Burch, 1959). Shamoo and Resnik, add interesting fourth and fifth Rs, Relevance and Redundancy avoidance. These concepts can be summarized by ensuring that the context of using animals have medical, scientific or social basis, and that the suffering an animal can be exposed to is justified by the benefits to humans and the animals. Additionally, the experiments should not be repeated unnecessarily, this can be achieved by thorough research review to check if the experiment has been done before (Shamoo and Resnik, 2009).

Local laws and institutional policies.

Further laws and regulations can be applied more specifically to countries or states, sometimes institutions will have specific set of policies or regulations that is characteristic to the local values and social or political circumstances. These rules, regulations or policies will generally have more specific restrictions or further protective measures but it is quite unlikely that any local law would contradict the above mentioned ethical guidelines. Such laws may include (but are not limited to):

- a. Record keeping requirements and retention of documents.
- b. Documentation requirements.
- c. Rules for handling and disposal of materials such as bioactive materials, biohazardous waste, dangerous chemicals.
- d. Genetic, cloning and stem cell research regulations.

B. Fabrication and Falsification in research

While the definitions of fabrication and falsification in the CFR may appear clear, falsification or fabrication can nonetheless take place during analysis and interpretation of data. While a researcher may not completely make up from data from the scratch, he or she could manipulate the data, add a value to extrapolate results, drop outliers without disclosure, perform statistical analysis in a dishonest way, ignoring results that do not match the hypothesis and even enhance or modify images from the research (Shamoo and Resnik, 2009).

C. Plagiarism and Authorship disputes

According to the Merriam Webster dictionary, the term plagiarism comes from plagiary of the Latin origin (plagiaries) which literally means “kidnapper”. Plagiarism is actually “kidnapping” ones words, ideas, and even expressions. Plagiarism definition is straight forward as per the code of federal regulation or any other definition in any guidelines or even a dictionary. However it remains as an ongoing issue among faculty, researchers and students. A study covering all PubMed accessible publications from 2008 to 2012 by Amos reveals the countries with the highest rates and largest numbers of retractions. China was the top reason for retraction due to either plagiarism or duplicate publications, Italy and Finland had the highest rates of plagiarism and the United States retracted the most publications (Amos, 2014). In 2008, Helen Zhang used CrossCheck text analysis software to detect plagiarism for the University of Zhejiang scientific journal in China, the results indicated that

31% of papers submitted over a period of 2 years were plagiarized the issue has been correlated to cultural aspects such as the tradition of quoting the exact masters word in Chinese tradition, a survey by the Chinese Association for Science and Technology showed that 31,000 researchers in China indicated that 43.4% regarded misconduct as a non-serious misconduct (Zhang, 2010). Yet this does not explain the reason for plagiarism in countries such as Italy and Finland. Other reasons include a lot of different aspects that in many times is more related to confusion or lack of understanding rather than intentional cheating (Bamford & Sergiou, 2005). Plagiarism is not necessarily copying word for a word that plagiarism detections software can detect, other forms of plagiarism includes plagiarizing ideas, self plagiarism that is a less severe form of plagiarism but results in double submission and possibility of copyright infringement (Shamoo and Resnik, 2009), or even rephrasing without citation, or citation without rephrasing. Academic Institutes like AUC have begun establishing strong policies to regulate plagiarism, mandatory trainings and practice using plagiarism detection software has helped students understand, avoid plagiarism and helped the faculty to detect plagiarized texts in assignments and manuscripts.

Disputes over authorship can be considered to fall under plagiarism, however authorship concerns expand beyond denying citation when referring to someone's words or ideas. It includes extreme cases such as denying authorship credit (or proper credit) to individuals who contributed substantively to a manuscript, or even giving authorship credit to individuals who had minimal or no contribution to a work as a form of mutual agreement. One example is to include the head of the department even if they practically did not contribute to the work done. The high competition among researchers to publish often causes disputes over authorship. Scholarly works are thought as important achievements for researchers to be promoted. Over the last decades the number of authors has increased surpassing the system of single author (Greene, 2007), especially in global collaborations and in huge research products and so did disputes over the extent of contributions and authorship. Authorship order is an important issue for discussion among collaborators, where traditionally the first author is the person who contributed most to the work and the last author is usually the principal investigator or the first author's advisor. The remaining authors from second to second last are listed on the basis of who contributed the most. A different order takes place in other fields such as in mathematics, where they put author's names in alphabetical order (American Mathematical Society, n.d.).

Another common issue that is relatively new and on the rise is ghost authorship, where real contributors are not featured in authors list, this often occurs in industry and in clinical trials, where the protocol developers, statisticians and even manuscript writers are not featured, it is common to have medical writers or similar roles, reaching up to 91% in industry initiated trials (Gøtzsch, *et al.* 2007).

D. Conflict of Interest

Conflict of interest can be defined as a situation where an individual or institution are biased to make a decision because it possibly affects another advantage they possess, leading to a lack of objectivity. Individuals and institutions who work in scientific research are often challenged by their multiple duties, multiple duties can be hard to attain especially if some of these duties are in the way of other duties; thus creating a conflict of interest. For example, a person working as clinical research monitor working in a sponsored clinical trial is obliged to verify the eligibility of the subjects participating in the trial to ensure they strictly match the inclusion and exclusion criteria. This task involves disenrollment of subjects who are ineligible. However, the same clinical research monitor often has a target set by the

sponsoring company to enroll a certain number of subjects upon which he gets his appraisal. Such set up makes the monitor have multiple conflicting objectives, in this situation to verify enrolled subjects for eligibility is not consistent with recruiting patients, because monitors in fact do not recruit patients, they just verify they are eligible to participate.

Clinical investigators working in similar sponsored trials are often paid a sum of money for each participating subject; the investigators will earn more money if they recruit more patients, the same investigators are often the ones who consent the patient and explain to them the risks of participation and talk them into accepting to participate.

Another area where conflict of interest may arise is with the intuitional review board. The IRB that reviews and grants approval to conduct the study may consist of colleagues and friends to the clinical investigator. The same institution that offers a clinical investigation site for the sponsoring company earlier on received a donation directed towards developing of the department that the clinical trial is conducted in, the same institution should be responsible in the investigation of any reported misconduct or handle complaints. While the above examples are hypothetical, they are inspired by realistic scenarios of observed current clinical research concerns. As the examples show, the conflicts of interest could be financial, ethical, social, personal and even political in addition to being complexly interlinked.

As science is becoming more associated with business, and as the competition grows bigger, the conflicts of interest may not be avoided. Therefore, conflicts of interest need to be declared to the ethical committees during review of the potential studies. While nondisclosure is misconduct itself, it can also be tied to other forms including but not limited to: fabrication and falsification to maintain a grant, to graduate, to start a spinoff company, authorship misconduct and disputes to get promoted, compromising scientific rigor of the design of studies or ignoring certain results to match your hypothesis, not respecting research ethics or not follow proper research practices to cut corners and to attain specific objectives while ignoring ethical duties.

Regulations determine how an investigator discloses a conflict of interest. For example, many peer-reviewed journals require statements from the authors declaring any potential conflicting interests they would have. The Code of Federal Regulation also requires principal investigators and sub-investigators to declare any financial conflict of interest on financial disclosure form for themselves or any of their dependents.

Prevalence of Research Misconduct

The available data regarding research misconduct is mostly associated with developed countries. This association may be due to available means of identifying such practices and a relatively higher level of transparencies from governments and institutions. Currently there is growing mass of collaborative work in the Middle East region, along with a general increase in the amount of research activities occurring in the region. Hence, data must be gathered to know how reliable is the structures of research integrity and responsible conduct are for producing scholarly, evidence-based research. Due to the lack of oversight of research integrity, current available data is scarce; therefore more research is needed in this realm.

In a study by Fanelli, who conducted meta-analysis and systematic review of quantitative survey data addressed to scientists, provided data that resulted with up to 14% of scientists in higher income countries have been observed to engage in falsification or fabrication and up to 75% have been involved in other practices that are questionable (Fanelli, 2009).

Data available from high income countries may also have limitations due to its reliability. Data from low and middle income countries are not available, yet many high profile cases of research misconduct have occurred in low and middle income countries. These cases, which received ethics approval, include a fraudulent clinical trial involving high doses of chemotherapy in South Africa, a study involving patients with liver cancer, and dozens of retracted publications from India (Ana, 2013).

Another example from a survey study conducted in India between August 2012 and March 2013 targeting medical researchers who had a minimum of five publications in several institutes showed that 53% of respondents had observed plagiarism, 33.5% of responders observed denial of authorship to individuals who had contributed significantly to the research, and 65% observed gift authorship (Dhingra and Mishra, 2014). Two studies from the Middle East (Kandeel *et al.* and El-Dessouky *et al.*) assessed awareness and attitudes of Egyptian faculty about research ethics. Both papers showed a positive attitude (reaching up to 90%) towards research ethics committees, but research ethics practices were suboptimal. For example, more than 35% of participants indicated that it is not necessary to provide patients with research details since they do not understand it (Kandeel *et al.*); 11.2% of responders found it acceptable to fabricate data to improve quality of the research as long as the patient is not harmed and 39.2% thought that vulnerable subjects such as the mentally challenged or children can provide consents for themselves. 32.8% thought informed consent was not necessary for obtaining blood tests for a clinical study (El-Dessouky *et al.*, 2011).

Possible Reasons for Research Misconduct:

Lack of training: Results from work done in the Middle East indicate gaps in training on research ethics, faculty members perceived ethics committees as reasons for delay in their research (Kandeel *et al.*, 2011; El-Dessouky *et al.* 2011). Moreover, data also suggest that only 20% of chairpersons of ethics committees and 25% of members of ethics committees in Eastern Mediterranean region received training in research ethics (Abou-Zeid A, Afzal M, & Silverman HJ, 2009).

Pressure to publish: "publish or perish" is a policy that significantly affect the pressure for misconduct (Casadevall and Fang, 2012), in almost all universities and institution the academic value of faculty members is based on how much they publish, where do they publish and how often their publications are cited. This defines promotions, grants, and prestige.

Ease of fabrication (Shamoo and Resnik, 2009): as in doing research backwards, starting with a hypothesis and creating data to support or modifying the available data to support it is a shortcut to obtain significance and publish.

Not reporting conflict of interest: Conflict of interest by itself may not be considered misconduct, but the presence of conflicts of interest or too much tempting conflicts could be a strong motive to do other misdeeds. Therefore not reporting conflict of interest is misconduct.

Lack of oversight and regulation: The lack of respect to the public, to research and the possibility of getting away with misconduct promote misconduct especially with corrupt regimes.

Culture and Environment: A culture that accepts cheating, could possibly create a negative pressure towards doing things ethically, as in individuals who wish to stick to ethical standards can never be taking equal or fair chances in an environment that is not ethical, if they will not engage in unethical practices it is likely that they will become at least neutral to it.

Effect and Consequences of Misconduct:

Losing Public trust: As mentioned earlier, most of the regulations were developed in response to scandals that went high profile, such as the Tuskegee experiment that was stopped by a congressional hearing after being featured in media, meaning that results after all affects the public and the scientific community cannot afford losing public trust when they eventually react to what affects them. For example a recent law suit is filed against Egyptian army officials for claiming to have invented a device that can completely “cure” patients infected with HIV and Hepatitis virus C raising hopes of millions of patients over exaggerated media propaganda that had no scientific basis whatsoever (El-Fekki, 2015).

Placing research subjects at risk: misconduct can result in patients receiving improper medical care based on fraudulent research or based on results of other fraudulent research. According to Steen the numbers of those patients are in hundreds of thousands, participating in multicentre clinical trials (Steen, 2011).

