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Lauren R. Powell  
*University of Massachusetts Medical School*

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CONCEPTUALIZING, UNDERSTANDING, AND ASSESSING  
RESEARCH LITERACY IN A DIVERSE POPULATION

A Dissertation Presented

By

LAUREN RENÉE POWELL

Submitted to the Faculty of the  
University of Massachusetts Graduate School of Biomedical Sciences, Worcester, MA  
in partial fulfillment of the requirements for the degree of

DOCTOR OF PHILOSOPHY

MARCH 22<sup>ND</sup>, 2016

CLINICAL AND POPULATION HEALTH RESEARCH

CONCEPTUALIZING, UNDERSTANDING, AND ASSESSING  
RESEARCH LITERACY IN A DIVERSE POPULATION

A Dissertation Presented  
By

LAUREN RENÉE POWELL

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Clinical and Population Health Research

March 22, 2016

## DEDICATION

*“Hold fast to dreams, for if dreams die, life is a broken winged bird that cannot fly.”*

*-Langston Hughes*

I dedicate this work to my ancestors, the black bodies of women, men, children, and families whose blacklives weren't recognized as mattering long before the trending hashtag. For the activists, martyrs, and trailblazers of all hues that pushed the boundaries of bigotry, marched in mayhem, and died for my destiny. Treading the path through the blood of the slaughtered, out from a gloomy past, I am here at last.

To my 93 year old grandmother whose steps I follow, to my beloved stepfather, the late Bishop Melvin Bolden whose faith I carry, and to the many loved ones who preceded me to heaven:

You held on to my dreams at times when I lost my grasp.

This is in remembrance of you.

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I am very grateful for my Thesis Research Advisory Committee (TRAC) of Dr. Sharina Person, Dr. Carol Bova, Dr. Jeroan Allison, and Dr. Milagros Rosal. They have provided thoughtful feedback on my dissertation. Their guidance has challenged me, enriched me, and greatly improved this process for me. I look forward to their co-authorship and collaboration in my future career endeavors. I am also grateful for the feedback from my Dissertation Examination Committee (DEC) of Dr. Sharina Person, Dr. Carol Bova, Dr. Jeroan Allison, and Dr. Kate Lapane. In addition, I would like to extend my gratitude for the time and feedback Dr. Nancy Kressin provided on this work as my external reviewer.

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## ABSTRACT

**Background:** Racial and ethnic minorities are under-represented participants in health-related research. Comprehension and understanding of the research process are a barrier to research participation. A potential approach to engaging underserved populations in research is through improving research literacy, which we define as “the capacity to obtain, process and understand basic information needed to make informed decisions about research participation.”

**Methods:** Through primary data collection and mixed-methods approaches, this doctoral thesis seeks to: 1) define and conceptualize the domains, determinants, and impacts of research literacy through the development of a multi-component comprehensive framework, 2) operationalize research literacy by developing and psychometrically testing the Research Literacy Scale, and 3) quantify differences in research literacy, measured by the Research Literacy Scale, by race/ethnicity, race-related factors, and other socio-demographic factors.

**Results:** We created a framework outlining eight domains of research literacy and multi-faceted influences of societal, community, researcher, and participant factors that may influence an individual’s level of research literacy. The Research Literacy Scale created is comprised of 16 items, with a KR-20 estimate of 0.81 and test-retest reliability of 0.84. We found differences in mean scale scores by race/ethnicity, age, education, income, and health literacy (all  $p < 0.01$ ). African-Americans and Latinos have lower research literacy scores, as compared to non-Latino Whites. Race-consciousness was associated with research literacy score.



**Conclusions:** This study is the first to define, assess, and quantify factors associated with research literacy in a diverse community sample and may provide insights on approaches to enhance minority engagement in health-related research.

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**PREFACE**

Chapter II of this dissertation is under review as:

Lauren R. Powell, Sharina D. Person, Jeroan J. Allison, Milagros C. Rosal, Stephenie C. Lemon. Research Literacy: a conceptual framework to inform individual understanding of health-related research. *Patient Education and Counseling*.

Chapter III of this dissertation is under review as:

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**CHAPTER I**  
**INTRODUCTION**

Racial and ethnic minorities are under-represented participants in clinical research. Less than thirty percent of those enrolled in research studies sponsored by the National Institutes of Health (NIH) are minorities,<sup>1</sup> with African Americans and Latinos comprising 11% and 8% of all participants, respectively.<sup>1</sup> There is widespread recognition of the importance of clinical research as a pathway for understanding and improving the health of the U.S. population. In order for scientific discoveries to achieve population benefit, however, a diverse pool of participants in clinical research studies is necessary. This provides insight into population-specific disease risk factors and approaches to increasing efficacy of targeted health interventions and treatments in these diverse populations.<sup>2</sup>

A historical legacy of exploitation and discrimination has contributed to widespread mistrust of health care systems and research, particularly among African Americans and Latinos.<sup>3</sup> Challenges identifying with researchers, limited cultural competency within the traditionally-defined or –recognized research community, and untargeted recruitment approaches further deter participation in clinical research among such populations.<sup>4-7</sup> Lack of understanding of the research process may also impede research involvement among under-served groups. Other than community-based participatory research initiatives, few approaches have aimed to improve research participation among under-served groups.<sup>4,8,9</sup>

A body of literature has assessed barriers and facilitators of research participation among diverse populations. Facilitators include perceived personal and societal benefits, or altruistic implications, rooted in cultural and community priorities<sup>10-12</sup>, and barriers include mistrust and lack of access to information about research opportunities.<sup>4,10,11,13-15</sup> The complex nature of the research process has also been well-documented. Despite this complexity and its potential implications for participation, the research community has done little to investigate the extent to

which the general population and research participants understand the research process.<sup>16-18</sup> To further enhance understanding of the barriers and facilitators to research participation, we conducted a series of focus groups with diverse samples of former research participants. The learning from these groups served as a foundation for the project and provided further evidence of the lack of understanding of the research process among research participants. Overall findings revealed limited memory of the informed consent review/completion process, and participants had trouble recounting the purpose of the research and their role in its development and execution. Some previous studies have explored participant comprehension and understanding of certain foundational components of the research process (i.e., informed consent, randomization, therapeutic misconception, etc.).<sup>17</sup> These studies consistently revealed bidirectional limitations, or challenges in both researchers' abilities to explain these concepts to potential research participants and participants' cognizing and/or processing of the information.<sup>16</sup> The ability to translate these concepts for diverse patient understanding and connection is imperative to the successful future of medical research.

A potential approach to engaging underserved populations in research is through improving research literacy, which we define as *“the capacity to obtain, process and understand basic information needed to make informed decisions about research participation.”* We conducted preliminary work (literature review, expert panel input, and focus groups) to inform the development of the research literacy definition and its associated domains and a broader framework of factors that may impact research literacy. Our multi-component domains of research literacy include several factors related to understanding of research concepts (goals/purpose of research, protections of human subjects and informed consent, relationship between research and treatment). We additionally developed attitude domains related to the

research process and meaning (value of research, responsibility of individual, participant deception, researcher integrity) that may be strongly associated with research literacy. In addition, our preliminary work suggested that use of a social ecological model<sup>19</sup>—one that attends to individual, sociocultural, and community level factors—may influence one’s level of research literacy. Our framework incorporates unique multi-dimensional factors, which have not been previously investigated and may influence the research literacy level of diverse racial/ethnic groups.

### **Disparities in health and health care access**

The rapidly changing demographics of the U.S. population indicate that minority populations will soon comprise the majority of the U.S. population. The 2012 U.S. Census reported that 50% of babies born nationwide were racial/ethnic minorities and that Latinos are the largest and fastest growing ethnic group, currently comprising 17% of the population.<sup>20,21</sup> At this rate of growth, it is postulated that the U.S. will be a majority minority society by 2050, if not sooner.<sup>21</sup>

Members of minority populations—particularly African-Americans and Latinos—and individuals with low socioeconomic status (SES) are disproportionately affected by poor health outcomes.<sup>22</sup> Despite the advancements in health and life expectancy in the country overall, population specific gaps persist for these under-served populations in areas such as access to care, quality of care, chronic disease risk factors, and disease incidence and related mortality.<sup>20,23,24</sup> These examples of disparities are intimately tied to inequity in the public health and healthcare systems, and research engagement is one significant and neglected component of the problem.

### **Disparities in clinical research participation**



In order for scientific discoveries to achieve population benefit, a diverse pool of participants in clinical research studies is necessary. This diversity provides insight into population-specific disease risk factors and enhanced perspective on how proposed interventions have been and can be more effective in these populations. There is increasing evidence that treatment outcomes, as well as disease progression and manifestation, may vary between racial/ethnic groups,<sup>25</sup> supporting the need for research within diverse populations. If the ultimate goal of clinical research is to improve the quality of care for all patients, then a diverse composition of patient participants is essential to investigate similarities and differences in the etiology of diseases, compare the true efficacy of treatments across populations, and develop targeted intervention and treatment approaches.<sup>25</sup> Diversity in clinical trial research is thus a prerequisite for equity in health. The NIH recognizes the importance of addressing this issue as a priority in the Research Capacity-Building portion of its current *NIH Health Disparities Strategic Plan*.<sup>26</sup> Despite this recognition, there is a paucity of interventions that specifically aim to improve research participation among under-served groups.<sup>4,8,9</sup> It is thus urgent that we improve access to and participation of members of under-served groups in clinical research.

### **Barriers and facilitators to research participation among under-served populations**

Continued and increased participation of minorities will ensure that findings from clinical research studies can be generalized and have beneficial implications for action/change across racial and ethnic populations.<sup>27-29</sup> Still, the recruitment of under-represented minorities into clinical trials continues to present special barriers. Commonly identified barriers to enrollment of minorities in prior research studies include linguistic differences, limited health literacy, distrust of the medical system, institutional racism, lack of information and understanding of research studies and informed consent, insufficient recruitment efforts by researchers, social stigma, and

financial considerations.<sup>10,15,24,30</sup> Prior studies have identified a few facilitators to research participation; these include perceived benefits to the individual participant and to society at large; the opportunity to access state-of-the-art medical care and/or free medications; and exposure to alternatives to standard therapies that are perceived to be ineffective.<sup>4,6,10,14,15,31,32</sup> However, the barriers are generally perceived to outweigh the benefits.

African American participants in particular have been found to question the actual benefit of clinical research findings for the broader African American community, and this is one reason many individuals choose not to participate at all.<sup>5</sup> The history of racism in the U.S., particularly in medical research and clinical care, has contributed to deep suspicion among communities of color about the motives of the U.S. health care system and medical research institutions.<sup>5</sup> Low research participation from minorities stems directly from these historical inequities and power imbalances and the consequential lack of trust between community and academic medical institutions.<sup>5,33</sup>

In addition, a limited understanding of the research process and medical research lingo may further contribute to the widespread skepticism in this population. While this has been partially investigated in previous studies (see section below), comprehensive examination of approaches to improving this understanding is few and far between. Equipping members of these marginalized populations with knowledge and familiarity of the research process may make significant strides in overcoming the numerous barriers to participation in research among underserved populations.