Wasting Resources: In addition to possible harm or lack of benefit to research participants, research misconduct leads to a waste of resources, including time, money and effort and could create confusion when trying to replicate results or base new advancement on older ones.

Retraction: In a study by Fang, examination of 291 retracted articles funded by NIH between 1992 and 2012 showed that about 96% of them were retracted due to either falsification or fabrication, the remainder of the retractions were due to other serious misdeeds such as conducting research without IRB approval. An estimated total of 1.67 billion USD (corrected to 2.32 billion USD in 2012 in consideration to inflation) of funding by NIH for papers that were later retracted for misconduct.

Other costs: Along with negative reputation and possibility of legal and civil liability, misconduct investigations can cost up to 500,000 USD for a single case, which could possibly be more than the amount of money spend on the research itself (Stern et al, 2014). In addition, the duration of investigations of the misconduct can take upwards of 10 months

from allegation to final action by an institution in the United States, without taking into consideration further appeals or deliberations by ORI (Shamoo and Resnik 2009).

The Study

A knowledge gap exists regarding attitudes of an prevalence of practices regarding research misconduct in the Middle East. Additionally, factors that can account for certain attitudes and practices need to be studied. Accordingly this study aims to:

- a. Determine the **prevalence** of attitudes and practices regarding research misconduct in Egypt.
- b. Determine the independent factors that might account for these attitudes and prevalence regarding research misconduct.

METHODS

Survey Tool

We adapted a survey tool from the Scientific Misconduct Questionnaire-Revised (SMQ-R) that was developed by Broom *et al.*. This tool is comprised of qualitative and quantitative questions designed to examine misconduct through seven domains: demographics, characteristics of the work place, work place environment perception, scientific misconduct prevalence, awareness about scientific misconduct and reporting it, attitudes and beliefs about misconduct, experiences with scientific misconduct and behavioral influences affecting it. The SMQ-R addressed research coordinators who enrolled and followed research subjects (Broom *et al.*, 2013).

Our adapted survey tool (Appendix I) consists of the following 6 sections:

I- Demographic Information: composed of ten questions to identify age, gender, nationality, highest degree achieved, location of graduate school, current academic position, previous scientific research experience, types of research activities and previous training in research ethics and research misconduct.

II- Prevalence of Scientific Misconduct: Divided into two sections; one set of questions asked the participants about their observations of misconducts among their colleagues while the other set of same questions asked the participants to self report their engagement in any of these practices. Each set of questions addressed six topics (two to four questions) in each of the following areas of misconduct: Research Ethics, Data Fabrication and Falsification, Plagiarism, Authorship, Conflict of Interest, and Research Practices. The responders were given the opportunity to reply for each question by either "Never", "Once or twice" or "Three or more".

III-Acceptability of Practices in Conduct of Research: Participants were asked general questions related to their perceptions regarding unethical practices in the areas of Research Ethics, Data Fabrication and Falsification, Plagiarism, Authorship and Conflict of interest. This section used a Likert-scale method to gauge participants' agreements regarding the acceptability of misconduct. The scale had five degrees of acceptability (Very Acceptable, Acceptable, Neutral, Unacceptable, and Definitely Unacceptable).

IV- Attitudes of Scientific Misconduct: A set of nine questions asking participants how much do they agree with the following: concerns about amount of misconduct, responsibility of misconduct lies with principal investigators only, commonality of dishonesty and misinterpretation of data, necessity of reporting instances of research misconduct, availability of appropriate mechanisms to report misconduct, pressure to publish is a reason for engaging in misconduct, necessity of declaring conflict of interest by investigators, monitoring trainees to ensure developing into responsible researchers, and awareness of regulations related to humans, animals and laboratory practices. Responders had the opportunity to strongly agree, agree, be neutral, disagree, or strongly disagree with each of these statements.

V- Questions about Scientific Misconduct: This part is comprised of five hypothetical cases involving misconducts related to conflicts of interest, plagiarism, fabrication, falsification,

and authorship. The responders were asked question about the proper course of action and were given four choices to choose from.

VI- Assessment of the Survey: This part was to assess how responders see the survey, how long did they need to complete it, what parts they thought were not important, other areas not addressed and if they had further comments.

Target Population

We targeted individuals involved in scientific research activities at the AUC. These included: undergraduate students, MSc students, PhD students, and individuals working in research positions (e.g. research assistants) and working in teaching academic positions that may also involve research activities (e.g. faculty)

Recruitment Methods

The recruitment method was based on convenience sampling technique. We distributed the survey via a web link on SurveyMonkey® and the link to the survey was distributed via a recruitment email (Appendix II). The email was sent to all graduate students and to members of the schools of sciences and engineering that included faculty, staff and students. Additionally, colleagues were verbally invited to complete the questionnaire and were encouraged to invite others who are eligible to complete it by word of mouth. An opportunity to enter a raffle to win an iPad mini, was used as an incentive to enhance recruitment efforts.

Ethical Considerations

Confidentiality: Due to the sensitivity of linking disclosed data to respondents, we collected all data anonymously. No names or other identifiers were requested from participants to be included in the survey. Those participants who entered the raffle sent separate emails with their names which can never be linked to their survey answers in SurveyMonkey. The participants were informed that their data will only be presented in aggregates and will never be used to identify or report individuals.

Informed Consent: Participants gave their informed consent as indicated when they clicked on the continue button after they read the first page of the survey (Appendix I) that included the necessary elements of informed consent.

Ethics Review: The study was exempted from the IRB of the University of Maryland, Baltimore (Appendix IV). It was reviewed and approved by the AUC-IRB (Appendix III), the AUC-IRB has reviewed the consent form, the recruitment email and methods and all suggested recommendations from the IRB side were implemented.

Sample Size Determination

An estimated population size of about 400 participants were identified with these criteria at AUC, the sample size calculation based on a confidence interval of 5 and a confidence level of 95% is 196 participants.

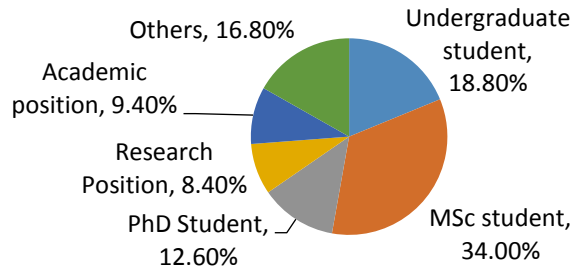
Data Analysis

The data extracted from SurveyMonkey were entered into SPSS statistical software. We used descriptive analysis and chi-square analysis to assess correlations between responses and independent factors that included gender, level of education, and presence of prior ethics training. A p-value of 0.05 or less was considered significant. Charts and graphs were constructed using SPSS or Microsoft Excel.

RESULTS

Demography and Background:

Figure 1: Positions held by participants



We obtained data from 191 participants from the American University in Cairo (AUC), 95 of whom completed the entire survey. Participants represented students, faculty and staff from the Schools of Sciences and Engineering. . Ages ranged from 18 to 64 years (mean of 28.2 years ($SD \pm 7.88$ years and median of 27.0 years) with about 140 participants (73.3%) falling between 20 and 30 years of age

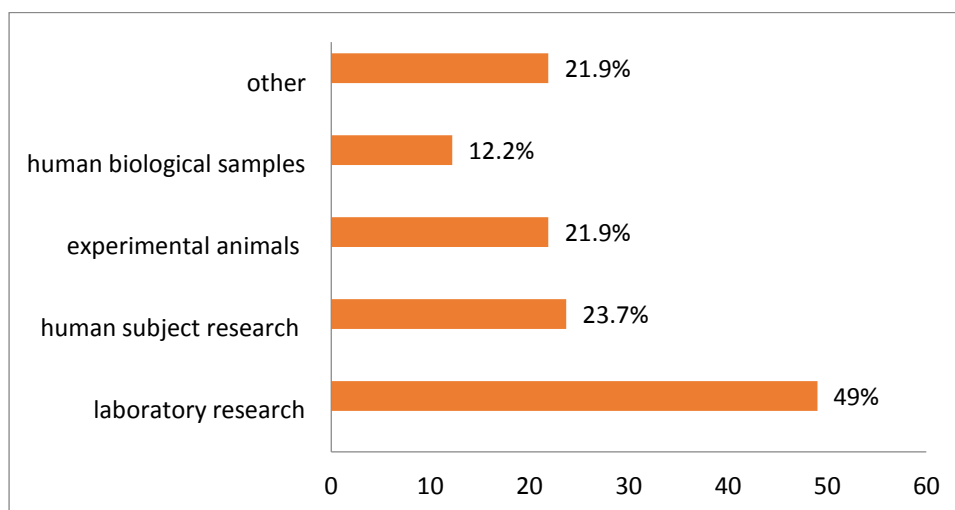
Table 1 shows that two thirds of participants were females, the majority were Egyptian (91%). More than 80% were students at different levels. 52.4% received ethics training, however 56% of which indicated that the training addressed research misconduct.

Research Experience:

Regarding participation in scientific research, about 60 % indicated previous experience in research. Only the answers of those who participated in scientific research were considered in analysis of the questions related to prevalence of misconduct as per one's self experience (Section III of results), responders answers - whether or not participated in research before - about prevalence based on observations of colleagues and their attitudes were still considered. Those who did not participate in research before were mostly undergraduates or graduate student who has probably not started working in research yet including their thesis ($p < 0.001$).

Figure 2 shows about half of the participants who worked in research were involved in laboratory research (49%) , specifications in "other" category (21.9%) included (but was not limited to), architecture, bacterial samples, bioinformatics, cell lines, engineering, ergonomics, software simulation and research using plants.

Figure 2: Types of research participants were involved in (y axis: Research Type, x axis: percentage)



Unethical Practices Prevalence and Acceptability:

Table 2 shows the response rate for different groups of questions and their percentages, the responses for different categories of research misconduct were as follows:

1. Research Ethics:

Table 3 shows the participants' responses regarding their views about several issues in research ethics.

Table 3 shows the out of the 112 participants (58.6%) who answered these questions, 10.7% of them believed it is very acceptable or acceptable to conduct research involving human subjects without IRB/EC approval and another 8.9% were neutral about the issue. In regards to use of confidential information without authorization from research participants, the degree of acceptability of use of confidential data without authorization (7.1%) and not obtaining proper informed consent (6.3%) were close, whereas twice as much of those who were neutral in regards to the use of confidential data without authorization (5.4%), were neutral about not obtaining informed consent (10.4%).

Table 4 shows approximately 15.4% of the responders observed one or two occurrences of research involving human subjects being conducted without prior IRB approval, and three or more times by 6.2% of the responders. Only 7.8% of the responders self reported as "once or twice" and three or more times by 2.6%. Use of confidential information about research

subjects without their authorization was observed once or twice by 15.4% of the responders, and by 4.6% of the responders, three or more times, while it was self reported as “once or twice” by 6.5% of the responders, nobody self reported use of confidential information without authorization more than two times. Not obtaining proper informed consent from participants was observed once or twice by 22.3% of the responders, and by 12.3% of the responders, three or more times, while it was self reported as “once or twice” by 7.8% of the responders, and three or more times by 2.6%.

2. Falsification and Fabrication:

The following set of questions were related to fabrication and falsification of research data, table 5 shows that making up of research data was indicated to be highly acceptable or acceptable by about 9.8% of the responders, however less than 2 % were neutral to making up of research data. Changing research data without mentioning it was indicated to be acceptable or very acceptable by 5.4 % and another 5.4% were neutral to it. Dropping outliers without mentioning it in particular was indicated as very acceptable or acceptable by 7.1% and 9.8% had a neutral opinion about it. Selection of data only that supports one's hypothesis was very acceptable or acceptable by 8.9% and 19.6% were neutral to this.