### **Informed consent and therapeutic misconception as sources of research participant confusion**

Informed consent, a cornerstone requirement to medical research, is the process during which details of a research study are disclosed to potential research participants towards the promotion of informed decision-making.<sup>34</sup> Modern informed consents emphasize five domains: voluntariness, disclosure, understanding, competence, and consent.<sup>34,35</sup> Despite advances in research ethics and the standardization of the informed consent process, substantial research indicates that participants remain misinformed about research, with piecemeal comprehension of information specific to studies in which they are involved.<sup>34-39</sup>

Parallel to the confusion raised by informed consent is the closely related concept of therapeutic misconception. Therapeutic misconception, as defined here and in the literature, is “when a research subject fails to appreciate the distinction between the imperatives of a medical research study and of ordinary treatment, and therefore inaccurately attributes therapeutic intent to research procedures”.<sup>40</sup> This misconception of the assumption that participation will guarantee certain treatment goals/outcomes, contributes to the perception of research as curative versus experimental. This misappropriation often involves deep emotional as well as practical investment. This investment is particularly pervasive among racial and ethnic minority participants,<sup>41</sup> suggesting perhaps that certain cultural and contextual factors may magnify the challenge of informed decision-making and therapeutic misconception. Yet, to our knowledge, attempts to further investigate these challenges have not focused on how well individuals understand the actual research process, to what extent cultural and contextual factors may influence attitudes and beliefs about research, and general comprehension of research concepts and vernacular.

While the current body of research on informed consent and therapeutic misconception is informative, a clear grasp on exactly what it is that confuses research patients about the research

process is lacking. The gap in the literature of this content specific area presents ample opportunity to propose conceptual approaches to better understand the medical research process through the consideration of a unique hybrid of individual, social, and cultural perspectives that may tarnish the research experience, specifically for racial/ethnic minorities. We propose *research literacy* as such a concept.

### **Research literacy to promote informed decision-making for research participation**

We created a new concept of research literacy, defining it as “*the capacity to obtain, process and understand basic information needed to make informed decisions about research participation.*” This definition, adapted from the U.S. Surgeon General’s definition of *health literacy*, seeks to capture the elements that we believe to be essential for one to function and communicate knowledgeably within the research setting. Our definition takes into account the fact that obtaining information about health related research and the way that this information is subsequently processed, may ultimately impact one’s ability to make informed decisions about research participation. The crafting of this definition is further rooted in our postulation that there may be multifaceted, individually-specific influences upon one’s ability to process health information and, in turn, make an informed decision about research participation. To advance our understanding of the new concept of research literacy, in-depth research is needed to further refine its domains/dimensions, identify how to measure it in a culturally- and literacy-appropriate way, and understand associated factors and implications for research participation.

### **Potential factors associated with research literacy**

While research literacy is a newly defined concept, we turn to previous literature in associated areas to inform our investigation of potentially associated or contributing factors. Previously published literature on barriers and facilitators indicate specific shared and distinct

barriers to participation among racial/ethnic groups.<sup>10,37,42</sup> Shared barriers to research participation included: mistrust, lack of access to information about research studies, competing demands, fear of unintended outcomes, and concerns related to health insurance coverage.<sup>10,42</sup> Altruism and access to health care resources were indicated as shared facilitators to research participation.<sup>5,10</sup> Recognizing that these barriers and facilitators exist is of limited benefit to improving research participation among racial/ethnic minorities if the underlying drivers of these sentiments have not been investigated. In some instances, the complex and/or subconscious cultural practices and nuances framing various barriers and facilitators make them particularly difficult to capture through conventional variables and constructs.<sup>10,42,43</sup> This may warrant the inclusion of new and unique assessment correlates or hypotheses. For example, it is plausible that one's life experiences with discrimination and individual demographics such as educational status, age, and gender may directly influence the way one processes and makes decisions about health-related research opportunities. Specific and distinct barriers to research participation among African-Americans include high levels of mistrust of the health care system and concerns related to the confidentiality and ethics of the research process. While African-Americans have acknowledged negative personal experiences with the health care system due to racially-driven differential treatment,<sup>10,42-45</sup> these perspectives and experiences have yet to be investigated in the context of how they influence the way such individuals obtain, process, and understand medical research. Our studies suggest that experiences such as racial discrimination, race consciousness, and one's knowledge about the Syphilis study at Tuskegee University<sup>11,12</sup> may be important correlates and help to inform the way minorities who are approached about participating in a research study interpret study-related information. Yet, to our knowledge, the connection between such sociocultural- and individually-specific influences and one's capacity

to understand (and, in turn, make a decision about participating in) medical research have not been explored.

Identifying correlates that may be associated with research literacy is key to improved engagement and understanding of the specific perspectives of minorities as it pertains to health-related research participation. In order to gain a more in-depth understanding of how these characteristics undergird one's understanding of research, we propose investigating a number of correlates which we posit may be associated with one's research literacy level. The correlates we have chosen to examine represent some of the individual factors that may greatly influence one's decision to participate in research but have not been explored in this context. We build upon the foundation of previously identified barriers and facilitators to research participation and branch into the demographic and individual experiences that may drive these qualities. To date, the literature summarizes the barriers and facilitators to research participation but glosses over the significance of sociocultural and demographic correlates and the potential impact they may have on minorities' understanding of, and subsequent willingness to participate in, research. Thus, we aim to investigate these correlates through their inclusion as survey items in the development of our measurement tool, and to comprehensively study the proposed concept of research literacy.

### **SPECIFIC AIMS**

The proposed thesis seeks to contribute to the advancement of health-related research through the targeted exploration and investigation of research literacy. The hope is that our work, and the tool we have developed for this purpose, will serve as a promising foundation for future expanded research and action. Thus, the proposed aims of this dissertation are:

**Aim 1: To develop a conceptual framework to define research literacy using qualitative methods.**

**Aim 2: To develop and psychometrically test a culturally responsive measure of research literacy in a diverse sample.**

**Aim 3: To quantitatively assess socio-cultural (experiences of discrimination, race consciousness) and individual level correlates (health literacy, previous experiences with research, demographics) of research literacy among a diverse sample of 430 individuals.**

H5: Research literacy score is associated with race and race-based treatment.

H6: The association between race-based treatment and research literacy differs by race/ethnicity and gender.

**CHAPTER II**

**RESEARCH LITERACY: A CONCEPTUAL FRAMEWORK TO INFORM  
INDIVIDUAL UNDERSTANDING OF HEALTH-RELATED RESEARCH**



**ABSTRACT**

**Objectives:** Racial/ethnic minority groups and individuals of low socioeconomic status (SES) are underrepresented in health research. We propose limited research literacy—defined as the capacity to obtain, process and understand basic information needed to make informed decisions about research participation—as a potential contributor to limited research participation. We sought to develop a conceptual framework of research literacy that operationalizes its domains and identifies its potential determinants.

**Methods:** We conducted a systematic literature review, facilitated eight focus groups with former research participants from diverse backgrounds, and conducted 15 key informant interviews with researchers and community members to inform development of the research literacy conceptual framework.

**Results:** We created a framework that outlines the multi-faceted influences—societal, community, researcher, and participant factors—that may contribute to an individual’s level of research literacy. Domains of research literacy included participants’ understanding of such facets as: the goals of research, ethical conduct, confidentiality, and researcher responsibility.

**Conclusion:** A comprehensive framework conceptualizing research literacy could be useful in enhancing researcher understanding of untraditional barriers and facilitators to research. Such influences may shape prospective participants’ understanding of and participation in health-related research and hold implications for reducing broad racial/ethnic and SES driven health disparities.

## Introduction

Health-related research is essential for understanding and improving the health of Americans,<sup>1</sup> but racial and ethnic minorities and persons of low socioeconomic status (SES) are under-represented as research participants. In 2012, less than one-third of those enrolled in research studies sponsored by the National Institutes of Health (NIH) were minorities. Given persistent disparities in health and shifting demographics, with projections that minorities will make up 54% of the population by 2060,<sup>26,46,47</sup> research that includes representative samples of minority and low SES individuals is critical to maximizing health equity. For scientific discoveries to achieve population benefit, a diverse pool of research participants is necessary to provide insight into disease risk factors for specific population sub-groups and perspectives on the benefits of treatments and interventions across diverse individuals.

The breadth of literature that has assessed barriers to and facilitators of research participation in diverse samples has focused primarily on African-Americans. Thus far, identified facilitators in this population include perceived personal benefits, altruistic values in the form of perceived benefits to society,<sup>10,45,48,49</sup> and culturally congruent study designs. Emerging studies indicate that research participants and the general population are often under-informed and misinformed about health-related research participation and procedures. While this literature summarizes individual-level barriers and facilitators to participation,<sup>10</sup> it glosses over the significance of how broad socio-cultural and demographic factors may impact individuals understanding of research. To

our knowledge, no previous attempt has been made to develop a comprehensive framework of participant understanding of all elements of the research process and factors associated with this understanding.

The research literacy framework presented here seeks to serve as a base for this effort—a tool to guide and inform researchers about barriers and facilitators to research participation that may not be recognized in traditional literature. In order to understand specific perspectives on research participation, we must first gain deeper understanding of what experiences and circumstances undergird individuals' understanding of health-related research. Empowering communities with knowledge is a fitting approach to counter misinformation and potential apprehension to research participation, and we propose that the research literacy construct (exploring individual and contextual factors) is a critical component in this process.

#### *Definition of Research Literacy and Implications for a Framework*

In the creation of this framework, we sought to define the construct of research literacy, operationalize domains that comprise it, and identify its potential determinants. We define research literacy as “the capacity to obtain, process and understand basic information needed to make informed decisions about research participation.” This definition, adapted from the U.S. Surgeon General’s definition of health literacy,<sup>50</sup> encompasses the elements that we believe are essential for one to effectively and knowledgeably function and communicate within the research setting. We drew upon previous literature defining health literacy.<sup>50-52</sup> Recognizing the importance of a broad

spectrum of researcher and participants' perspectives, we engaged primary qualitative data and literature sources to inform this definition.

Similar to health literacy we posit that research literacy may be characterized as a dynamic concept varying by situation and circumstance and influenced by a number of contextual factors.<sup>52,53</sup> Grounded in the tenets of the social ecological model,<sup>54</sup> we include numerous constitutional, individual, interpersonal, societal, and system-level factors that may influence one's perception and understanding of health-related research. We further sought to distinguish determinants of research literacy and did so with the help of prior studies examining informed consent and research best practices. To understand how to improve research literacy in underserved populations, we acknowledged that the participant perspective has historically been missing. We made it a priority to include this vantage point in creating a broad framework to further refine and outline determinants of research literacy.

## **Methods**

### *Framework Development*

The research literacy framework was first informed by a literature review and focus groups. Our approach included: 1) creating the definition of research literacy, 2) receiving input from key informant community members and academic researchers on the conceptualization of the construct and the definition, 3) defining the domains of research literacy by coding conversation transcripts from focus groups with diverse groups of former research participants, and 4) identifying determinants of research

literacy through integrated qualitative focus group data and existing literature.

### *Literature Search*

We performed a comprehensive literature review on known barriers and facilitators to research participation, informed consent, and therapeutic misconception. This included searches of PubMed, PsycINFO, and Google Scholar databases through the end-date of November 2014. We used basic search terms such as “facilitators clinical research participation” and “barriers clinical research participation.” We also used specific search terms to identify literature on informed consent and therapeutic misconception. Search terms varied slightly by search engine in an attempt to reach saturation of search results on the topic. As the literature on barriers and facilitators to research participation is limited, we applied no restrictions to publication date or by disease-specific studies (i.e., those related to HIV/AIDS trials, cancer trials, etc.). While the literature on informed consent and therapeutic misconception are rooted in the tenets of medical ethics and bioethical perspectives, we decided that a truly comprehensive search should extend beyond this constricted focus.

Abstracts for articles identified by search terms were reviewed by the study team for relevance and rigor. We reviewed 42 abstracts for relevance to barriers and facilitators to clinical research participation, patients’ understanding of informed consent, and patients’ experiences with therapeutic misconception. We excluded 13 abstracts that were not research-based, such as commentaries. We also excluded seven abstracts for studies of poor quality, such as those that did not include qualitative or quantitative results or

clear research methodology. Twenty-two articles were deemed relevant, read in their entirety, and then grouped by theme using a grounded theory approach<sup>55</sup> by LP. Themes included: distinct barriers for minority participants, shared barriers, distinct facilitators for minority participants, shared facilitators, process of informed consent, components of informed consent, patient challenges with informed consent, patient challenges with therapeutic misconception, and approaches to alleviating therapeutic misconception. Findings summarizing knowledge to date on barriers and facilitators to research participation informed the domains of research literacy.

*Iterative development of the research literacy conceptual framework*

To create the research literacy framework, we: 1) co-analyzed literature search reviews with qualitative data from focus group findings, 2) identified and cross-referenced domains of research literacy identified from focus groups with barriers and facilitators identified in the literature, 3) created a basic framework draft, 4) conducted primary key informant interviews (n=10), 5) revised the framework based on key informant feedback, 6) conducted secondary key informant interviews (n=5), and 7) made suggested edits to the framework from secondary key informants .

Based on knowledge gleaned from our formative work, we created a preliminary draft of the conceptual framework. The research literacy framework was subjected to two rounds of refinement. Once a draft was developed, key informant interviews were conducted to refine the framework. Edits to the framework and development of the final version involved an iterative process informed by equal influences of focus group

findings and key informant interviews.

### *Focus groups*

We conducted focus groups with former research participants of diverse racial/ethnic and socioeconomic backgrounds to further inform the definition of research literacy. A total of 80 African-American (n=22), Latino (n=32), and non-Latino White (n=26) former research participants participated in the focus groups. Focus group eligibility required having taken part in community-based intervention research studies, survey studies, and/or minimal risk healthy volunteer studies within the past three to five years. Eight focus groups were conducted with former research participants throughout Summer 2013 in Worcester, Lawrence, and Boston, Massachusetts. Focus groups were clustered by participant demographics and location: Worcester (non-Latino Whites), Boston (African-Americans), Lawrence (Latino/as). Using this criteria, we recruited a volunteer sample of focus group participants via posters and flyers on the University of Massachusetts Medical School bulletin boards, University of Massachusetts Boston bulletin boards, and community sites. Participants in Lawrence were identified through partnerships at the Lawrence Senior Center where a number of ongoing research studies are conducted in this community. Recruitment efforts also relied heavily upon community-based relationships and contacts in greater Boston to identify former research participants. Groups in Boston and Worcester were held in the evening or during lunch hours. Groups in Lawrence were held in mid-afternoon. Each group lasted 60-90 minutes and consisted of discussion guided by a script. A light meal was served, and participants

received a \$20 honorarium for participation. Eight to ten individuals were enrolled in the Boston and Worcester focus groups. The focus groups in Lawrence consisted of five to seven participants.

We assessed former research participants' reactions and opinions regarding research participation and knowledge of the research process. We used a standardized facilitator's guide to inform this process, querying specific factors that might influence the experiences of participants in a research study. These included: barriers and facilitators to participation, how to find out about studies, experiences with the entire research process (e.g., invitation to the study, the informed consent process, randomization and study involvement), and the personal decision-making process involved in determining whether to be a part of a research study. A study team member (LP, SL, MR) facilitated the groups, which were audio recorded. Additional study staff members took notes for future transcription using audio recordings.

We followed general inductive methodology for analysis of primary collected qualitative data.<sup>55</sup> A primary analyst (LP) reviewed audio recordings and notes from each focus group, noted common reactions and response patterns to questions, and coded conversations into common themes. A secondary reviewer (SL) reviewed these themes and provided input. Themes were summarized into an initial conceptualization of the domains of research literacy including: goals of research, protections of human subjects, experimentation, and research as a responsibility.

#### *Key informant interviews*



We interviewed six researchers and nine community members with varied levels of involvement in research. We conducted primary (n=10) and secondary (n=5) key informant interviews. Interviews were 30-45 minutes long and were completed via phone, in person, or via video-chat using Face-time and Google Hangout. Researcher interviewees included NIH senior scientists, academic researchers, and physician scientists. We also spoke with community members of diverse backgrounds who were not research experts including: a tax attorney, a financial analyst, a nutritionist, and a hospital administrator. We saw these individuals as well-informed professionals in areas outside of research and gave equal credence to researchers and community informants in framework development.

We created an interview script of key open-ended questions. Interviewees were asked to identify potential gaps and confusion regarding the framework and to explain in their own words how they would define research literacy. We employed think-aloud interviewing techniques to engage key informants in conversation. Notes were taken for each interview, and feedback from interviewees was synthesized by common theme.

## **Results**

### ***Refined research literacy definition & framework***

#### *Structuring the research literacy framework*

Our preliminary qualitative work suggests that the social ecological model,<sup>19,54</sup> encompassing individual, sociocultural, and community level factors, may serve as an

appropriate foundation for our framework. The framework incorporates unique multidimensional influences, often neglected in prior studies, impacting the research literacy level of diverse racial/ethnic groups. Figure 2.1 depicts the final research literacy framework, which was mirrored after a prominent health literacy framework<sup>52</sup> that captured broad factors impacting experience and perspective. In this figure, we illustrate how individual-level factors (far left boxes) and system- and interpersonal-level factors (middle boxes) are ultimately connected to research literacy.

#### *Research literacy definition*

Our definition of research literacy, “the capacity to obtain, process and understand basic information needed to make informed decisions about research participation,” was open to examination throughout the several rounds of key informant interviews. Interviewees did not suggest any changes to the definition. The final research literacy definition thus reflected general consensus and corresponding refinement by researchers and community member interviewees.

#### *Identifying the domains of research literacy*

Through literature reviews and evaluations of best practices in the informed consent process, we identified domains of research literacy including: goals and purpose of research, risks/benefits and protections of human subjects and informed consent, and the relationship between research and treatment. We deemed these elements to be the foundational concepts most necessary and critical to understanding research-based language and to functioning within a research setting (regardless of the specific type of

health-related research study). We detail the domains of research literacy and a description of each in Table 2.1.

### *Classifying determinants of research literacy*

Although research literacy is a newly defined concept, we used previous literature and our focus group findings to inform an investigation of multi-level factors potentially associated with research literacy. Literature on barriers and facilitators does identify specific shared and distinct barriers to participation among racial/ethnic groups.<sup>10,42,56</sup> Merely recognizing the existence of such barriers and facilitators is of limited benefit to improving research participation among racial/ethnic minorities, however, if underlying drivers have not been identified. When barriers and facilitators are rooted in cultural practices and nuances, they occur at a subconscious level that may not be captured through conventional variables and constructs.<sup>10,42,43</sup> This may warrant the inclusion of unique determinants or assessment variables that may be shaping research literacy. For example, it is plausible that life experiences with discrimination and individual characteristics such as educational status, age, and gender may directly influence the way decisions about health-related research opportunities are made. Research suggests, for instance, that specific and distinct barriers to research participation among African-Americans include high levels of mistrust of the health care system and concerns related to confidentiality and ethics of the research process. While African-Americans have acknowledged negative personal experiences with the health care system due to race-based differential treatment,<sup>10,42-45</sup> the influence of these perspectives and experiences

on individual understanding of medical research has yet to be investigated. Perhaps racial discrimination, race consciousness (how often one thinks about their race), and knowledge about the Syphilis study at Tuskegee University are potential determinants that could more strongly inform the way minorities interpret research-related information as compared to non-Latino Whites.

The connections between such socio-cultural and individual influences and one's capacity to understand—and, in turn make a decision about participating in—medical research have not been explored. We account for these aspects in the research literacy framework and parallel the layers of influence illustrated in the social ecological model: system-level influences (societal factors), interpersonal level influences (community factors, researcher factors, and patient factors), and individual level influences (individual factors). We describe each level of influence and associated determinants independently and justify their inclusion in the research literacy framework, moving from system-level factors to individual-level factors.

### ***System-level Influences***

We classified societal factors as systems and policies that govern society and may influence research literacy. Racial/ethnic minorities have identified both overt and subtle systemic racism, embedded within multiple facets of their social existence, as barriers to their representation in health research.<sup>10,56-59</sup> Skepticism produced by these systemic racially biased encounters can shape minorities' interactions within the education, criminal justice, and healthcare systems, which can simultaneously and significantly

influence their ability to understand information about health-related research.

Perspectives from our focus group participants validated this reality. These perspectives also emphasized the role that mass media coverage can play in highlighting stories of unethical research. Participants noted the frequency and severity of these cases, even in present-day headlines. Though our present-day culture and dialogue sometimes assumes that these experiences are an entity of the past, yet our focus group participants highlighted the connection between past and present concerns of the occurrence of unethical research studies. We used summary analysis to identify the societal factors, or overarching systems, shaping an environment that ultimately promotes and/or hinders one's ability to become research-literate.

### ***Interpersonal-level Influences***

#### *Community Factors*

Our findings indicated that community norms and community culture may be a particularly pervasive influence on exposure and ability to pursue information about, and express interest in, health-related research. While previous studies have mentioned the association of culture and cultural beliefs as a significant barrier to research participation in minorities,<sup>10,60-62</sup> the complexity in identifying the core of these cultural influences lies within the deeply-rooted role of culture within ethnic communities.<sup>63</sup> Culture is ingrained in beliefs, attitudes, and values individuals bring with them into all encounters, including those with health care providers and health-related researchers.<sup>63</sup> Considerations for community factors also included location (e.g., rural geographic location, which has been

associated with low participation in health-related research<sup>64</sup>) and conditions (e.g., built environment, an influence identified by focus group participants). Focus group participants also emphasized how the historical context of experiences of injustice or exploitation (resulting in communal mistrust in governing systems, leaders, and institutions) may be a significant influential factor when considering participation in health-related research studies. We also identified community factors—summarized as local culturally-grounded norms, secondary to broader societal factors—which help to create the local environment that shapes one’s ability to become research literate.

### *Research Factors*

Research factors include those related to the research process and the researcher. Specific elements, such as study design, risks for participation, and convenience of participation, are all associated with lower future rates of participation in health-related research among potential racial/ethnic minority participants.<sup>10,43,65-68</sup> Focus group participants also noted how the design of research studies may pre-emptively preclude research involvement within certain communities. For instance, the limited size and resources of community clinics and smaller medical centers, often the only source of health care in minority communities, may inhibit participation. Conversely, study benefits and incentives (e.g., honorariums, free meals, health screenings and checkups, and health improvement opportunities such as weight loss) have been identified as facilitators for research participation.<sup>10,45,48,67,69</sup> Researcher factors such as communication skills of providers, cultural competency of researchers, and cultural

congruence (e.g.-congruence between researcher and participant cultural identities) have been identified as important to prospective racial/ethnic minority research participants.<sup>10,36,43,70</sup> Focus group participants also identified the length of face-to-face contact with researchers in community and clinic settings (where appropriate) as a potential facilitator of research involvement. As such, we identified research factors—summarized as the set of research process and researcher-driven standards—which work together to create an environment within the proverbial research setting that either promotes or hinders one’s ability to become research-literate. Perhaps promoting diverse research participation involves active reshaping definitions of research and study designs, interactions with participants, and perceptions of researchers.

### ***Influence of Patient Attitudes towards Research***

Our focus groups emphasized that individual beliefs and opinions could greatly influence willingness to even consider learning more about research, let alone making the decision to participate. We synthesized these reactions to inform the components of an expanded understanding of patient attitudes towards research—one that highlights the individual settled opinions, feelings, and emotions about research gleaned from interpersonal life experiences. For example, experiences of interpersonal racial discrimination may result in poor health care experiences and health outcomes for minorities, which have been associated with low research participation rates.<sup>10,71-77</sup> As a result, mistrust of researchers, scientists, institutions that conduct research, and the government is particularly pervasive among African-Americans.<sup>60</sup> Feelings of skepticism

stemming from interpersonal experiences of racial discrimination may lead to ongoing concern about ethical conduct of research among socioeconomically disadvantaged or minority patients,<sup>60</sup> which may in turn contribute to negative thoughts and attitudes about all forms of health-related research. In contrast, research suggests that reverence for community—often noted to be of great importance in racial/ethnic minority cultures—may contribute to strong altruistic desires that shape research participation. Specifically, those who reference this altruism may see participation in health-related research as an opportunity to somehow help family or community and thus view their participation in studies as an individual responsibility.<sup>10,48,78-80</sup> The values and importance of research from this perspective may inform a general positive attitude towards research participation. We thus identified the patient factors summarized in our research findings as a set of patient experiences and attitudes which may either enhance or impede one's ability to become research literate.