Table 6 compares observations and self reporting of misconducts, where it is shows higher rates of observation of misconduct than self reporting. Where no self reporting of more than 2 times recorded except for “selecting only those data that support your hypothesis”

3. Plagiarism

Another set of questions introduced to participants were related to plagiarism, Table 7 shows that 4.5% of responders indicated that it is very acceptable to publish results that belong to someone else, no body found this only acceptable or was neutral about it though. Using others words or ideas was indicated to be very acceptable or acceptable by 5.4%, and no body as well was neutral in this regard. 6.3% of the responders to this set of questions indicated that multiple submissions were very acceptable or acceptable, and another 5.4% were neutral about double submissions.

Table 8 shows that 43.8 % of responders observed plagiarism while about 9.1% self reported plagiarism. The trend also shows that observation or self reporting or “once or twice” is always higher than “three or more times”

4. Authorship

The next set of questions addressed ethical issues related to authorship, 8% of the responders indicated that is very acceptable or acceptable to give authorship credit to someone who has not substantively contributed to a manuscript. On the other hand 4.5% found it very acceptable to deny authorship credit to someone who substantively contributed to a manuscript. And 7.1% found it either very acceptable or acceptable to have their names put as a contributor on a paper they have not made reasonable contribution to. The responders who were neutral to giving false authorship credit, denying authorship credit and being

mentioned as one of the authors without a significant contributor were 4.5%, 0.9% and 4.5% respectively as summarized in Table 9

Table 10 shows that giving authorship credit to someone who has not contributed substantively to a manuscript was observed at least once by 37% of the responders, and while it was self reported at least once by about 15%. Denying authorship credit to someone who has contributed substantively to a manuscript was observed at least once by 25% of the responders, and by and it was self reported by about 5% of the responders..

5. Conflict of interest

About 4.5% of responders indicated that not disclosing conflict of interest (like financial interest with a drug company) to the journal or ethics committee is very acceptable or acceptable. 3.6% found it very acceptable or acceptable to compromise the rigor of the study design or methodology or to inappropriately alter or suppress the results in response to pressure. 8% were neutral towards all three aspects namely not disclosing such conflicts of interest, compromising the rigor of study design or methodology and suppressing research results in response to pressure as summarized in Table 11,

Table 12 comparing the rates of observed and self reported misconducts indicate that about 13% of the responders were aware of a conflict of interest that was not disclosed to either the ethics committee or a journal at least once, while it was self reported as “once or twice” by 5.2% of the responders. Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source was observed once or twice by 11.5% of the responders, and by 1.5% of the responders, three or more times, while it was self reported as “once or twice” by 3.9% of the responders, and none self reported more than once or twice. Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source was observed once or twice by 10.0% of the responders, and by 0.8% of the responders, three or more times, while it was self reported as “once or twice” by 3.9% of the responders, and none self reported more than once or twice.

6- Prevalence of misconduct in other Research Practices

Looking at misconducts related to Research Practices, Table 13 summarized rates of misconducts observed and self reported for Ignoring aspects of animal-subjects research requirements, material handling and providing inappropriate recommendation letters. It was observed at least once by 17.7%, 34.6% and 23% of the responders respectively while it was self reported by responders at least once by 9.1%, 27.3% and 6.5% respectively.

Attitudes towards misconduct and responsibilities

A- Similarly, nine statements were presented to participants, and respondents had to choose between strongly agree, agree, neutral, disagree or strongly disagree for each statement. 110 participants responded representing 57.6 % of all participants. Results summarized in Table 14.

B- Additionally, the 5 case studies were presented and participants were asked to choose the best answer from multiple choice pre-defined answers, the questions and the answers of respondents were as follows:

In case 1: 49.7% of participants responded to this question (95 responders), 71.6% of which, answered correctly by choosing answer C. (Table 15)

In case 2: 49.7% of participants responded to this question (95 responders), 51.6% of them chose not to go with the company proposal, while 41.6% see that the company proposal is acceptable as long as the ethics committee is notified.(Table 16)

In Case 3: 49.7% of participants responded to this question (95 responders), 74.7% of responders chose to talk to Dr. Ahmed while 16.8% chose to report him to the ethics committee. A minority chose to remain silent (3.2%).(Table 17)

In Case 4: 49.7% of participants responded to this question (95 responders), 82.1% of which chose to report the findings as such, the remaining 17.9% chose answers that are considered either falsification or fabrication or both. (Table 18)

In Case 5: 49.7% of participants responded to this question (95 responders), 76.8% of which chose to withdraw the paper, a 13.7% thought it is sufficient to apologize to the author of the other paper. (Table 19)

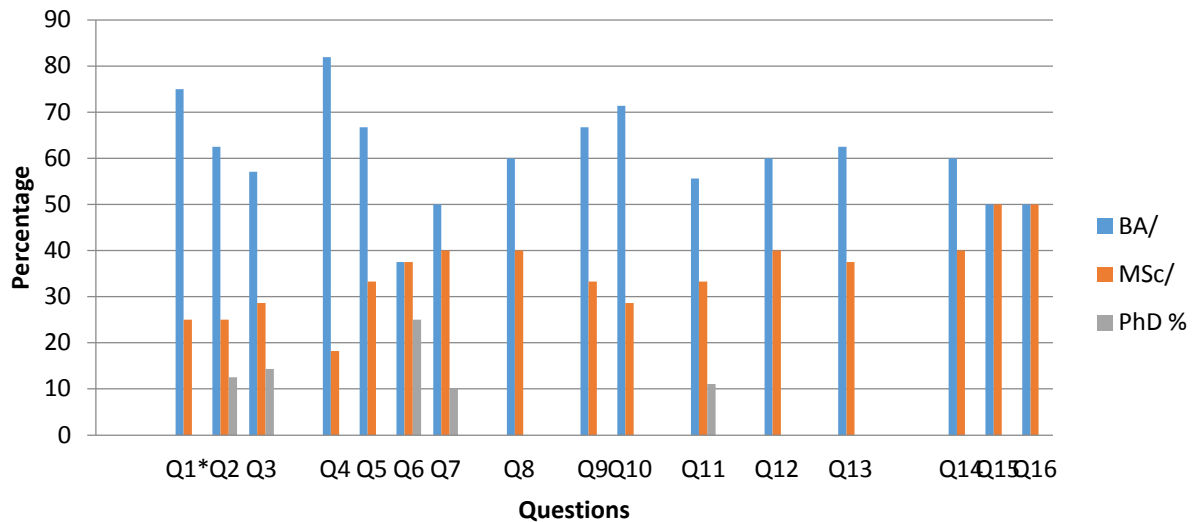
Correlation Data

I. Correlation between Degree Earned and Acceptability of Research Ethics Practices.

Figure 3 shows participants' acceptability of misconduct in different categories correlated to degree earned. The correlations show that at least 50% of those who found unethical practices acceptable had BSc or BA as their highest degree of education, reaching up to 81.9% in fabrication for example. The percentages of acceptability of unethical practices generally becomes less as the highest degree becomes higher this was statistically significant for Q1, the percentage of MSc or MPH holders who find unethical practices acceptable is consistently less with the exception of conflict of interest questions, it is also notable that the overall number of those who found conflict of interest acceptable is only

4 participants PhD holders generally did not find any of these misconducts acceptable, with the exception of a single person in each of the questions related to use of confidential information without authorization, not obtaining proper informed consent, dropping outliers without mentioning it and selecting data that only support their hypothesis. (Figure 3)

Figure 3: Correlation between Degree Earned and Acceptability of Research Ethics Practices (n= 112)



Key:

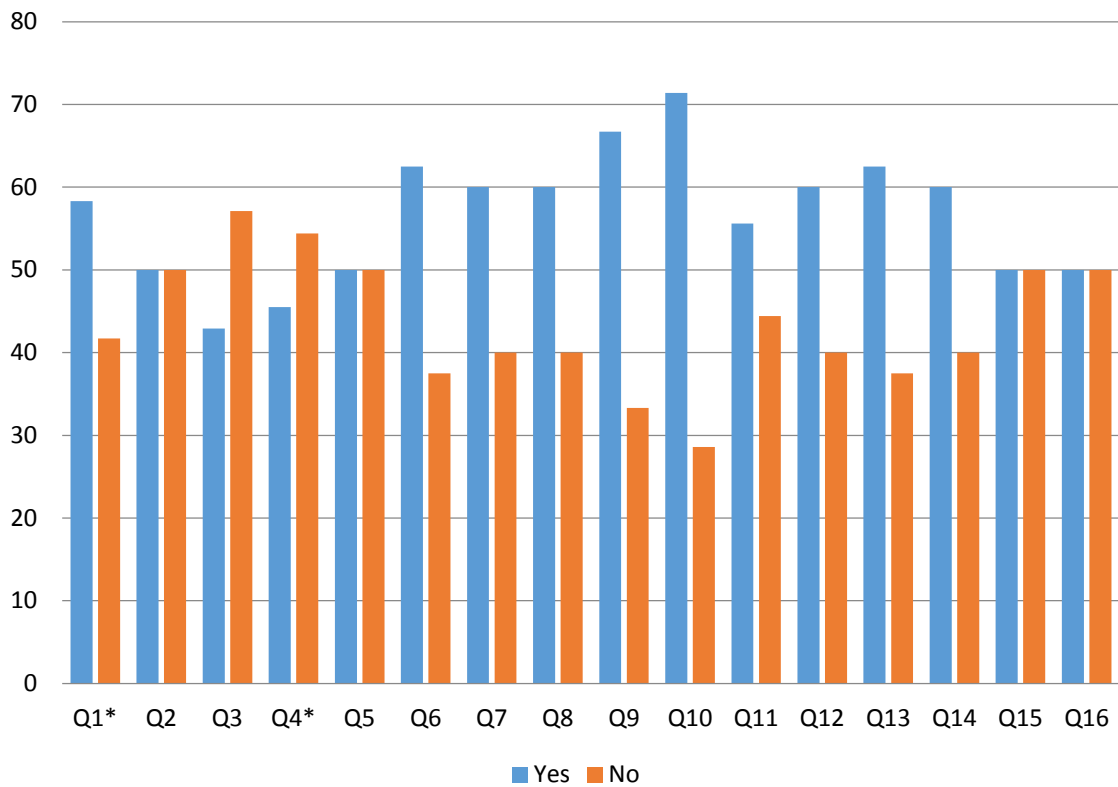
*p<0.05

- Q1: Conducting research involving human subjects without prior approval from an Institutional Review Board or Ethics Committee
- Q2: Use of confidential information about research subjects without their authorisation
- Q3: Not obtaining proper informed consent from participants
- Q4: Making up research data
- Q5: Changing research data without mentioning it.
- Q6: Dropping "outliers" without mentioning it
- Q7: Selecting only those data that support your hypothesis
- Q8: Publishing results that belong to someone else
- Q9: Using someone else's words or ideas without giving proper credit
- Q10: Submitting a manuscript to a journal that you already published in another Journal
- Q11: Giving authorship credit to someone who has not contributed substantively to a manuscript
- Q12: Denying authorship credit to someone who has contributed substantively to a manuscript
- Q13: Allowing your name to be put on papers to which you have made no reasonable contribution to
- Q14: Aware of a conflict of interest (e.g. you have a financial interest with a drug company and you are conducting a study for them) and did not disclose it to either the ethics committee or a journal
- Q15: Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source
- Q16: Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source

II. Correlation to Experience in research:

Figure 4 shows participants' acceptability of misconduct in different categories correlated to their previous experience in scientific research.

Figure 4: Correlation between prior Research Experience and Acceptability of Research Ethics Practices (n= 112)



Key:

*p<0.05

Q1: Conducting research involving human subjects without prior approval from an Institutional Review Board or Ethics Committee

Q2: Use of confidential information about research subjects without their authorisation

Q3: Not obtaining proper informed consent from participants

Q4: Making up research data

Q5: Changing research data without mentioning it.

Q6: Dropping "outliers" without mentioning it

Q7: Selecting only those data that support your hypothesis

Q8: Publishing results that belong to someone else

Q9: Using someone else's words or ideas without giving proper credit

Q10: Submitting a manuscript to a journal that you already published in another Journal

Q11: Giving authorship credit to someone who has not contributed substantively to a manuscript

Q12: Denying authorship credit to someone who has contributed substantively to a manuscript

Q13: Allowing your name to be put on papers to which you have made no reasonable contribution to

Q14: Aware of a conflict of interest (e.g. you have a financial interest with a drug company and you are conducting a study for them) and did not disclose it to either the ethics committee or a journal

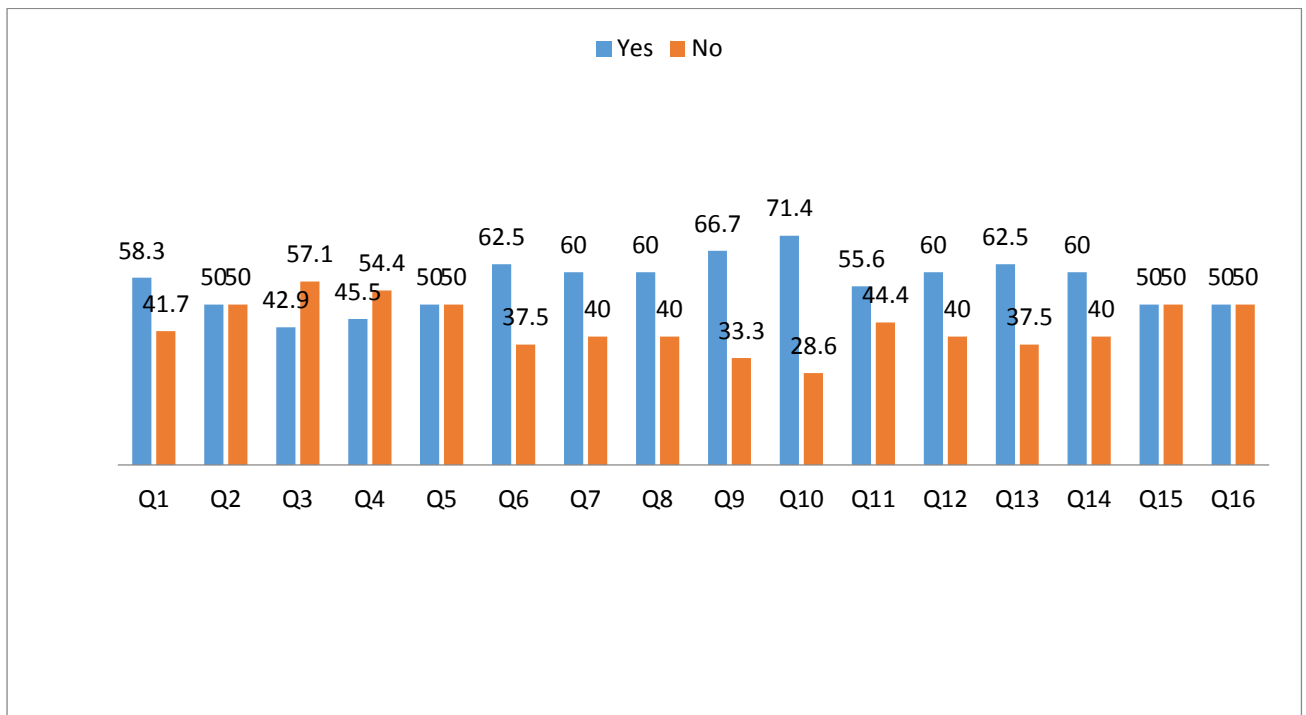
Q15: Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source

Q16: Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source

III. Correlation to prior ethics training:

Data for participants who found any of the questions about misconduct in different categories acceptable or unacceptable were extracted and correlated to their previous training .(Figure 5).

Figure 5: Correlation between prior Training on Research Ethics and Acceptability of Research Ethics Practices (n= 112)



Key:

- Q1: Conducting research involving human subjects without prior approval from an Institutional Review Board or Ethics Committee
- Q2: Use of confidential information about research subjects without their authorisation
- Q3: Not obtaining proper informed consent from participants
- Q4: Making up research data
- Q5: Changing research data without mentioning it.
- Q6: Dropping "outliers" without mentioning it
- Q7: Selecting only those data that support your hypothesis
- Q8: Publishing results that belong to someone else
- Q9: Using someone else's words or ideas without giving proper credit
- Q10: Submitting a manuscript to a journal that you already published in another Journal
- Q11: Giving authorship credit to someone who has not contributed substantively to a manuscript
- Q12: Denying authorship credit to someone who has contributed substantively to a manuscript
- Q13: Allowing your name to be put on papers to which you have made no reasonable contribution to
- Q14: Aware of a conflict of interest (e.g. you have a financial interest with a drug company and you are conducting a study for them) and did not disclose it to either the ethics committee or a journal
- Q15: Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source
- Q16: Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source

IV. Correlation with Gender:

Self reporting among males and females and acceptance of unethical behavior among males and females was cross tabulated against all questions to identify percentages differences between both genders. Comparing percentages among males and females in regard to self reporting shown in Table 20, and percentages of males showing acceptance to unethical behavior, are shown in Table 21.

DISCUSSION

Self reported and Observed practices

Evidence of intentional misconduct is difficult to identify, however, there is no better evidence than self-reporting of the person who committed the misconduct, even though it is unlikely though that a person who would commit misconduct will admit it, the survey still yielded responses in self reporting. The presence of questions related to acceptability of these misconducts, previous training and awareness of regulations helped to understand whether engaging in misconduct is intentional, or is it unawareness or peer or environment pressure.

The case studies presented to the participants, reflect a general tendency of the majority to do what is ethical or likely ethical from their perceptions in a real situation, the choices being close ended did not give the participants a chance to elaborate why this particular action was particularly chosen yet some responses even though not correct reflect a sense of decency or respect of the participants to the research set up, for example in case 2, 51.6% of participants would turn down the offer from the pharmaceutical company, possibly because it sounds fishy or because it is a conflict of influence that can impose a strong influence on the investigator, this might also indicate that the responders may not be aware of that under some conditions it is acceptable to have some conflict of interest but it is important to be declared. Only 2.1% went with accepting the proposal and not disclosing conflict of interest. Another example is in Case #5 where the majority of the responders chose to withdraw the paper, while the second most common answer was to apologize to the author, it is not the correct answer, but it reflects that responders are aware that this is something wrong and willing to correct it, but maybe they are not aware of the most proper corrective action to take. Nevertheless, the remaining wrong choices reflect a tendency engage in falsification, fabrication and plagiarism.

Prevalence of misconduct in regards to falsification and fabrication as per self reporting (ranged between 9.1% and 26% in different questions as shown in table 6). This is much higher as compared to the rates of self reporting in response to direct questions regarding altering data in the study of Fannelli which was only 0.3% to 4.9%. Similarly for observed misconduct the rate of reported observation lied between 5.2% and 33.3% as compared to 30.8% and 46.9% in our survey (Fannelli, 2009). This is not conclusive because the population demographics are different and the questions asked were phrased differently.

In regards to the prevalence based on observation of other colleagues the results suggest that misconduct is generally observed at a higher rate than self reported misconduct. This is consistent with the earlier indication that self reporting could always be an underestimate. The results summarized in Table 14 show that 77% of the responders indicated that the amount of misconduct that occurs is concerning, 50% of the responders believe that dishonesty or misrepresentation are common, and another 25.5% are neutral in this regard. 72% of the responders indicated that they are aware of the regulation that govern research involving humans, animals or laboratory practices, and 66.4% also believe that the responsibility of the misconduct does not only lie with the principal investigator. About 64% of the responders believe that the pressure to publish studies to gain promotion is a major reason for engaging in misconduct. About 85% of the responders agree or strongly agree that investigators need to declare conflict of interest and those investigators should report instances of research misconduct, however, 66% monitor their trainees to develop responsible

researchers and about 50% agree that the mechanisms to report the misconduct are appropriate

Correlation Analysis

Kisamore *et al.* have identified in their study that “integrity culture” was the most influential factor to variance academic misconducts such as cheating (Kisamore, 2007). It was also noticeable that observations were consistently higher with higher self reporting in an indication that a causal relationship might exist between observation of misconduct and tolerating or engaging in it.

Taking a deeper look at the results of questions in every area of misconduct showed that a number of participants ranging from 3.6% to 10.7% find such misconducts acceptable or very acceptable.

Accordingly several correlation factors were studied to assess the possible factors that could contribute to such acceptance of misconduct and to engagement misconduct.

Highest degree obtained in relation to acceptance of misconduct: The survey results suggest that acceptability of misconduct becomes less among responders who hold higher level degrees, the comparison in Figure 3, between BA/BSc degrees, MSc. degrees, and PhD holders, indicate that PhD holders were less accepting to unethical behavior than MSc. holders. Similarly Msc. holders were less accepting to unethical behavior than BSc. Holders. This could possibly be explained based on the fact that PhD programs and most of the MSc. programs would include research work such as thesis as part of their requirements to obtain the degree, which is not the case with BSc. where only some programs require this.

Research experience effect on acceptance of misconduct: Another correlation to research experience was studied to confirm this, but it was not conclusive as the individuals identified as accepting research misconduct were almost equally distributed between those who had research experience and those who had not. This correlation could not confirm if the experience of the participants had an effect on their views acceptance of unethical practices, the percentages of participants who find unethical practices acceptable or very acceptable were equally distributed among those who previously conducted research or those who have not previously conducted research, it was statistically significant that those who conducted research previously found conducting human subject research without IRB approval acceptable (Q1), while it was also statistically significant that making up of research data was found acceptable by those who did not conduct research. In some instances, those who conducted research were more accepting of unethical practices (e.g. dropping outliers without mentioning it was accepted by 62.5% of the responders who previously conducted scientific research) and in other instances it was the other way around (Figure 4)

Prior ethics training effect on accepting misconduct: Correlation to prior ethics training as well could not confirm if the prior training of the participants had an effect on their views regarding acceptance of unethical practices, the percentages of participants who find unethical practices acceptable or very acceptable were close in those who received training on research ethics and those who did not. However, particularly in the questions related to plagiarism the results were much higher in those who have received trainings however this was not statistically significant (Figure 5) This could possibly relate to inefficiency of the

training, misconceptions not addressed by such training or other factors influencing the acceptance of those responders to unethical practices despite being trained.

Gender effect on engaging in research misconduct or accepting it: Comparing percentages among males and females in regard to self reporting shows no significant differences (Table 20), on the other hand, percentages of males showing acceptance to unethical behavior, is generally higher than females, yet, this was only statistically significant for the use of confidential information about research subjects without their authorization. (Table 21)

Research Environment effect on acceptance of unethical behavior: Those who indicated acceptability of unethical practices without observing colleagues engage misconduct were found to be the lowest, with a highest percentage 11.6% for those who found giving authorship credit to someone who has not contributed substantively to a manuscript acceptable or very acceptable. In some instances however the percentages of those who never observed a misconduct and find it acceptable were higher than those who observed it at least once, such an example include not obtaining proper informed consent which is something that will not usually be openly observed. Another example is changing research data without mentioning it which is also something that will not be openly observed. Most of these correlations were statistically significant.