### ***Individual-Level Influences***

Race/ethnicity, age, and gender, have been established as characteristics that may influence participation in health-related research.<sup>42,81,82</sup> Low socioeconomic status,<sup>64</sup> employment status,<sup>42,83</sup> insurance status,<sup>10,64</sup> immigration status,<sup>43,84</sup> and language barriers<sup>85,86</sup> have also been associated with low rates of participation. Health literacy may also be an important influence on research literacy. High health literacy has been positively associated with patient involvement in shared decision-making and communication within the health environment.<sup>87</sup> The nature of the informed consent



process and its parallels to the shared decision-making process thus enhance the argument for the inclusion of health literacy as an individual factor that may influence one's research literacy level. We also included cognitive ability—encompassing such elements as verbal ability, memory, and reasoning—as foundations of health literacy.<sup>52,53,88</sup> The individual factors we've included incorporate both well established, and some potentially overlooked yet powerful, characteristics which may shape understanding of health-related research and the research process.

## **Discussion**

To our knowledge, we are the first to combine existing literature with input from research participants and researchers in such a way—to establish a greater understanding of, and framework to define and describe factors related to, research literacy. In our framework, we outline the multi-faceted influences of societal, community, research, and patient factors that may impact how well individuals obtain, process, and understand health-related research information. We emphasize the interrelated nature of these multi-faceted influences shaping understanding of health-related research. While our comprehensive framework attempts to synthesize knowledge about research literacy from a variety of sources, additional aspects remain to be explored. It is important to note also that research literacy is different and should be distinguished as a separate concept altogether from health literacy and scientific literacy. Health literacy focuses on one's ability to understand basic health information and services needed in order to make health decisions.<sup>51</sup> Scientific literacy emphasizes knowledge and understanding of scientific

concepts applied broadly in civic/cultural affairs and economic productivity.<sup>89</sup> Neither encompasses the specifics of research literacy—a domain which focuses on understanding the concepts and processes of health-related research and underscores the importance of clear communication between researchers and participants.

There are specific components of the research process that have been indicated as sources of confusion that necessitate enhanced clarity for research participants. An example is therapeutic misconception, which often results in the misappropriation of deep emotional investment in medical research outcomes as curative rather than experimental.<sup>40,41</sup> This dangerous misconception is particularly pervasive among racial and ethnic minority participants,<sup>41</sup> suggesting that certain cultural and contextual factors may magnify the challenge of informed decision-making. While this lack of understanding has not been documented as a distinct barrier to research participation, it indicates that some individuals who participate in health-related research are likely misinformed about important research concepts and procedures. This is problematic and a diversion from the ethical safeguards that govern research.

Mistrust and trepidation stemming from historical racial injustices may amplify misinformation about health-related research within racial/ethnic communities. Thus it was important to include trust within the individual-level factors of the framework and acknowledge the situational and context-driven settings where trust is developed. Due to its strong influence upon multiple aspects of life experiences, we contend that increasing trust is the most imperative step in promoting research literacy in racial/ethnic minorities

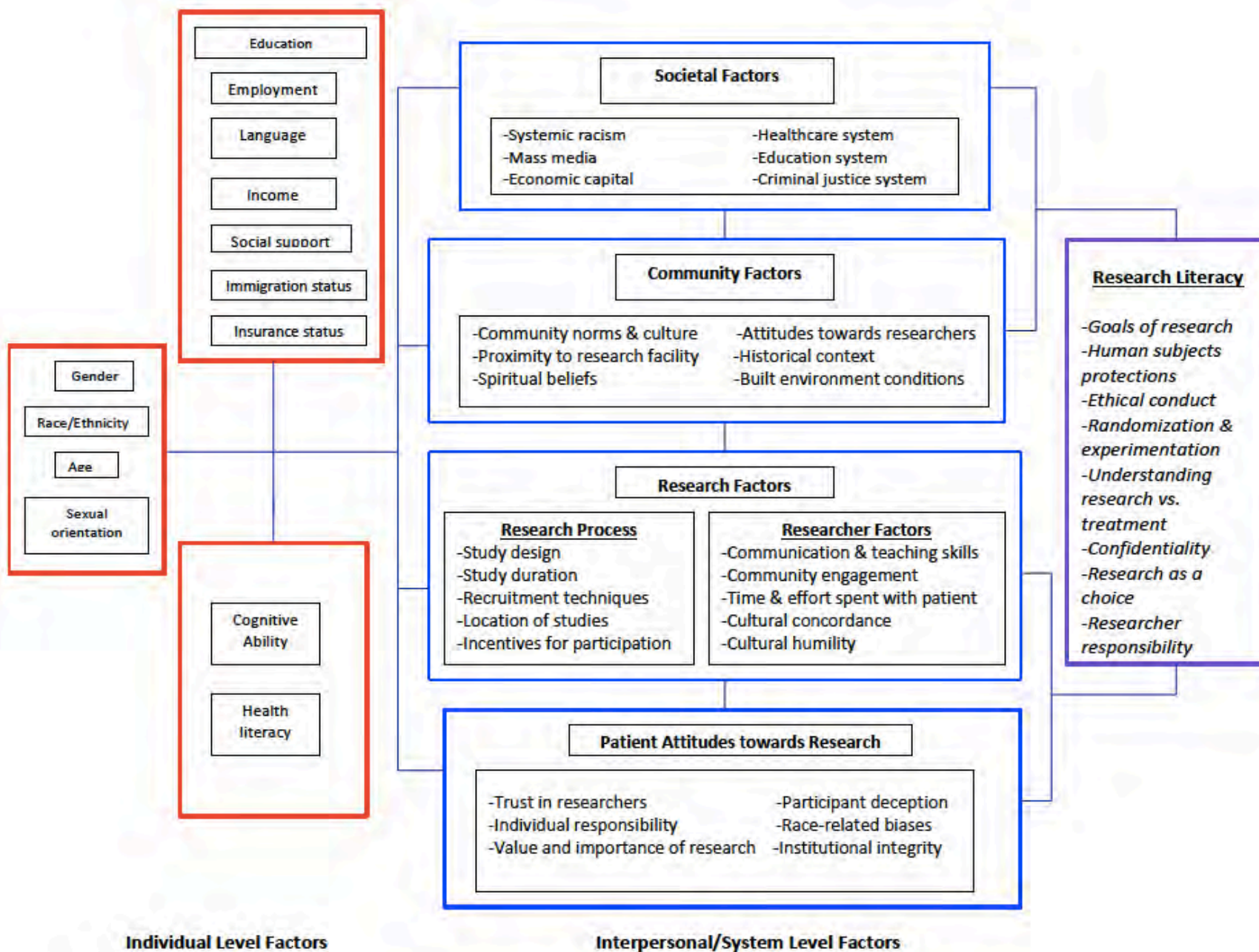
and individuals of low SES. We felt strongly that the complex relationships between trust and other characteristics should be captured within this framework.

There are several innovative aspects to our study. Our in-depth qualitative and literature-based approach used to define and outline a conceptual framework depicting research literacy is unique and offers a perspective on research participation among minorities that is lacking in the current literature. Further, we consider non-traditional socio-cultural and individual-level factors that may influence research literacy. The collaboration of academic researchers and community members in the development of this concept and framework also reflects our commitment to creating a term and a tool that will be meaningful for both researchers and potential research participants.

Our conceptual framework depicts our attempt to illustrate the complex intertwined and overlapping nature of components that may be associated with research literacy or one's decision to participate in health-related research. While the framework we propose may not capture all possible factors of influence, we believe it to be exhaustive of the information gleaned from the existing scientific literature and our qualitative findings. Future research should explore: mechanisms for measuring research literacy through quantitative methods, classifying potential outcomes of research literacy, and interventions to promote research literacy. To engage underserved populations in research, it is important to invest in the enhancement of research literacy as a tool to inform and promote transparency in the motives and intentions of human research. Researchers should consider how broad social experiences and influences may shape

prospective participants' understanding of and participation in health-related research.

Figure 2.1: Research Literacy Framework



**Table 2.1: Research Literacy Domains**

<b>Research Literacy Domain</b>	<b>Description</b>
Goals of research	The ability to recognize and appreciate underlying goals and general purpose of: 1) health-related research, and 2) specific health-related research studies in which one may be invited to participate.
Human subjects protections	Knowledge of basic protections afforded to human subject participants in health-related research studies.
Ethical conduct	Knowledge of expectations of ethical conduct of researchers who design and implement health-related research studies.
Randomization & experimentation	The ability to recognize and appreciate the process and potential outcomes of randomization and the overarching experimental nature of health-related research.
Understanding research vs. treatment	The ability to distinguish between processes related to participation in a health-related research process as distinctly different than the receipt of standard medical treatment.
Confidentiality	Knowledge of procedures that seek to maintain confidentiality of research participants, and risks that may accompany breaches in confidentiality.
Research as a choice	The ability to recognize the voluntary and non-binding nature of participation in a health-related research study.
Researcher responsibility	Knowledge of general responsibilities and expectations of researchers who conduct health-related research studies.

**CHAPTER III**  
**PSYCHOMETRIC DEVELOPMENT OF THE RESEARCH LITERACY SCALE**

**Abstract**

**Background:** While many research participants are misinformed about research terms, procedures, and goals, no validated instruments exist to assess individuals' comprehension of health-related research information. We propose research literacy as a concept that incorporates understanding about the purpose and nature of research.

**Objectives:** We developed the Research Literacy Scale to measure research literacy in a culturally-sensitive and literacy-sensitive manner. We describe its development and psychometric properties.

**Research Design:** Qualitative methods were used to assess perspectives of research participants and researchers. Literature and informed consent reviews were conducted to develop initial items. These data were used to develop initial domains and items of a Research Literacy Scale, and expert panel reviews and cognitive pre-testing were done to refine the scale. We conducted psychometric analyses to evaluate the scale.

**Subjects:** The cross-sectional survey was administered to a purposive community-based sample (n=430) using a web-based data collection system and via paper.

**Measures:** We did classical theory testing on individual items and assessed test-retest reliability and Kuder Richardson-20 (KR-20) for internal consistency. We conducted exploratory factor analysis and analysis of variance to assess differences in mean research literacy scores in socio-demographic subgroups.



**Results:** The Research Literacy scale is comprised of 16 items, with a KR-20 estimate of 0.81 and test-retest reliability of 0.84. There were differences in mean scale scores by race/ethnicity, age, education, income, and health literacy (all  $p < 0.01$ ).

**Conclusions:** This study provides preliminary evidence for the reliability and validity of the Research Literacy Scale. This scale can be used to measure research participants' understanding about health-related research processes and identify areas to improve informed decision-making about research participation.

## Introduction

Medical researchers have an ethical and legal obligation to thoroughly inform research participants about studies for which they volunteer.<sup>90</sup> The informed consent process was developed to protect participants from harm and promote informed decision-making.<sup>91,92</sup> Despite advances in research ethics and standardization of the informed consent process, many research participants remain misinformed about research terms, procedures, and goals.<sup>34,36,38,40,56,93</sup>

A meta-analysis of recent clinical trials measuring participant understanding of informed consent<sup>94</sup> showed that 25-50% of research participants did not understand specific components of informed consent. These estimates have remained consistent over the last three decades.<sup>94</sup> Poor comprehension of the informed consent process is also coupled with misunderstanding of therapeutic aspects of clinical trials. Some research participants believe that research is being conducted for their personal advantage rather than for generalized knowledge or for future patients' benefits.<sup>93</sup> This belief has been described as therapeutic misconception and further highlights knowledge gaps within the research process.