Research Environment effect on engagement in unethical behavior: The comparison suggests a significant correlation between observing colleagues doing misconduct and engaging in misconduct. This correlation is evident as the highest self reported rate of misconduct that the reporters confirmed never observing a colleague do it was 5.3% for dropping outlier without mentioning it. Participants who never did misconduct yet observed it were as well consistently less than those who never observed it among their colleagues. For example making up of research data, was not committed by 56.3% of those who observed it, as compared to 96.3% to those who never observed it. Most of these correlations were statistically significant.

THE CASE OF BIOTECHNOLOGY RESEARCH

In AUC's Biotechnology Department, several different types of research are being performed. Our results have strong implications for the ethical conduct of all of these types of researches.

For example, researches that involve the obtainment of human biological samples, such as blood and urine, are commonly performed. Our data showing the prevalence of different types of research misconducts either observed or self reported have the following relevance:

- Breach of confidentiality of participants' data: Such breaches can lead to adverse social consequences, including stigma and discriminatory actions, such as inability to gain employment and health insurance. For example, inappropriate release of information related to a participants' hepatitis C virus or HIV status could affect their employability, insurance eligibility and their social engagement. These effects are also more likely to occur when the data involve genetic information.
- Lack of protection of research participants: An important function of an institutional review board (IRB) is to ensure that research does not contain unnecessary risks. The IRB also identifies other risks that might not be appreciated by the investigators. As a significant proportion of our sample size thought it was proper not to obtain IRB review, the lack of such review can result in undue risks to research subjects.
- Potential research participants might not be adequately informed regarding important aspects of the research: Such lack of information could also be a consequence of not obtaining IRB review and approval, since a function of the IRB is to ensure that consent forms contain the necessary basic elements of information needed for potential research participants to make a decision regarding their participation in the research. IRBs also review the process of informed consent to certify that the consenting process is done in such a manner that ensures that consent is given voluntarily and does not involve coercion. Lack of a proper consent process can eventually lead to participants not being aware of their rights (e.g., not knowing their rights to decline or withdraw at any point of time).

Obtaining an IRB approval is a corner stone in ensuring the rights and welfare of human research subjects. The IRB acts as an independent body that adequately weighs risks and benefits, ensures risks are minimized, assesses conflicts of interests, reviews recruitment methods, responds to allegations and complaints of misconducts. Due to these important review functions of IRBs, our survey study indicating that the conduct of human subject research without IRB approval, as self reported by more than 10% of the participants and observed at least once by more than 21%, warrants immediate attention.

Other types of research at AUC include laboratory researches that involve bacterial and plant samples, all of which require best practices in the analysis and reporting of results obtained in these researches.

However, fabrication and falsification of results can occur in any of the above mentioned types of biotechnology results. As such, an aspect that was of significant concern in our study involving investigators at the AUC was the extent of reported incidence of fabrication and falsification, which was self reported by 26%, and observed by nearly 47% of the participants. Such misconducts could be a result of conflicting interests such as:

- Pressure to maintain grant/funding: because biotechnology is a quickly developing field that occurs amidst much competition for funding.
- Presence of potential commercial rewards: by selling the findings, starting a spinoff company or patenting inventions, most biotechnological findings can have great commercial value.
- Pressure to publish/get promoted or even graduate.

Biotechnology research might also involve the use of animals. It is worth mentioning that at the AUC, ethical review of research involving animals is not currently being performed, as an animal research ethics committee does not exist. Such animal research ethics committees ensure that the welfare of animals used in research are maintained. While Animal Rights principles are against using animals as experimental subjects, regulations describes what is known as Animal Welfare as a method to ensure animals are not cruelly abused. The federal law that regulates animal welfare is known as Animal Welfare Act, with the objective of minimizing the discomfort, pain and distress to the animals. It sets basic rules for feeding, housing, handling, veterinary care, and even psychological well-being (CFR, n.d.). Our results indicate the ignoring aspects of animal subject requirement were observed at least once by 17.7 % of the participants, and not abiding to biosafety regulation by more than 34%.

Regardless of one's reasons to engage in such misconduct, the consequences have been shown to be quite severe in previous biotechnology studies. I would like to review two such studies that demonstrate the severity of adverse outcomes stemming from research misconduct.

One case involved that of Jesse Gelsinger, who died at the age of 18 as a result of his participation in a gene therapy clinical trial in 1999. The trial testing for a new treatment for a genetic liver disease known as ornithine transcarbamase deficiency; This genetic disorder was due to a lack of the gene that encodes for ornithine transcarbamase. The trial was investigating the introduction of a functional copy of the gene in participants by means of an adenovirus vector. Being a phase I trial, it was the first in human trial and it had no benefits anticipated for the participants. The maximum tolerable dose of the adenovirus vector was given to Gelsinger that caused a severe immune reaction leading to multiple organ failure and his death a few days later. (Shamoo and Resnik, 2009)

There was several ethics violation in this trial. For example, Jesse Gelsinger was not properly informed about the risks that he would be exposed to by participating in the study. This included the effects of the intervention on liver function, as adverse events that occurred in pre-clinical animal trials and in human subjects who had been enrolled prior to Jesse's

participation were not properly reported to the FDA. There were also issues with conflict of interests, as the principal investigator of the trial had ownership rights in the institute that would market any commercial tests that would result from the study.

Another infamous scandal that combines conflict of interest, fabrication, and falsification was that of Duke University, in North Carolina. In pre-clinical research, Dr. Annil Potti had fabricated and falsified results of a cancer treatment method that depended on genomic matching of patient's DNA to the most suitable treatment. Subsequently, a large clinical trial was conducted involving hundreds of patients who were led to believe that they might receive clinical benefit from their participation. A company was started with the "discovery" and more patients became involved, and due to the continued falsification and manipulation of the data, patients were not receiving the best treatments for their cancers as promised.. The university itself was accused of continuing to support the fraudulent research to make money (Deception at Duke, n.d.). In January 2015, The Cancer Letter published a report indicating that a whistleblower has been asked to remain quiet by Duke University's professors and deans. The University eventually settled all lawsuits related to Potti's research for undisclosed terms. A number of Potti's publications have been retracted.

While biotechnological research at AUC may not involve treating patients and may not carry risks with extreme outcomes such as death, the same tools of bioinformatics, genomics, transcriptomics are being used in research done in the AUC. As such, misconducts involving falsification, fabrication and conflicts of interest that occurred in the Gelsinger and the Duke studies can also occur at the AUC. Similar pressures to keep grants, get promoted, graduate or publish exists. Publishing of fraudulent results that are not of direct application at the moment may not be of direct harm to anyone, but such published results present opportunities to generate new results that can be misleading and eventually be harmful.

CONCLUSION

The prevalence of misconduct observed was higher than self reported prevalence. Variations in the amount of misconduct were observed in different categories, the lowest related to conflict of interest and the highest related to falsification and fabrication. In self reported misconducts, the highest was in a question related to research practices and the lowest in question related to conflict of interest.

In regards to attitudes, participants ranging from 3.6% to 10.7% found unethical misconducts acceptable or very acceptable. The majority of responders generally chose the “responsible conduct” responses in the study cases, choices that were not correct were more inclined towards less extreme unethical decisions. Responses were generally positive in regards to reporting of misconduct, monitoring of trainees and declaration of conflict of interest. However, the majority expressed concerns over amount of misconduct and indicated the commonality of dishonesty and misinterpretation of data.

Cross tabulating results showed significant correlations highest degree with the acceptability of misconduct, showing that the higher the scientific grade the lower is the acceptability of misconduct. It also suggested significant effect of the research environment on the acceptability of misconduct and the incidence of engaging in it. Correlation to research experience and training could not be established but the correlation suggested that trainings could possibly be not effective.

LIMITATIONS

This study included self-reporting of self-identified practices, which could represent an underestimate of actual practice. Individuals who committed misconduct may be reluctant to admit it even though the survey is anonymized and they cannot be identified, additionally people participants might as well be reluctant to report others or admit to own gaps. Also, results from a single university may not be generalizable to other universities in Egypt.

NEXT STEPS

Further data using the same survey is being collected from other institutes in Egypt and the Middle-East particularly from Bahrain and Lebanon and will be pooled to results from AUC to get a broader image.

It is also recommended that further qualitative research (e.g., interview studies) is needed to explore further the possible reasons for the correlations identified.

CONCLUDING REMARKS

Even though different misconducts in different research fields can have different impact on people, and the amount of harm (or possibly no harm) can vary widely, misconduct remains an abuse against the science and the scientific method that we trust. Advances in science is primarily based on data assumed correct, where one builds on it, cite it and use it as building base to new concepts and to advance current applications. Falsified or fabricated data serve as an imaginary base that nothing can be based on, and building on it would consequently lead to waste of time and resources on top of possibility of harming research subjects or at the very least affecting the career of researchers depending on peers previous work. Accordingly, research misconduct should be taken very seriously, simply retracting and refunding of grants serve as a corrective action to a wrong situation, but it is not enough of a preventative action, civil and criminal liability based on the harm and even potential harm from such misconduct would be an example that would make anyone think twice before recklessly attempting misconduct.

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Tables

Table 1: Demographics of participants

Gender	Males	31.9%
	Females	66.5%
Nationality	Egyptian	91.1%
	Non-Egyptian	8.9%
Position	Undergraduate student	18.8%
	MSc student	34.0%
	PhD Student	12.6%
	Research Position	8.4%
	Academic position	9.4%
Received Ethics Training?	No	43.5%
	Yes	52.4%
If yes, training included research misconduct?	Yes	56.0%
	No	11.0%
	Not sure/cannot remember	33.0%

Table 2: response rates to different types of questions.

Total:	Response rate	percentage
Initiated survey	191/191	100
Completed survey	95/191	49.7
Responders to questions about acceptance of misconduct	112/191	58.6
Responders to questions about prevalence of misconduct	130/191	68.1
Responders to questions about self-reporting of misconduct	114/191	59.7
Responders to questions about self-reporting of misconduct who conducted research	77/114	67.5

Table 3: Acceptability of participants to misconducts related to Research Ethics

	Very acceptable %	Acceptable %	Neutral %	Unacceptable %	Definitely unacceptable %
Conducting research involving human subjects without prior approval from an Institutional Review Board or Ethics Committee	8	2.7	8.9	25	55.4
Use of confidential information about research subjects without their authorisation	5.4	1.8	5.4	9.8	77.7
Not obtaining proper informed consent from participants	5.4	0.9	10.7	24.1	58.9

Table 4: Comparison between self reporting and observed misconduct in Research Ethics.

Questions	Observed				Self reported			
	n (response rate%)	Never %	Once or twice %	Three times or more %	n (response rate%)	Never %	Once or twice %	Three times or more %
Conducting research involving human subjects without prior approval from an Institutional Review Board or Ethics Committee	130 (68.1)	78.5	15.4	6.2	77 (67.5)	89.6	7.8	2.6
Use of confidential information about research subjects without their authorisation	130 (68.1)	80	15.4	4.6	77 (67.5)	93.5	6.5	0
Not obtaining proper informed consent from participants	130 (68.1)	65.4	22.3	12.3	77 (67.5)	89.6	7.8	2.6

Table 5: Acceptability of Falsification and Fabrication (n=112)

	% Very acceptable	% acceptable	% Neutral	% unacceptable	% Definitely unacceptable
Making up research data	5.4	4.5	1.8	13.4	75
Changing research data without mentioning it.	2.7	2.7	5.4	22.3	67
Dropping “outliers” without mentioning it	3.6	3.6	9.8	33.0	50.0
Selecting only those data that support your hypothesis	5.4	3.6	19.6	24.1	47.3

Table 6: Comparison between self reporting and observed misconduct related to Falsification and Fabrication.

Questions	Observed				Self reported			
	n (response rate%)	Never %	Once or twice %	Three times or more %	n (response rate%)	Never %	Once or twice %	Three times or more %
Making up research data	130 (68.1)	65.4	29.2	5.4	77 (67.5)	88.3	11.7	0
Changing research data without mentioning it.	130 (68.1)	69.2	24.6	6.2	77 (67.5)	90.9	9.1	0
Dropping “outliers” without mentioning it	130 (68.1)	63.8	26.9	9.2	77 (67.5)	81.8	18.2	0
Selecting only those data that support your hypothesis	130 (68.1)	53.1	35.4	11.5	77 (67.5)	74.0	22.1	3.9

Table 7: Acceptability of Plagiarism (n=112)

Plagiarism	% Very acceptable	% acceptable	% Neutral	% unacceptable	% Definitely unacceptable
Publishing results that belong to someone else	4.5	0	0	8.9	86.6
Using someone else's words or ideas without giving proper credit	3.6	1.8	0	22.3	72.3
Submitting a manuscript to a journal that you already published in another Journal	4.5	1.8	5.4	20.5	67.9

Table 8: Comparison between self reporting and observed misconduct related to Plagiarism

Questions	Observed				Self reported			
	n (response rate%)	Never %	Once or twice %	Three times or more %	n (response rate%)	Never %	Once or twice %	Three times or more %
Publishing results that belong to someone else	130 (68.1)	73.1	19.2	7.7	77 (67.5)	92.2	6.5	1.3
Using someone else's words or ideas without giving proper credit	130 (68.1)	56.2	35.4	8.5	77 (67.5)	90.9	7.8	1.3
Submitting a manuscript to a journal that you already published in another Journal	130 (68.1)	83.8	13.1	3.1	77 (67.5)	94.8	3.9	1.3

Table 9: Acceptability of misconducts related to Authorship (n=112)

Authorship	%Very acceptable	% acceptable	% Neutral	% unacceptable	%Definitely unacceptable
Giving authorship credit to someone who has not contributed substantively to a manuscript	3.6	4.5	4.5	36.6	50.9
Denying authorship credit to someone who has contributed substantively to a manuscript	4.5	0	0.9	14.3	80.4
Allowing your name to be put on papers to which you have made no reasonable contribution	2.7	4.5	4.5	24.1	64.3

Table 10: Comparison between self reporting and observed misconduct related to Authorship

Questions	Observed				Self reported			
	n (response rate%)	Never %	Once or twice %	Three times or more %	n (response rate%)	Never %	Once or twice %	Three times or more %
Giving authorship credit to someone who has not contributed substantively to a manuscript	130 (68.1)	62.3	23.8	13.8	77 (67.5)	85.7	10.4	3.9
Denying authorship credit to someone who has contributed substantively to a manuscript	130 (68.1)	75.4	20.0	4.6	77 (67.5)	94.8	3.9	1.3
Allowing your name to be put on papers to which you have made no reasonable contribution	NA	NA	NA	NA	77 (67.5)	90.9	7.8	1.3

Table 11: Acceptability of misconduct related to Conflict of Interest (n=112)

CONFLICT OF INTEREST	% Very acceptable	% acceptable	% Neutral	% unacceptable	% Definitely unacceptable
Aware of a conflict of interest (e.g. you have a financial interest with a drug company and you are conducting a study for them) and did not disclose it to either the ethics committee or a journal	2.7	1.8	8.0	28.6	58.9
Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source	2.7	0.9	8.0	27.7	60.7
Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source	2.7	0.9	8.0	21.4	67.0

Table 12: Comparison between self reporting and observed misconduct related to Conflict of Interest

Questions	Observed				Self reported			
	n (response rate%)	Never %	Once or twice %	Three times or more %	n (response rate%)	Never %	Once or twice %	Three times or more %
Aware of a conflict of interest and did not disclose it to either the ethics committee or a journal	130 (68.1)	86.9	12.3	0.8	77 (67.5)	94.8	5.2	0
Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source	130 (68.1)	86.9	11.5	1.5	77 (67.5)	96.1	3.9	0
Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source	130 (68.1)	89.2	10.0	0.8	77 (67.5)	96.1	3.9	0

Table 13: Comparison between self reporting and observed misconduct related to Research Practices

Questions	Observed				Self reported			
	n (response rate%)	Never %	Once or twice %	Three times or more %	n (response rate%)	Never %	Once or twice %	Three times or more %
Ignoring aspects of animal-subjects research requirements such as care, feeding, monitoring,	130 (68.1)	82.3	12.3	5.4	77 (67.5)	90.9	6.5	2.6
Ignoring aspects of materials-handling research requirements such as biosafety, radioactive materials,	130 (68.1)	65.4	23.8	10.8	77 (67.5)	72.7	18.2	9.1
Providing an inappropriately negative or positive letter of recommendation	130 (68.1)	76.9	19.2	3.8	77 (67.5)	93.5	6.5	0

Table 14: Attitudes of participants towards misconduct (n=110)

Statement	Strongly agree %	Agree %	Neutral %	Disagree %	Strongly disagree %
I am concerned about the amount of misconduct that occurs	30	47.3	16.4	5.5	0.9
The responsibility of misconduct lies with the principal investigator only	10	12.7	10.9	48.2	18.2
Dishonesty and misrepresentation of data are common	15.5	34.5	25.5	13.6	10.9
Investigators should report instances of research misconduct	44.5	40.9	9.1	3.6	1.8
There are appropriate mechanisms in place to report misconduct at my institution	20.9	24.5	32.7	16.4	5.5
The pressures to publish studies to gain promotion is a major reason why investigators engage in research misconduct.	22.7	41.8	19.1	13.6	2.7
Investigators should declare conflicts of interest to the appropriate officials	42.7	42.7	12.7	0.9	0.9
I monitor my trainees' work to ensure that they are developing into responsible researchers	36.4	30.9	30.9	1.8	0
I am aware of regulations that govern research involving humans, animals, or laboratory practices.	31.8	40.0	17.3	10.9	0

Table 15: Responses rates to different answer choices for Case 1

<i>Case 1- You have received a manuscript for review from a journal editor. You believe the paper is very good and realize that it contains a new insight that is relevant to the content of a paper you are currently writing. Which of the following actions is most appropriate?</i>	
A. <i>Tell the journal editor that the paper you reviewed should not be published.</i>	8.4%
B. <i>Implement the ideas in your own paper and quickly prepare to submit it for review. When your own paper has been submitted, return the manuscript to the editor with the comment that you cannot review it because of a conflict of interest.</i>	13.7%
C. <i>Promptly write a conscientious review, but delay implementing the ideas that would facilitate your own research until the reviewed paper has been published.</i>	71.6%
D. <i>Implement the ideas in your own paper and quickly prepare to submit it for review. Delay returning your favorable review of the journal's manuscript until your own paper has been submitted.</i>	6.3%

Table 16: Responses rates to different answer choices for Case 2

<i>Case 2- You are performing a study on the side effects of a newly approved drug, Restex, compared to other sleep aids drugs that are currently approved. The company who makes Restex finds out about the study and offers to provide you with financial support to complete the study more quickly. The company will pay you \$200 per participant recruited into the study; it will also pay for the Restex drug, key personnel working on your study, and any study related procedures required to evaluate the drug's effectiveness. In exchange, the company wants to have access to the data and to your paper before you publish. What action would you take?</i>	
A- <i>Don't agree to the company's proposal.</i>	51.6%
B- <i>Agree to the company's proposal but do not disclose the agreement to the Research Ethics Committee.</i>	2.1%
C- <i>Agree to the company's proposal and disclose the information to the Research Ethics Committee.</i>	46.3%
D- <i>Agree to the company's proposal and give them false data in return.</i>	0%

Table 17: Responses rates to different answer choices for Case 3

<i>Case 3- Dr. Ahmed and her graduate student, Samer, are working together on a study about alternative therapies for fever. Dr. Ahmed is unwilling to share her entire dataset with colleagues before publishing her interpretation of the data. Samer, however, has access to the database as part of his current project and decides that it is ethical for him to look more closely at the data. Samer realizes that Dr. Ahmed has excluded specific data points that impact her interpretation. Samer realizes that if he includes these data points, an entirely new understanding of therapies to treat fever will emerge. What should Samer do?</i>	
A- <i>Do nothing since Dr. Ahmed is his superior</i>	3.2%
B- <i>Write a separate paper on his findings</i>	5.3%
C- <i>Immediately report Dr. Ahmed to the Research Ethics Committee</i>	16.8%
D- <i>Talk to Dr. Ahmed about his findings</i>	74.7%

Table 18: Responses rates to different answer choices for Case 4

<i>Case 4- Mohamed is in the final stage of his dissertation work involving a survey study. While performing his statistical analysis, he realizes that none of his results are statistically significant. He thinks that if he had a larger sample size (about 20 more samples) his results would gain significance, but it is too late to recruit more participants and he needs to get his final draft to his advisor by the end of the week in time to finish his PhD requirements. What should Mohamed do?</i>	
A- <i>Duplicate some of the sample responses to gain significance</i>	6.3%
B- <i>Report his findings as is</i>	82.1%
C- <i>Find twenty friends to complete the survey although they would not meet study inclusion criteria.</i>	3.2%
D- <i>Report the p values as being significant (i.e., $p < 0.05$)</i>	8.4%

Table 19: Responses rates to different answer choices for Case 5

<i>Case 5- Your paper was published in a premiere international medical journal, but one of your students has noticed that several paragraphs in your paper contain sections that were copied word for word directly from another publication without referencing this other publication. What should you do?</i>	
A- <i>Call the editor to withdraw the paper</i>	76.8%
B- <i>Tell the student that it is too late to withdraw the paper</i>	5.3%
C- <i>Call the author of the other paper to apologize</i>	13.7%
D- <i>Wait and see if anyone else notices the copied material</i>	4.2%

Table 20: Rates of self reporting and gender

Questions	Never %		Once or twice %		Three or more times %	
	M	F	M	F	M	F
Research Ethics						
Conducting research involving human subjects without prior approval from an Institutional Review Board or Ethics Committee	95.5	87	0	11.1	4.5	1.1
Use of confidential information about research subjects without their authorisation	95.5	92.6	4.5	7.4	0	0
Not obtaining proper informed consent from participants	86.4	90.7	9.1	7.4	4.5	1.9
Fabrication and Falsification						
Making up research data	81.8	90.7	18.2	9.3	0	0
Changing research data without mentioning it.	90.9	90.7	9.1	9.3	0	0
Dropping “outliers” without mentioning it	81.8	81.5	18.2	18.5	0	0
Selecting only those data that support your hypothesis	72.7	74.1	22.7	22.2	4.5	3.7
Plagiarism						
Publishing results that belong to someone else	90.9	92.6	9.1	5.6	0	1.9
Using someone else’s words or ideas without giving proper credit	90.9	90.7	9.1	7.4	0	1.9
Submitting a manuscript to a journal that you already published in another Journal	100	92.6	0	5.6	0	1.9
Authorship						
Giving authorship credit to someone who has not contributed substantively to a manuscript	90.9	83.3	4.5	13	4.5	3.7
Denying authorship credit to someone who has contributed substantively to a manuscript	100	92.6	0	5.6	0	1.9
Allowing your name to be put on papers to which you made no reasonable contribution	100	87	0	11.1	0	1.9
Conflict of Interest						
Aware of a conflict of interest (e.g. you have a financial interest with a drug company and you are conducting a study for them) and did not disclose it to either the ethics committee or a journal	95.5	94.4	4.5	4.6	0	0
Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source	100	94.4	0	5.6	0	0
Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source	100	94.4	0	5.6	0	0