Several tools have been developed to assess comprehension of informed consent and the research process.<sup>16</sup> However, very few have been validated,<sup>16,95,96</sup> and their effectiveness during the informed consent process remains unexplored.<sup>16</sup> Among existing scales, none addressed the concepts we were interested in or were developed for diverse groups. Additionally, although health literacy and reading levels have been associated

with comprehension of informed consent, <sup>97,98</sup> most tools do not consider these influences. <sup>16,99</sup> This is a significant concern and may have particular implications when performing studies among vulnerable and diverse populations. Given the need to elucidate knowledge gaps among diverse research participants, validated surveys that assess comprehension in a literacy- and culturally-sensitive manner are essential.

We propose research literacy as a comprehensive concept that incorporates individuals' understanding about the goals and nature of research and contributes to informed decision-making in research participation. <sup>100</sup> We define research literacy as “the capacity to obtain, process, and understand basic information needed to make informed decisions about research participation.” Our definition, adapted from the U.S. Surgeon General's definition of health literacy, <sup>50</sup> was developed using a mixed method-approach with lay and expert participants. We sought to develop a novel scale to measure research literacy, using the Research Literacy Scale, in a manner sensitive to diverse cultural backgrounds and literacy levels. The goal of this manuscript is to describe development and psychometric properties of the Research Literacy Scale.

## **Methods**

### Developing the Research Literacy Scale

We took a multi-step approach to developing the Research Literacy Scale, depicted in Figure 3.1. We first conducted a literature review and synthesized best practices of the informed consent process by reviewing common components of informed consent forms. We additionally conducted qualitative research to include perspectives of

both research participants and researchers. Initial domains and items were developed, reviewed, and refined through expert panels and cognitive pretesting. Finally, a community-based survey was administered to conduct psychometric analysis and finalize the scale. All procedures were approved by the University of Massachusetts Medical School Institutional Review Board.

#### *Literature and informed consent reviews*

We performed a comprehensive literature search pertaining to patients' understanding of research using PubMed, Google Scholar, and PSYCInfo databases, with search terms “patient AND understanding AND research”, “understanding AND research”, and “patient AND confusion AND research”. After title and abstract review, 22 articles were identified. We reviewed all articles identified for common themes and relevance. We coded findings into themes representing unique areas of confusion for participants. Concurrently, we reviewed generic informed consent templates to provide a foundational understanding of assumed best practices in research. We also used this review process as a guide by which to define and enhance research literacy, ensuring that participants understand all aspects of a study before consenting to take part.

#### *Focus groups*

To inform development of the domains of research literacy and the resulting Research Literacy Scale, we conducted eight focus groups with 80 former research participants (22 African-American, 32 Latino, 26 Non-Latino White). During Summer 2013, we held focus groups in Massachusetts locations including: 2 groups in Worcester,

(UMass Medical School), 2 groups in Lawrence, (Lawrence Senior Center), and 4 groups in Roxbury (Reggie Lewis Center). These were facilitated by a member of our research team (LP) using a scripted guide of open-ended questions. Participants were asked to share perspectives on their research experience including: 1) how they learned about the study, 2) their decision-making process after being offered participation in the study, 3) the informed consent process, and 4) what advice they would offer others who may consider participating in a study. Questions and prompts for the focus group guide were based on concepts covered in an informed consent form, developed by LP, and refined with the input of additional study team members. We included questions such as: “Can you tell me the details about the research study you were a part of?”, “Can you explain how you signed up for the study?”, “How well do you think the study was explained to you?”. Focus groups were audio-recorded and responses were coded by LP using thematic analysis to group common subjects and identify recurring themes. The focus groups revealed important areas of confusion for research participants. Transcripts and thematic analysis coding were reviewed by LP and another research team member (SL).

#### *Initial survey item format*

Combining results from the literature and informed consent reviews and focus groups, we identified eight potential domains of research literacy. These included understanding of: the goals of research, human subjects protections, ethical research conduct, randomization and experimentation, the relationship between research and treatment, confidentiality, research as a choice, and researcher responsibility.<sup>100</sup> Each

domain reflects an important facet of concepts inherent in all types of health-related research studies. An initial bank of 22 survey items based on these domains was drafted. Participants were asked to indicate whether they think each statement is True or False. Statements were worded positively (e.g., “Health-related research studies are done to provide data for medical-decision making”) and negatively (e.g., “People who take part in health-related research do not have legal rights”) to add variety and limit respondent reporting bias.

### Refining the Research Literacy Scale

#### *Cognitive pretesting*

We conducted fifteen cognitive pretesting interviews on the initial 22 survey items. Participants were community members identified through postings on Craigslist, emailed invitations, and word of mouth. LP conducted individual 60-minute interviews following a scripted guide. Participants 1) decided whether each statement was true or false, 2) paraphrased each item in their own words, identifying words or phrases that were confusing, and 3) described how they decided upon the answer to each question. Interviews were conducted in-person, via phone, and via video-chat using Facetime and GoogleHangout. Participants received a \$25 Target gift-card for their time.

#### *Expert panel review*

A panel of research experts (researchers, scientific thought leaders, and former/current research participants) was assembled to review the 22 initial survey items

and assess content validity. LP conducted individual interviews with ten individuals (six researchers, four research participants). Each expert was asked to assess: 1) the relevance of each item to constructs being measured, 2) clarity and conciseness of items, and 3) if there were any missing concepts that would be relevant to determining research literacy level. A content validity index score for the scale was calculated based on each expert's feedback using previously defined methods.<sup>101</sup>

### Testing the Research Literacy Scale

#### *Sample*

We conducted a cross-sectional administration of the research literacy scale using purposive sampling methodology (n=430). We aimed to recruit a sample that was diverse with respect to age, race/ethnicity (mostly African-Americans, Latinos, Whites) and socioeconomic status (low, middle, and high) and had equal gender representation. Participants were U.S. residents at least 18 years of age, English speaking, and cognitively able to provide informed consent to complete the survey. We implemented a multi-tiered strategy of recruitment including: engagement of community partners and attendance at community-based events, email blasts, and web-based posts on social media (Twitter, Craigslist).

#### *Administration*

We used the University of Massachusetts' accessed Research Electronic Data Capture (RedCap) web-based system to administer, store, and manage data collected.

Participants recruited in person were offered the option of completing the survey by paper or online via wireless tablets. Individuals recruited through social media, email, and Craigslist were sent a link to their email address to complete the survey from their own personal web-enabled device. This embedded link was specific to the participant's email address and could not be forwarded for completion by anyone else. Whether recruited in person or via other methods, the survey was self-administered. We entered data for individuals who completed the survey in person at community events into RedCap.

In addition to the items in the Research Literacy Scale, we also collected socio-demographic data on age, race/ethnicity, gender, level of education, health literacy, and perceived income. To assess health literacy, we used the question, "how comfortable are you filling out medical forms by yourself?" (*Extremely, quite a bit, somewhat, a little bit, not at all*).<sup>102,103</sup> We used a perceived income variable developed by community-engaged researchers at UMass Medical School: "in general, would you say you (and your family living in the same household) have more money than you need, just enough money for your needs, or not enough money to meet your needs?".

Participants who indicated willingness to complete the Research Literacy scale again, two weeks after their initial survey completion date, were asked to provide their email address for follow-up. They were then flagged in the RedCap system and sent an automated email 14 days later to complete the Research Literacy scale.

### *Psychometric Analyses*



Figure 2 outlines the psychometric analyses conducted to evaluate the Research Literacy Scale. We incorporated the “I don’t know” answer option initially in response to feedback from cognitive pretesting of the scale, and to discourage guessing, but we ultimately collapsed “I don’t know” responses into the incorrect response category per item for analysis. For all analyses, we recoded respondents’ answers as 1=correct, 0=incorrect.

First, we assessed individual item characteristics and item-test correlation for each item in the Research Literacy Scale. We assessed each item for missingness, and summarized mean, standard deviation, and item-test correlation. We eliminated items in this step based on low item-test correlation ( $r < 0.40$ ). Second, we conducted exploratory factor analysis. Using a polychoric correlation matrix structure to account for our strictly binary survey response options, we built exploratory models that included all remaining factors that had high item-test correlation values. Models were rotated using varimax rotation to simplify interpretation of loadings. We evaluated the exploratory factor loadings for each individual item and classified factors from those that had a correlation  $r > 0.40$  per the respective loadings.<sup>104,105</sup> Items with low ( $r < 0.40$ ) or negative correlations were dropped. We evaluated whether items cross-loaded on multiple factors and if grouping of individual items loading onto factors made conceptual sense. Third, in order to assess internal consistency reliability, we calculated a Kuder-Richardson-20 score for the overall scale and by administration method (online vs. paper). A canonical correlation estimate was calculated to evaluate test-retest reliability of the scale.<sup>106,107</sup>

To assess convergent validity, we also conducted analyses of variance (ANOVA) to test differences in mean Research Literacy score within certain socio-demographic subgroups and examined the Kuder Richardson-20 reliability of the Research Literacy scale within demographic subgroups. We hypothesized that mean research literacy scores would be significantly higher among non-Latino Whites, women, and those with higher education, perceived income, and health literacy compared to their counterparts. All statistical analyses were performed using STATA 14.

## **Results**

### Face/Content Validity

Expert panel reviews and cognitive pretesting interviews confirmed the overall face/content validity of the scale. All 22 items initially created were retained at this stage and no new items were developed. Minor wording changes that improved the comprehension and conciseness were identified. Cognitive pretesting interview participants indicated the importance of adding an “I don’t know” response option to the True/False format. We refined the Research Literacy Scale to reflect this feedback. The content validity index score for the initial 22-item scale was 0.85.

### *Classical Item Testing of the Research Literacy Scale*

The mean, standard deviation, and item-test correlations for each item are presented in Table 3.1. Most items demonstrated variability in response. Items with the highest mean of 0.83 were #1 (Health-related research studies are done to provide data

for medical decision making.) and #2 (People who take part in health-related research do not have legal rights.). Items were eliminated based on low item-test correlations (ITC) ( $< 0.40$ ); thus #7 (All health-related research is experimental), #10 (Randomization means researchers choose which treatment is received by participants in a health-related research study.), and #21 (Agreeing to take part in the study always involves signing a document.), with respective correlations of 0.14, 0.11, and 0.08, were eliminated at this stage.

### Construct Validity

Exploratory factor analysis was performed. Factor structures were explored using eigenvalues greater than one and evaluation of the scree plots. Two, three, and four factor solutions were explored but were a poor fit with the data either because of multiple cross-loadings, low factor loadings, or poor conceptual fit. Thus, a single factor structure fit the data best and explained 76% of the variance in research literacy.

### Test-Retest Reliability

We assessed the stability of answers in a sub-sample of respondents ( $n=84$ ) over a 14-day period of time. The canonical correlation for test-retest reliability of the scale was 0.84.

### Internal Consistency Reliability.

We assessed the Kuder Richardson-20 reliability of the scale by administration method. It did not differ greatly by online ( $r=0.82$ ) versus paper ( $r=0.79$ ) methods, so it

was unnecessary to further evaluate the scale stratified by these methods. The internal consistency reliability for the full Research Literacy Scale using Kuder-Richardson-20 was 0.81.

#### Convergent Validity: Demographic Differences in Mean Research Literacy Scale Score

Mean Research Literacy Scale scores and KR-20 reliability estimates by socio-demographic subgroups are detailed in Table 3.2. There were statistically significant differences in mean scores by age, education, perceived income, and health literacy. Persons who were over age 50 (compared ages 18-34 and 35-49 vs. 50-64 and 65+), had a college degree (vs. not having a college degree), perceived their income to be enough to meet their needs (vs. not enough) and had high health literacy (vs. low health literacy) had higher mean Research Literacy Scale scores (all  $p < .01$ ). No gender differences were observed.