(Males=22, Females=54, no response =1, Total=77)

Table 21: Rates of acceptance of misconduct and gender

Questions	Acceptable %		Neutral %		Not Acceptable %	
	M	F	M	F	M	F
Research Ethics						
Conducting research involving human subjects without prior approval from an Institutional Review Board or Ethics Committee	91.0	11.5	9.1	7.7	81.8	80.7
Use of confidential information about research subjects without their authorisation*	12.1	5.1	6.1	3.8	81.8	91
Not obtaining proper informed consent from participants	9.1	51.4	9.1	11.5	81.8	83.3
Fabrication and Falsification						
Making up research data	12.2	8.9	3	1.3	84.9	89.7
Changing research data without mentioning it.	9.1	3.9	9.1	3.8	81.8	92.3
Dropping “outliers” without mentioning it	15.2	3.9	18.2	6.4	66.7	89.8
Selecting only those data that support your hypothesis	12.2	7.7	18.2	20.5	69.7	71.8
Plagiarism						
Publishing results that belong to someone else	6.1	3.8	0	0	94	96.1
Using someone else’s words or ideas without giving proper credit	9.1	3.8	0	0	90.9	96.1
Submitting a manuscript to a journal that you already published in another Journal	9.1	5.1	3	6.4	87.9	88.4
Authorship						
Giving authorship credit to someone who has not contributed substantively to a manuscript	12.1	6.4	3	5.1	84.8	88.4
Denying authorship credit to someone who has contributed substantively to a manuscript	6.1	3.8	3	0	90.9	96.1
Allowing your name to be put on papers to which you made no reasonable contribution	9.1	6.4	6.1	3.8	84.9	89.8
Conflict of Interest						
Aware of a conflict of interest (e.g. you have a financial interest with a drug company and you are conducting a study for them) and did not disclose it to either the ethics committee or a journal	6	3.9	6.1	9	87.9	87.1
Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source	6	2.6	9.1	7.7	84.9	89.8
Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source	6	2.6	3	10.3	90.9	87.2

(*p<0.05, Males=33, Females=78, no response=1, Total=112)

APPENDICES

Appendix I	Consent and Survey Tool
Appendix II	Recruitment Email
Appendix III	AUC-IRB Approval
Appendix IV	UMB-IRB Exemption
Appendix V	Tables

INVITATION TO PARTICIPATE IN A RESEARCH SURVEY STUDY: You are being asked to volunteer to participate in an anonymous survey study. We are asking active researchers, in either human subject or laboratory research, to complete this survey.

LENGTH OF SURVEY: This study should take about 30 minutes to complete.

PURPOSE OF THE STUDY: This study aims to assess the attitudes and self-perceived behaviors of research misconduct by investigators in various institutions in the Middle East region. The objectives of this study are to:

- a. Assess attitudes toward research misconduct in the Middle East.
- b. Assess personal and environmental perceptions of prevalence and practice of research misconduct.
- c. Measure and compare the results of the survey across multiple sites in the region.

NUMBER OF PARTICIPATING SITES: This survey is being distributed at research organizations in three countries in the Middle East, including Bahrain, Egypt and Lebanon. We are expecting to enroll approximately 450 participants.

VOLUNTARINESS: Your decision to participate is completely voluntary. If you choose to decline to participate in this survey study, there is no way for anyone to determine who has declined.

CONFIDENTIALITY: This survey is anonymous, as we are not asking for your name. There is no way to determine who completes this survey. All data will be presented in aggregate form in a report that will be made public. Aggregate scores will not be linked to your identity.

POTENTIAL BENEFITS: There are no direct benefits to you by participating in this survey, although you might gain some knowledge about the issue of research misconduct from the questions itself. Your organization might receive some benefits in knowing information regarding research misconduct so that they can develop any required educational programs.

RESEARCH RISKS: Since the survey is anonymous, there are no risks from breaches of confidentiality. The questions do not involve sensitive topics, hence, there are no psychological risks for the individual completing this survey.

ETHICS APPROVAL: The investigators of this study have obtained ethics approval from their respective Research Ethics Committees.

CONTACT INFORMATION: For further information about this study, you can contact any one of the following Principal Investigators from your country:

Bahrain: Ghufraan Jassim, gjassim@rcsi-mub.com, RSCI Bahrain

Egypt: Mohamed Salem, dr_m_esam@yahoo.com, Marwan Felaefel, mar.fel@aucegypt.edu, American University in Cairo

Lebanon: Rola Jaafar, rola.jaafar@gmail.com, Ain Wazeln Medical Center

If you desire to participate in this survey, please click on the "next" button.

Continuing with the next page of the survey constitutes your giving informed consent to participate in this survey.

Once you are done with a page, please click "next" to move to the next page. You will need to answer all questions on a page before continuing to the next page. If you would like to go back to a previous page, please click "Prev" at the bottom of the page. If you would like to leave the survey at any time, just click "Exit this survey". Your answers will be saved.

Click "next" to get started with the survey

DEMOGRAPHIC INFORMATION

*1. What is your age?

*2. What is your gender?

- Male
- Female
- Prefer not to respond

*3. What is your nationality?

- Egyptian
- Lebanese
- Bahraini
- Other (please specify)

*4. Highest degree so far:

- BSc
- MSc
- MPhil
- MD
- PhD
- Other (please specify)

*5. Attended Graduate School in:

- Canada
- European Union
- Middle East
- United States of America
- Other (please specify)

***6. Current position:**

Undergraduate

MSc student

PhD student

Postdoctoral

Assistant Professor (or equivalent)

Associate Professor (or equivalent)

Full Professor (or equivalent)

Emeritus Professor

Technician

Research Assistant

Lecturer

Other (please specify)

***7. Have you ever conducted a scientific research study including in your thesis?**

Yes

No

8. What type(s) of research were you involved in (check all that apply)?

Human subject research (e.g. clinical trials or survey studies)

Experimental animals

Human biological samples

Laboratory research

Other (please specify)

***9. Have you had prior ethics training?**

Yes

No

10. Did this training include education in research misconduct?

Yes

No

Not sure / Cannot remember

PREVALENCE OF SCIENTIFIC MISCONDUCT - YOUR COLLEAGUES

Within the last three years, have you observed or had other direct evidence of any of your COLLEAGUES engaging in any of the below behaviors within the last 3 years? Please indicate the frequency.

*11. RESEARCH ETHICS

	Never	Once or twice	Three or more
Conducting research involving human subjects without prior approval from an Institutional Review Board or Ethics Committee	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Use of confidential information about research subjects without their authorisation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Not obtaining proper informed consent from participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*12. DATA FABRICATION & FALSIFICATION

	Never	Once or twice	Three or more
Making up research data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changing research data without mentioning it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dropping "outliers" without mentioning it	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Selecting only those data that support your hypothesis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*13. PLAGIARISM

	Never	Once or twice	Three or more
Publishing results that belong to someone else	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Using someone else's words or ideas without giving proper credit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Submitting a manuscript that has already been published in another journal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***14. AUTHORSHIP**

	Never	Once or twice	Three or more
Giving authorship credit to someone who has not contributed substantively to a manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Denying authorship credit to someone who has contributed substantively to a manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***15. CONFLICT OF INTEREST**

	Never more	Once or twice	Three or
Having a conflict of interest (e.g. a person had a financial interest with a drug company and were conducting a study for the company) and not disclosing it to either the ethics committee or a journal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***16. RESEARCH PRACTICES**

	Never	Once or twice	Three or more
Ignoring aspects of animal-subjects research requirements such as care, feeding, monitoring, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ignoring aspects of materials-handling research requirements such as biosafety, radioactive materials, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Providing an inappropriately negative or positive letter of recommendation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Inadequate record keeping related to research proposals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cutting corners because one was in a hurry to complete a project	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

17. Were any of the question on this page difficult or confusing to understand? If so, which

questions?

5

6

PREVALENCE OF SCIENTIFIC MISCONDUCT - YOURSELF

Please tell us how many times YOU have engaged in any of these behaviors within the last three years.

*18. RESEARCH PRACTICES

	Never more	Once or twice	Three or
Ignoring aspects of animal-subjects research requirements such as care, feeding, monitoring, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ignoring aspects of materials-handling research requirements such as biosafety, radioactive materials, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Providing an inappropriately negative or positive letter of recommendation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Inadequate record keeping related to research proposals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cutting corners because you were in a hurry in order to complete a project	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*19. RESEARCH ETHICS

	Never	Once or twice	Three or more
Conducting research involving human subjects without prior approval from an Institutional Review Board or Ethics Committee	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of confidential information about research subjects without their authorisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not obtaining proper informed consent from participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*20. DATA FABRICATION & FALSIFICATION

	Never more	Once or twice	Three or
Making up research data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Changing research data without mentioning it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dropping "outliers" without mentioning it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Selecting only those data that support your hypothesis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*21. PLAGIARISM

	Never	Once or twice	Three or more
Publishing results that belong to someone else	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Using someone else's words or ideas without giving proper credit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Submitting a manuscript to a journal that you already published in another journal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*22. AUTHORSHIP

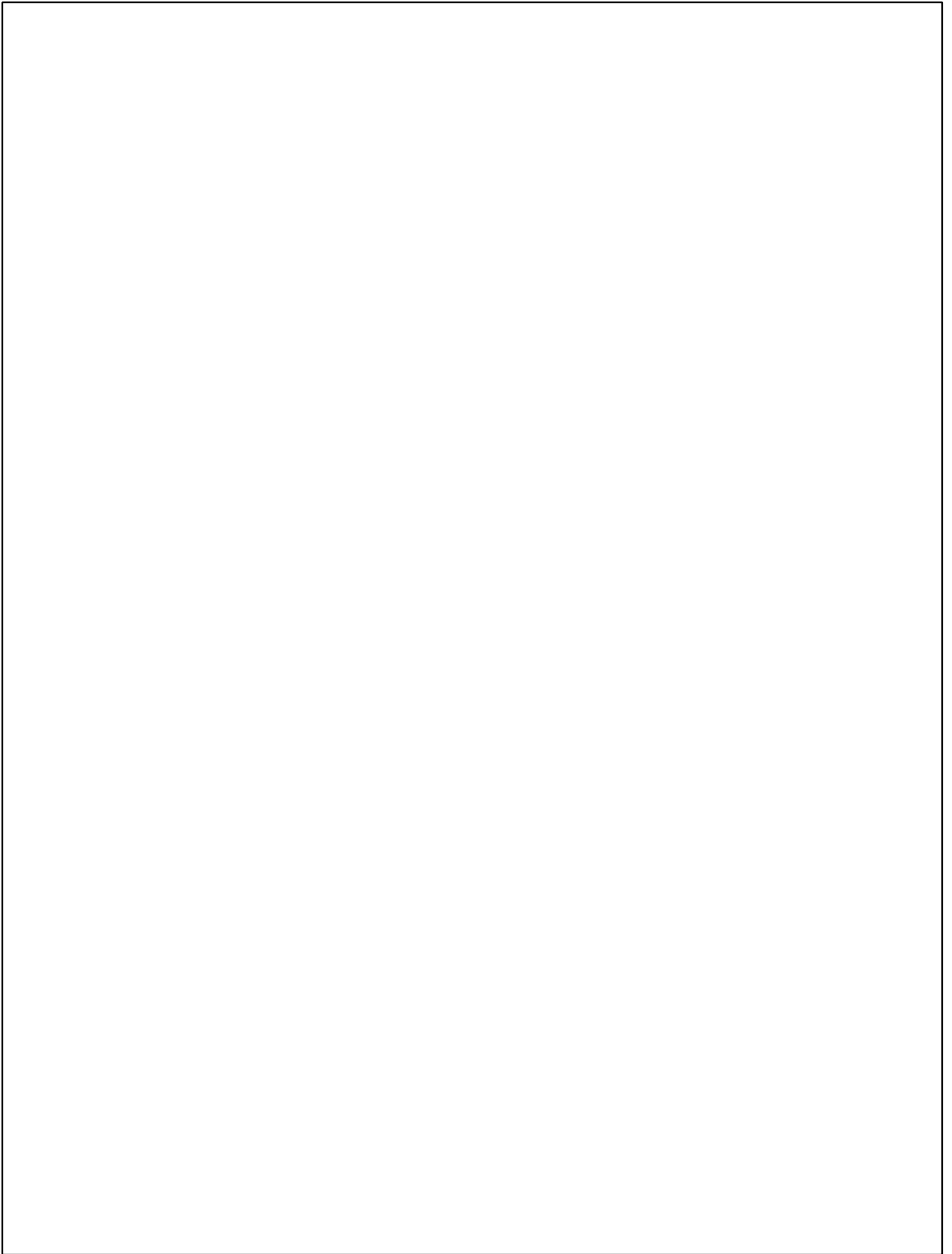
	Never	Once or twice	Three or more
Giving authorship credit to someone who has not contributed substantively to a manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Denying authorship credit to someone who has contributed substantively to a manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Allowing your name to be put on papers to which you have made no reasonable contribution	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*23. CONFLICT OF INTEREST