#### **Discussion**

Mandates from the National Institutes of Health, the Food & Drug Administration, and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, articulate the necessity of processes and methods to ensure that participants in health-related research studies have a clear understanding of the studies in which they participate and are able to make informed, un-coerced decisions about participation.<sup>108-112</sup> The Research Literacy Scale is responsive to such mandates and was developed to measure individuals' "capacity to obtain, process, and understand basic information needed to make informed decisions about research participation."<sup>100</sup>

Our findings preliminarily support the internal consistency, reliability, and validity of the Research Literacy Scale as a tool to assess individual understanding of health-related research procedures and expectations. The good internal consistency estimate ( $KR-20 = 0.81$ ) and test-retest reliability ( $r = 0.84$ ) for the Research Literacy Scale suggest that the 16 items comprising the scale collectively form a consistent and preliminarily reliable measure of the research literacy construct. Further, our exploratory factor analysis results suggest that the Research Literacy scale is unidimensional and that all 16 items assess an aspect of one's understanding of health-related research.

We examined preliminary construct validity by evaluating mean research literacy scale score across socio-demographics. The scale demonstrated high reliability within the demographic subgroups we evaluated (Table 3.2). Excluding gender differences, our hypothesis of difference in mean scores by demographic subgroups was supported. Scores varied across race/ethnicity (mean research literacy score: 12.3 vs. 11.3 vs. 9.9 among Non-Latino Whites, Blacks, and Latinos, respectively). This suggests an important place for research literacy within the broader understanding of race-related treatment and racial discrimination, both within greater society<sup>113-115</sup> and specifically within the healthcare sector.<sup>116-118</sup> These experiences impact the way minorities are perceived and interact with the healthcare system,<sup>116,118,119</sup> which may also impact the exchange (or lack thereof) of knowledge as health care consumers. It is logical, therefore, that experiences of race-based treatment and racial discrimination would extend to research literacy.

Research literacy was also lower among those with lower education and health literacy levels. This is consistent with literature suggesting a positive association between those with higher levels of formal education and health literacy proficiency and generally better-informed healthcare consumers.<sup>87,120-123</sup> Research literacy was also higher among older participants, particularly those over age 50. Plausible explanations for this finding may point to prolonged exposure to the healthcare system throughout the lifespan, which has been associated with increased e-health literacy (use of internet and social media to locate and evaluate health information) and health consumerism.<sup>124</sup> In addition, it is possible that increased frequency of interaction with health care providers as we age contributes to more familiarity with research studies as treatment options and thus higher research literacy.<sup>124</sup>

The variations in scores shown across socio-demographic subgroups demonstrates the potential of the Research Literacy Scale to discriminate differences across substrata within the general population. These differences in levels of understanding coincide with literature that also shows lower likelihood of participating in health-related research among individuals with these demographic characteristics, particularly race/ethnicity.<sup>38,43,81,83</sup>

Misperceptions about health-related research may influence these numbers, deterring racial/ethnic minorities and individuals of low socioeconomic status from participating in research.<sup>43</sup> With wide and growing racial/ethnic and socioeconomic diversity in this country and abroad,<sup>21</sup> researchers need to engage broad groups of

potential participants, and clear and effective communication of information about the research process is critical to this effort. The scale holds promise as a potential screening tool to verify participants' understanding of research expectations and procedures prior to enrolling in a study. Further, the Research Literacy Scale could be administered widely to identify specific areas of misperception in the greater population and use to help shape the design of targeted interventions. Such interventions could result in increased engagement, appropriate decision-making, and greater participation of more diverse individuals in health-related research.

Our findings should be viewed within the context of certain limitations. First, the Research Literacy Scale was administered as a cross-sectional survey; except for 84 individuals who retook the scale after 14 days (in order to assess test-retest reliability), the research literacy level of respondents was captured at one time-point. Thus, we cannot draw definitive longitudinal conclusions about research literacy as either a trait or state. Plausibly, research literacy is also similar to health literacy—a trait for which proficiency is hypothesized to be context- and situation-specific.<sup>51</sup> We also observed a ceiling effect, suggesting the Research Literacy Scale's limitations for further distinction of relatively well-informed respondents, or those with very high scores. This ceiling effect conversely suggests the tool's particular and/or potential strength identifying individuals who score lower and therefore struggle with understanding health-related research information—which is its purpose. Second, it is possible that there are context-specific facets to participation in health-related research that we were not able to assess through the Research Literacy Scale. For example, since the logistics of participating in

an industry-driven medical drug trial versus a community-engaged weight-loss prevention study vary, it is likely that there are additional nuances of participating in these studies not included in the Research Literacy Scale. We recognize that we could not accommodate the unique aspects of the range of health-related research studies, so we chose to focus on the core understanding essential to being an informed research participant, regardless of type of study in which one may choose to participate. Further work on this topic might include subscales specific to research literacy of participants for different types of research studies. Third, we did not assess the potential sensitivity of the Research Literacy scale to change in the context of an intervention. While we believe this to be an important aspect to consider, it was not the focus of this project and is a topic that warrants future investigation. Finally, the potential for bias related to self-report and guessing are a threat to any psychometric self-administered assessment. Many items included in the Research Literacy Scale relied upon the ability of participants to recall information that they may have either previously been exposed to or never known. Thus, we cannot guarantee prevention of guessing or application of prior experience/knowledge to the results.

The Research Literacy Scale attempts to evaluate how well individuals process and understand the regulations and expectations of health-related research. To our knowledge, the scale is the first of its kind to: 1) evaluate the concept of research literacy in a diverse sample, 2) rely on both qualitative and literature findings and conceptual grounding as the basis for defining and measuring research literacy, and 3) incorporate the perspectives of both former/current research participants and researchers in its



development. Research literacy is a relatively new and dynamic concept. The Research Literacy Scale is a tool that could be used for screening to better facilitate research participants' understanding prior to consenting to a study. Future research should explore whether levels of research literacy are associated with one's willingness to participate in a research study. The Research Literacy Scale has the potential to foster transparency and progress towards long-term improvements in engaging and communicating with research participants.

**Table. 3.1: Summary Statistics for 16- items included in the Research Literacy Scale: Item means, standard deviations, Item-test correlation, (n=430)**

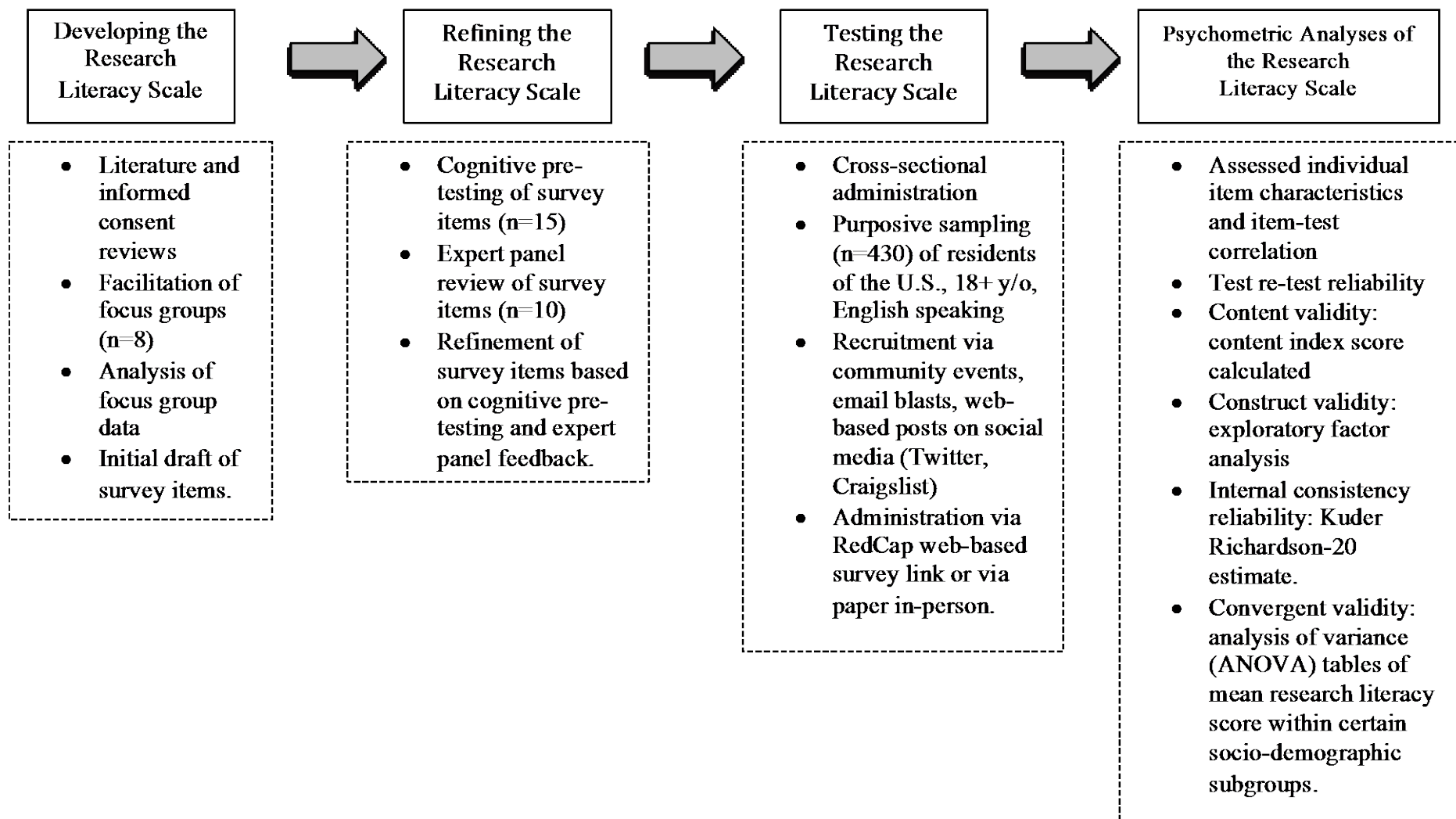
Full item ( <i>Short-item wording</i> )	M	SD	Item-Test
1. Health-related research studies are done to provide data for medical decision making. ( <i>Medical decision</i> )	0.83	0.37	0.37
2. People who take part in health-related research do not have legal rights. ( <i>Legal</i> )	0.83	0.37	0.56
4. Agreeing to take part in a health-related research study allows the research team access to a study participant's medical records even when the study is over. ( <i>Medical record access</i> )	0.52	0.50	0.51
5. The potential risks and harms for taking part in a health-related research study are explained upfront. ( <i>Risks and harms</i> )	0.75	0.44	0.58
6. Informed consent is not required to take part in a health-related research study. ( <i>Informed consent required</i> )	0.72	0.45	0.51
8. The potential risks and harms for taking part in a health-related study are not always discussed upfront with the participant. ( <i>Risks/harms discussed upfront</i> )	0.60	0.49	0.53
9. Health-related research studies do not follow strict rules and regulations. ( <i>Rules and regulations</i> )	0.71	0.46	0.59
11. Taking part in a health-related research study means that you will receive the best treatment option available. ( <i>Best treatment option</i> )	0.55	0.50	0.42
12. The personal information shared as a research participant will be kept strictly confidential. ( <i>Personal information confidential</i> )	0.73	0.44	0.55
13. Taking part in a health-related research study is the same as receiving standard medical care. ( <i>Standard medical treatment</i> )	0.78	0.42	0.43
14. Individuals cannot change their mind after signing a consent form agreeing to take part in a research study. ( <i>Cannot change mind</i> )	0.78	0.41	0.51
15. Personal information about individuals who take part in health-related research studies can be listed in reports related to the study findings. ( <i>Personal information listed in reports</i> )	0.49	0.50	0.46
16. Individuals who are asked to be in a health-related research study must participate. ( <i>Must participate</i> )	0.79	0.41	0.49
17. Informed consent is an on-going process that starts when you are invited to be in a study and continues throughout participation in the study. ( <i>Informed consent on-going</i> )	0.67	0.47	0.49
18. Individuals who enroll in a research study can quit at anytime, with or without any reason. ( <i>Can quit anytime</i> )	0.78	0.41	0.51
22. Individuals who take part in health-related research studies can ask researchers questions throughout their time in the study. ( <i>Ask questions</i> )	0.81	0.39	0.40

Note. M= mean, SD= standard deviation, Item-test= Item-test correlation

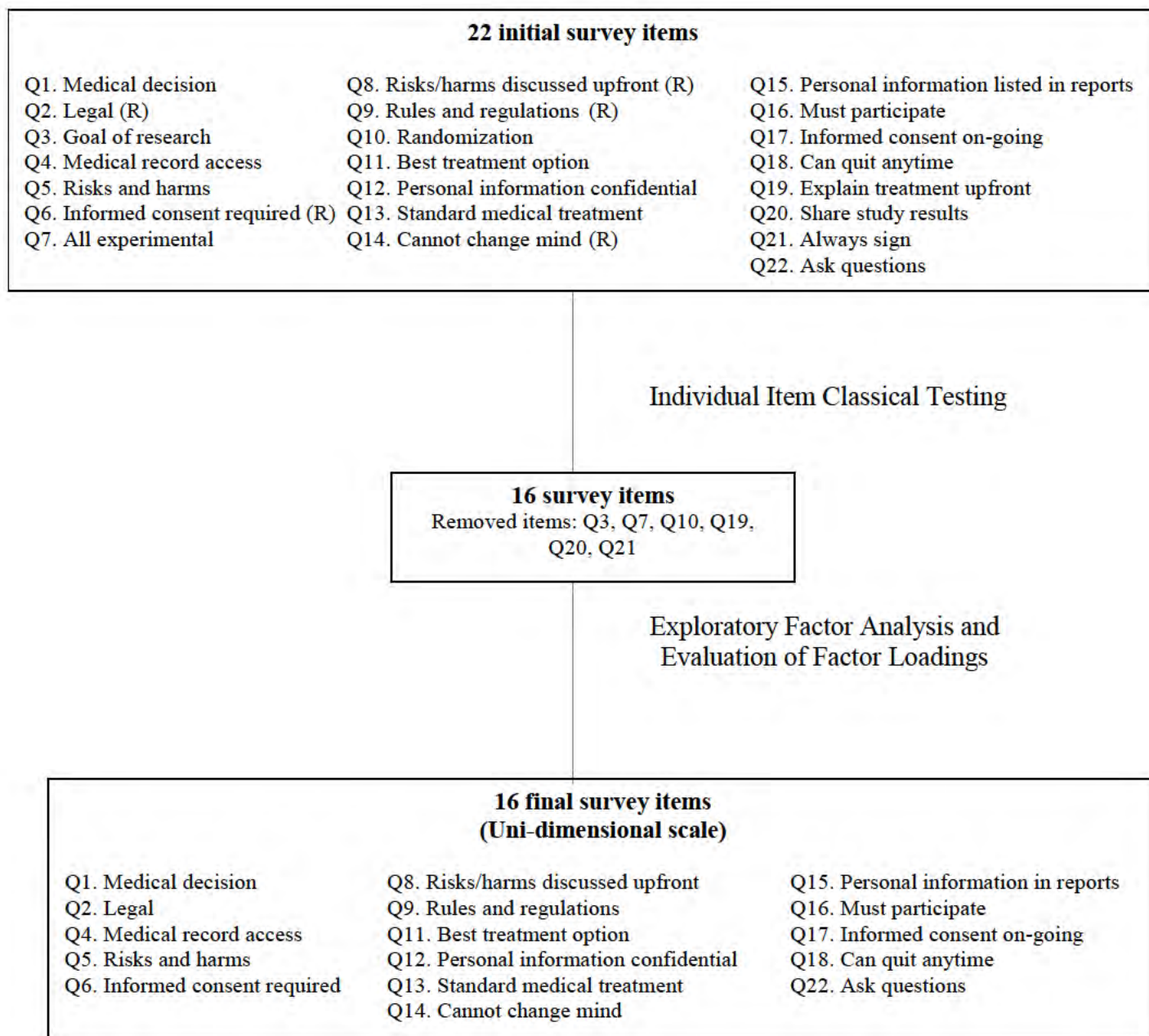
**Table 3.2: Analysis of Variance (ANOVA) of final 16-item Research Literacy Scale mean scores and Kuder Richardson-20 reliability estimate, by socio-demographic subgroup, (n=430)**

		Research Literacy Mean Score M (SD)	ANOVA		KR-20 Reliability Estimate
<b>Total sample</b>		11.3 (3.6)	-	-	0.81
<b>Demographic characteristic</b>			<b>F statistic</b>	<b>P-value</b>	
<b>Gender</b>					
	Women	11.1 (3.8)	--	--	0.78
	Men	11.6 (3.3)	2.1	0.14	0.83
<b>Age</b>					
	18-34	11.3 (3.5)	--	--	0.79
	35-49	11.2 (3.7)	--	--	0.82
	50-64	12.1 (3.3)	--	--	0.79
	65+	12.0 (3.2)	5.8	<0.01	0.79
<b>Race/Ethnicity</b>					
	Non-Latino, White	12.3 (3.3)	--	--	0.80
	Black	11.3 (3.4)	--	--	0.78
	Latino	9.9 (3.6)	7.3	<0.01	0.77
<b>Education completed</b>					
	>College educated	12.7 (3.0)	--	--	0.77
	<College educated	9.8 (3.5)	44.53	<0.01	0.76
<b>Perceived Income</b>					
	Enough	12.0 (3.4)	--	--	0.81
	Not enough	10.8 (3.6)	10.94	<0.01	0.79
<b>Health Literacy</b>					
	High	11.8 (3.4)	--	--	0.80
	Low	9.6 (3.6)	21.2	<0.01	0.76

Figure 3.1: Research Literacy Scale development and psychometric analysis process



**Figure 3.2. Research Literacy Scale item selection process, starting from psychometric analysis (Short-item wording)**



(R): denotes items that were reverse-coded

**CHAPTER IV**

**RACE (STILL) MATTERS: THE ASSOCIATION OF**

**RACE AND RACE-BASED TREATMENT WITH RESEARCH LITERACY**

**Abstract:**

**Objectives:** Racial/ethnic minorities are under-represented in clinical research and may be common targets of racial discrimination. We aim to investigate the associations of race and race-based treatment with research literacy.

**Methods:** A cross-sectional survey was conducted in the Summer of 2015. Research literacy scores (range: 0-16) were calculated using the 16-item Research literacy Scale (cite). Race-based treatment variables included: race consciousness (“How often do you think about your race?”) and perceived discrimination when seeking healthcare. Multivariable Poisson regression was used.

**Results:** Our sample consisted of 188 African-American, 143 Non-Latino White, and 70 Latino participants. African-Americans had a 10% lower (Adjusted Incidence Rate Ratio: 0.90, 95% CI: 0.84-0.96), and Latinos had an 18% lower (AIRR: 0.82, 95% CI: 0.75-0.89), expected research literacy score as compared to non-Latino Whites. Race consciousness was associated with an expected higher research literacy score (<daily: AIRR: 1.18, 95% CI: 1.06-1.31; daily: AIRR 1.24, 95% CI: 1.08-1.43; > daily: AIRR: 1.27, 95% CI: 1.12-1.43). The AIRR for the association of perceived discrimination when seeking healthcare with research literacy was 0.92 (95% CI=0.85-1.00).

**Conclusions:** Our findings advance knowledge on the influences of race and race-based treatment on participation in clinical research.

## Introduction

Disease presentations, progression, and treatment outcomes often differ across racial and ethnic populations.<sup>25,125,126</sup> Furthermore, African Americans, Latinos, and individuals from a low socio-economic status continue to be disproportionately affected by poor health outcomes.<sup>127</sup> A process by which such health outcomes can be improved is through increased understanding of determinants and the development of both preventive strategies and treatments discovered through health-related research. Yet, minorities and individuals of low socio-economic status remain highly underrepresented, if not invisible, as participants in health-related research studies.<sup>128</sup>

Federal agencies, including the National Institute of Health, and The Agency of Health Research and Quality, have employed policies that aim to increase minority inclusion in clinical research and thus reduce health inequities.<sup>129</sup> Yet, 20 years after these mandates, efforts to improve treatment outcomes are significantly limited by poor representation of minorities in health-related research.<sup>128</sup> For example, researchers have found that, even after these stringent policy changes, to date less than 5% of trial participants are non-White, and less than 2% of clinical cancer research studies focus on non-White ethnic or racial groups.<sup>128</sup> Further, a 2011 review of 86 randomized controlled clinical trials revealed that only 36% of studies reported analysis by race or ethnic groups.<sup>128,129</sup> This was mostly attributed to insufficient numbers of participants for subgroup racial/ethnic analyses.<sup>129</sup> The importance of health-related research lies within



the lifesaving new treatments, medical devices, and preventative health measures that can be discovered through this process.

Recruitment efforts to increase minority research participants are countered by mistrust of researchers, which stems from a historical legacy of exploitation<sup>10,24,30</sup> and perceived experiences of racial discrimination within the healthcare system.<sup>10,42,43,45,130</sup> Limited understanding of the research process may also act as a barrier to medical research participation among minorities. Despite advances in research ethics and standardization of the informed consent process, several research participants remain misinformed about research terms and procedures.<sup>16,34,36,131</sup> Specific areas of confusion and doubt include the informed consent process and therapeutic intentions of clinical research.<sup>5,16</sup>

It is possible that perspectives gleaned from personal and historical experiences affect one's understanding of the research process and influence decisions regarding research participation, particularly among minorities.<sup>5,38</sup> For example, a 2003 study on how African-Americans view research supports the notion that race, racial discrimination, and other socio-demographic factors influence research participation.<sup>5,42,132</sup> Minorities' experiences of discrimination in broad sectors of society (such as interactions with law enforcement, the criminal justice system, and the education system) are major drivers of these encounters.<sup>114,133-136</sup> It is plausible then that experiences of discrimination may influence minority participation in research and understanding of the research process. Yet, little is known about how race and race-based treatment influence

the way minorities process and understand information about clinical research. Improving research literacy, which we define as “the capacity to obtain, process, and understand basic information needed to make informed decisions about research participation,”<sup>100</sup> may enhance minority research participation.

Using a novel scale developed to measure research literacy,<sup>137</sup> we aim to investigate the associations of race and race-based treatment, including self-reports of discrimination when seeking medical care and race consciousness, with research literacy in a diverse sample. We additionally examined whether these associations differed by experiences of race-based treatment, race/ethnicity, and gender.

## **Methods**

We conducted a cross-sectional study using primary data collected online and in-person during the Summer of 2015. Survey participants were at least 18 years old and English speaking. We recruited participants in person at community events in Worcester and Boston, Massachusetts. Participants recruited in person were offered the choice to complete the survey via paper or on a web-enabled tablet. Online participants were recruited via online postings (through Craigslist and Twitter) and community email listservs. We provided participants with a personalized and private link to complete the survey on a web-enabled personal device. Respondents were compensated \$25 for their participation and provided informed consent prior to study procedures. All study procedures were approved by the University of Massachusetts Medical School Institutional Review Board.