	Never	Once or twice	Three or more
Aware of a conflict of interest (e.g. you have a financial interest with a drug company and you are conducting a study for them) and did not disclose it to either the ethics committee or a journal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

24. Were any of the question on this page difficult or confusing to understand? If so, which

questions?



ACCEPTABILITY OF PRACTICES IN CONDUCT OF RESEARCH

Please rate the extent (on the below 5 point scale) to which you think any of the below behaviors are acceptable.

*25. RESEARCH ETHICS

	Very Acceptable	Acceptable	Neutral	Unacceptable	Definitely Unacceptable
Conducting research involving human subjects without prior approval from an Institutional Review Board or Ethics Committee	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Use of confidential information about research subjects without their authorisation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Not obtaining proper informed consent from participants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*26. DATA FABRICATION & FALSIFICATION

	Very Acceptable	Acceptable	Neutral	Unacceptable	Definitely Unacceptable
Making up research data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changing research data without mentioning it.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dropping "outliers" without mentioning it	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Selecting only those data that support your hypothesis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*27. PLAGIARISM

	Very Acceptable	Acceptable	Neutral	Unacceptable	Definitely Unacceptable
Publishing results that belong to someone else	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Using someone else's words or ideas without giving proper credit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Submitting a manuscript to a journal that you already published in another journal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***28. AUTHORSHIP**

	Very Acceptable	Acceptable	Neutral	Unacceptable	Definitely Unacceptable
Giving authorship credit to someone who has not contributed substantively to a manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Denying authorship credit to someone who has contributed substantively to a manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Allowing your name to be put on papers to which you have made no reasonable contribution	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***29. CONFLICT OF INTEREST**

	Very Acceptable	Acceptable	Neutral	Unacceptable	Definitely Unacceptable
Aware of a conflict of interest (e.g. you have a financial interest with a drug company and you are conducting a study for them) and did not disclose it to either the ethics committee or a journal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Compromising the rigor of a study's design or methodology in response to pressure from a commercial or not-for-profit funding source	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Inappropriately altering or suppressing research results in response to pressure from a commercial or not-for-profit funding source	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

30. Were any of the question on this page difficult or confusing to understand? If so, which

questions?

5

6

ATTITUDES OF SCIENTIFIC MISCONDUCT

***31. Please indicate the extent of the degree with which you agree or disagree with the following statements**

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
I'm concerned about the amount of misconduct that occurs.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The responsibility for misconduct lies with the principal investigator only.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dishonesty and misrepresentation of data are common	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Investigators should report instances of research misconduct.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There are appropriate mechanisms in place to report misconduct at my institution	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The pressures to publish studies to gain promotion is a major reason why investigators engage in research misconduct.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Investigators should declare conflicts of interest to the appropriate officials	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I monitor my trainees' work to ensure that they are developing into responsible researchers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am aware of regulations that govern research involving humans, animals, or laboratory practices.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

32. Were any of the question on this page difficult or confusing to understand? If so, which questions?

QUESTIONS ABOUT SCIENTIFIC MISCONDUCT

***33. You have received a manuscript for review from a journal editor. You believe the paper is very good and realize that it contains a new insight that is relevant to the content of a paper you are currently writing. Which of the following actions is most appropriate?**

- Tell the journal editor that the paper you reviewed should not be published.
- Implement the ideas in your own paper and quickly prepare to submit it for review. When your own paper has been submitted, return the manuscript to the editor with the comment that you cannot review it because of a conflict of interest.
- Promptly write a conscientious review, but delay implementing the ideas that would facilitate your own research until the reviewed paper has been published.
- Implement the ideas in your own paper and quickly prepare to submit it for review. Delay returning your favorable review of the journal's manuscript until your own paper has been submitted.

***34. You are performing a study on the side effects of a newly-approved drug, Restex, compared to other sleep aids drugs that are currently approved. The company who makes Restex finds out about the study and offers to provide you with financial support to complete the study more quickly. The company will pay you \$200 per participant recruited into the study; it will also pay for the Restex drug, key personnel working on your study, and any study-related procedures required to evaluate the drug's effectiveness. In exchange, the company wants to have access to the data and to your paper before you publish. What action would you take?**

- Don't agree to the company's proposal
- Agree to the company's proposal but do not disclose the agreement to the Research Ethics Committee
- Agree to the company's proposal and disclose the information to the Research Ethics Committee
- Agree to the company's proposal and give them false data in return

***35. Dr. Ahmed and her graduate student, Samer, are working together on a study about alternative therapies for fever. Dr. Ahmed is unwilling to share her entire dataset with colleagues before publishing her interpretation of the data. Samer, however, has access to the database as part of his current project and decides that it is ethical for him to look more closely at the data. Samer realizes that Dr. Ahmed has excluded specific data points that impact her interpretation. Samer realizes that if he includes these data points, an entirely new understanding of therapies to treat fever will emerge. What should Samer do?**

- Do nothing since Dr. Ahmed is his superior
- Write a separate paper on his findings
- Immediately report Dr. Ahmed to the Research Ethics Committee

Talk to Dr. Ahmed about his findings

***36. Mohamed is in the final stage of his dissertation work involving a survey study. While performing his statistical analysis, he realizes that none of his results are statistically significant. He thinks that if he had a larger sample size (about 20 more samples) his results would gain significance, but it is too late to recruit more participants and he needs to get his final draft to his advisor by the end of the week in time to finish his PhD requirements. What should Mohamed do?**

- Duplicate some of the sample responses to gain significance
- Report his findings as is
- Find twenty friends to complete the survey although they would not meet study inclusion criteria.
- Report the p values as being significant (i.e., $p < 0.05$)

***37. Your paper was published in a premiere international medical journal, but one of your students has noticed that several paragraphs in your paper contain sections that were copied word for word directly from another publication without referencing this other publication. What should you do?**

- Call the editor to withdraw the paper
- Tell the student that it is too late to withdraw the paper
- Call the author of the other paper to apologize
- Wait and see if anyone else notices the copied material

38. Were any of the question on this page difficult or confusing to understand? If so, which questions?

ASSESSMENT OF THIS SURVEY

*39. Assessment

Please choose the best answer for each of the following statements.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The time to complete this survey was reasonable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The instructions were easy to follow.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The questions were clear and understandable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The questions on the survey were appropriate.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
This survey will produce useful information.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***40. Please select the choice that best represents the time it took to complete this survey:**

- Less than 30 minutes
- Between 30 and 60 minutes
- Between 1 and 2 hours
- Greater than 2 hours

41. Which items on the survey are not important?

5

6

42. What other items should be on the survey?

5

6

43. Please add any additional comments

5

6

Thank you for completing this survey!

Appendix II

Dear Investigator:

We are conducting a research survey involving researchers in several countries in the Middle East. The purpose of this survey is to know better the attitudes of researchers regarding their conduct in research.

This survey will take approximately 30 minutes to complete.

Further information and the survey can be accessed via the following link

<https://www.surveymonkey.com/s/rcregypt>

Your responses will be anonymous. Data will never be reported in a way that identifies individuals.

Your participation in this survey is completely voluntary. This survey has been reviewed by the research ethics committees at several institutions.

If you include your contact information at the end of the survey, you will be included in a raffle to win one of three Apple iPad Minis.

Thank you in advance for your participation.

Regards,



To: Marawan Felaefel
Cc: Hind Helaly
From: Atta Gebril, Chair of the IRB
Date: Nov. 9, 2014
Re: Approval of study

This is to inform you that I reviewed your revised research proposal entitled "Attitudes and Behaviors toward Research Misconduct in the Middle East: a multi-site study," and determined that it required consultation with the IRB under the "expedited" heading. As you are aware, the members of the IRB suggested certain revisions to the original proposal, but your new version addresses these concerns successfully. The revised proposal used appropriate procedures to minimize risks to human subjects and that adequate provision was made for confidentiality and data anonymity of participants in any published record. I believe you will also make adequate provision for obtaining informed consent of the participants.

Please note that IRB approval does not automatically ensure approval by CAPMAS, an Egyptian government agency responsible for approving some types of off-campus research. CAPMAS issues are handled at AUC by the office of the University Counsellor, Dr. Amr Salama. The IRB is not in a position to offer any opinion on CAPMAS issues, and takes no responsibility for obtaining CAPMAS approval.

This approval is valid for only one year. In case you have not finished data collection within a year, you need to apply for an extension.

Thank you and good luck.

A handwritten signature in black ink that reads 'Atta Gebril'.

Dr. Atta Gebril
IRB chair, The American University in Cairo
2046 HUSS Building
T: 02-26151919
Email: agebril@aucegypt.edu



Institutional Review Board
The American University in Cairo
AUC Avenue, P.O. Box 74
New Cairo 11835, Egypt.
tel 20.2.2615.1000
fax 20.2.27957565
Email: aucirb@aucegypt.edu



University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: irbo@som.umaryland.edu

EXEMPT DETERMINATION

Date: October 28, 2014

To: Henry Silverman
RE: HP-00060625
Type of Submission: Initial Review
Type of IRB Review: Exempt

Determination Date: 10/28/2014

This is to certify that University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) has reviewed the above referenced protocol entitled, "*Attitudes and Behaviors toward Research Misconduct in the Middle East: a multisite study.*"

Your protocol has been determined to be exempt under 45 CFR 46.101(b) from IRB review based on the following category(ies):

Category (2): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that Human Subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the Human Subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation. If the research involves children the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and (2) the use of educational tests.

The IRB made the following determinations regarding this submission:

- No specific determinations made.

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL.

Investigators are reminded that the IRB must be notified of any changes in the study.

Research activity involving veterans or the Baltimore VA Maryland Healthcare System (BVAMHCS) as a site, must also be approved by the BVAMHCS Research and Development Committee prior to initiation. Contact the VA Research Office at 410-605-7131 for assistance.

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL.

Investigators are reminded that the IRB must be notified of any changes in the study. Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@som.umaryland.edu.