### *Measures*

The Research Literacy Scale is a 16-item measure assessing goals of research, human subjects protections, ethical conduct, randomization, experimentation, understanding research versus treatment, confidentiality, research as a choice, and researcher responsibility. Item response options were True/False, and individual scores were calculated based on how many items respondents correctly answered. Research literacy scores ranged from 0-16, with higher scores indicating better research literacy. The Research Literacy Scale has demonstrated good internal consistency reliability ( $\alpha = 0.81$ ), test-re-test reliability (insert  $r = 0.84$ ), and content, criterion, and construct validity.<sup>137</sup>

Race and ethnicity were assessed by participants' responses to "What is your race?" (White, Black/African/African-American, American Indian/Alaska Native/Tahino, Asian, Native Hawaiian/Pacific Islander, Other) and "Do you consider yourself to be Hispanic/Latino?" (Yes/No). Due to low numbers of respondents from certain racial/ethnic groups, this analysis was restricted to non-Latino Whites, Black/African-Americans, and Latinos.

Race-based treatment was assessed using variables rooted in measuring experiences of perceived discrimination (discrimination when seeking healthcare) and factors that may influence internalized coping processes related to the experience of discrimination (race consciousness). Race consciousness was assessed from response to the question: "How often do you think about your race [*Never, Once a year, Once a*

*month, Once a week, Once a day, Once an hour, or Constantly]?” We re-categorized race consciousness into four distinct groups based on the frequency distributions: never (Never), < daily (Once a year, once a month, once a week), daily (Once a day), and > daily (Once an hour or constantly). Discrimination when seeking healthcare was assessed from response to the question: “Have you ever experienced discrimination, or been made to feel inferior, while getting medical care because of your race, nationality/ethnicity, or skin color?” (Yes/No).*

Covariates included age in categories (*18-34; 35-49; 50-64; 65+*) and gender (*female; male*). We also included a single item as a proxy measure of health literacy, “How comfortable are you filling out medical forms by yourself?” (*Extremely, quite a bit, somewhat, a little bit, not at all*), as well as the question “Have you ever been in a health-related research study?” (*Yes/No*) to assess previous history of research participation.

### *Analytic Approach*

Descriptive statistics were first computed to describe the study sample. We then conducted bivariate analyses of race-related treatment and other covariates by race/ethnicity. We also assessed mean research literacy score by socio-demographic and race-based treatment characteristics, stratified by race/ethnicity to assess differences in scores, and used analysis of variance tests to assess statistically significant differences. We assessed for over-dispersion of data using maximum likelihood statistics from negative binomial regression models, then conducted Poisson regression models to assess

the association between race and race-based treatment (race consciousness and discrimination when seeking healthcare) and research literacy score. We ran unadjusted and multivariable adjusted models. We included covariates in the model based on a forward stepwise approach considering conceptual connections between potential confounders that may impact the relationship between research literacy score and race/race-based treatment. We also closely considered the potential for collinearity by including covariates in our model and thus built parsimonious models adjusting for race, gender, age in years, health literacy, and previous history of research participation. We tested three interaction terms in our multivariable adjusted model based on originally hypothesized conceptual connections between: 1) race and race consciousness, 2) perceived discrimination when seeking healthcare and race consciousness, and 3) gender and race consciousness to test for statistical interaction. In instances where we found a significant interaction, we built models stratified by gender to assess for further differences. We completed multiple imputation to account for data missing at random (<10%). Chained multiple imputation, an imputation method that can handle variables of varying types as well as complexities such as bounds or survey skip patterns,<sup>138</sup> was used to impute missing data for the following: race consciousness, discrimination when seeking medical care, gender, age, health literacy, past experiences with research, and interaction variables. All estimates are reported as incidence rate ratios, and the significance level was set at  $p < 0.05$ . STATA 14 was used for all statistical analyses.

## **Results**

*Sample characteristics*

Our sample consisted of 401 participants (188 African-American, 143 Non-Latino White, 70 Latino). Socio-demographic characteristics of the sample are stratified by race/ethnicity in Table 4.1. The majority of the overall sample was comprised of women (59%) and individuals younger than 50 years of age (72%). The sample was primarily composed of individuals of moderate socioeconomic status (60% of the sample indicated having at least enough income to meet household bills), the majority of whom completed at least a college education (55%). Roughly 24% of individuals had previously been involved in a health-related research study. With respect to race consciousness in our sample, 23% of respondents reported thinking about their race more than daily, while 14% reported thinking about their race daily. Approximately 31% of respondents reported thinking about their race less than daily, and 32% reported never thinking about their race. Twenty-four percent of respondents indicated experiencing discrimination when seeking healthcare.

Table 4.1 also presents the study sample according to race/ethnicity. African-Americans had the highest unemployment (62%). In addition, African-Americans had the lowest perceived household income, with 47% reporting having less than enough money to pay their bills. Roughly 1 in 4 African-Americans indicated having previous experiences with research. Latinos had the lowest self-reported educational status, with 62% indicating that they have less than a college education. In addition, low health

literacy level was highest among Latinos (36%), as compared to only 11% of non-Latino Whites.

*Race and race-based treatment and mean research literacy score*

Mean research literacy scores by race-based characteristics, both in the total sample and stratified by race/ethnicity, are detailed in Table 4.2. Overall, the mean research literacy score in the total sample was 11.3 (SD=3.6). Mean research literacy score differed by race/ethnicity, with non-Latino Whites averaging a score of 12.3 (SD=3.3), African Americans averaging a score of 11.3 (SD=3.4), and Latinos averaging a score of 9.9 (SD=3.6).

There were statistically significant differences in mean scores by health literacy, previous participation in research, and race consciousness in the overall sample. Within non-Latino Whites, individuals who had high health literacy and previous experience with research had a higher mean research literacy score ( $p<0.01$ ). Within African-Americans, individuals who had a high health literacy level also had a higher mean research literacy score ( $p<0.01$ ). Within Latinos, mean research literacy score varied across race consciousness and health literacy statuses ( $p<0.01$ ).

*Multivariable association of research literacy score with race, race-based treatment, and socio-demographic characteristics*

Results of the Poisson regression models of the associations of race and race-based treatment and socio-demographic characteristics with Research literacy score are

presented in Table 4.3. We report on the multivariable model adjusting for race, gender, age in years, health literacy, and previous history of research participation. This included a significant interaction term between gender and race consciousness ( $p=0.03$ ). The other interaction terms included in our model were not significant. In the multivariable model, the expected count of correct responses would result in a 10% lower (Adjusted Incidence Rate Ratio: 0.90, 95% CI: 0.84-0.96) research literacy score among African-Americans and an 18% lower (AIRR: 0.82, 95% CI: 0.75-0.89) score among Latinos, as compared to non-Latino Whites. Greater race consciousness, or reported thoughts about one's race, was associated with a higher research literacy score. For instance, thinking about one's race on a less than daily frequency (AIRR: 1.18, 95% CI: 1.06-1.31) would increase the expected count of items by 18% as compared to individuals who reported never thinking about their race. Even bigger differences were apparent among those who reported thinking about race more frequently: Thinking about one's race daily (AIRR: 1.24, 95% CI: 1.08-1.43) and more than daily (AIRR: 1.27, 95% CI: 1.12-1.43) would increase the expected count of items correct and research literacy score by 24% and 27%, respectively, as compared to individuals who reported never thinking about their race. The AIRR for the association of perceived discrimination when seeking healthcare with research literacy score, was 0.92 (95% CI: 0.85-1.00).

Socio-demographic characteristics were also associated with Research literacy score. Health literacy was associated with an expected 15% lower count of correct responses, resulting in a lower research literacy score (AIRR: 0.85, 95% CI: 0.78-0.92). Previous participation in research was associated with an expected 11% increased count



of correct responses and thus a higher research literacy score (AIRR: 1.11, 95% CI: 1.04-1.17).

*Multivariable associations of interactions of race and gender with race-based treatment with research literacy score*

The adjusted model we built to include interaction terms further complicated the understanding of research literacy and its associations with other variables. For instance, stratified analyses yielded a statistically significant interaction between gender and race consciousness, where high race consciousness resulted in an expected 24% increased count of research literacy scale correct responses for women (AIRR: 1.24, 95% CI: 1.09-1.41) versus an expected 5% increased count of correct responses for men (AIRR: 1.05, 95% CI: 0.90-1.23). Additionally, the AIRR for the association of perceived discrimination when seeking healthcare and research literacy score was 0.97 (95% CI= 0.88-1.07) in women and 0.84 (0.73-0.97) in men. We did not find statistically significant interactions, by race.

## **Discussion**

While previous studies have examined general barriers and facilitators to research participation in racial/ethnic minorities,<sup>10,22,139-141</sup> few studies have considered how race and race-based treatment may impact research literacy (defined here as the capacity to comprehend and understand research terms and procedures) in underrepresented populations.<sup>100</sup> To our knowledge, our study was the first to investigate the associations between different race-related variables (race, experiences with racial discrimination, and

race consciousness) and research literacy. Overall, a higher research literacy score was associated with race and race consciousness, consistent with our original hypothesis. In this racially/ethnically diverse sample, African-Americans and Latinos had lower research literacy scores compared to non-Latino Whites. We saw statistically significant differences in mean research literacy score by socio-demographic characteristics, within racial/ethnic group. An association between the statistical interaction of gender and race consciousness, and perceived discrimination when seeking healthcare, on research literacy score was observed. Although not statistically significant at the conventional  $p < .05$  level, those who reported experiencing discrimination in the health care system had lower research literacy scores in the total sample. We observed differences by gender, with perceived discrimination when seeking healthcare associated with lower research literacy scores among men. We did not find associations between the statistical interactions of the race and race-based treatment variables with research literacy.

As it pertains to the findings on race, there were differences in Research literacy score by racial/ethnic group. Mean research literacy score was lower in African-Americans and Latinos versus non-Latino Whites. We observed these associations independent of socio-economic status, previous experience in research, and health literacy factors.

Differences in research literacy score by racial/ethnic group emphasize that there may be important distinctions in the understanding of core research study components by

minorities. These differences may be driven by factors related more broadly to trust and knowledge of past injustices.<sup>5,58,61,142,143</sup>

Previous studies have demonstrated specific perspectives regarding mistrust in research among African Americans (particularly stemming from knowledge of the syphilis experiment at Tuskegee), but these studies have not gone further to explore socio-demographic differences (e.g., in education, income, and employment) that may be impacting these broader perspectives.<sup>5,58,143</sup> Research attitudes and perspectives among Latinos have received even less attention. This is despite the fact that Latinos comprise the nation's fastest growing minority demographic,<sup>21</sup> and neglects specific factors such as language barriers<sup>144-146</sup> and immigration status<sup>146-148</sup> that often contextualize the way Latinos interact with the health care system. These culturally specific experiences of discrimination faced by Latinos are relevant to how this population experiences health care, as well as their expectations regarding healthcare services.<sup>144,146,148,149</sup> This may extend to Latinos' approach to, trust in, attitudes towards, and understanding of research. Therefore, it is plausible that the associations we observed with regard to race, may extend beyond an individual's attitudes towards research to directly shape their understanding of research.<sup>5,150</sup> Thus our findings regarding the associations observed between race and research literacy, may be driven by factors unrelated to just socio-demographics among African-Americans and Latinos. The connection between sociodemographics and research participation may not just reside on perceptions about past experiences, but also about how researchers address these past experiences through

the design and recruitment of research participants. Enhancing research literacy has the power to increase research participation and quality by acknowledging these connections.

We measured two constructs to assess race-based treatment in our sample: one measuring perceived discrimination (experiencing racial discrimination when seeking medical care) and one measuring race consciousness (which has been defined among racial/ethnic minorities as a component/type of internalized coping to address ongoing experiences of discrimination<sup>133,151-155</sup> and refers in this study to frequency of thoughts about one's race). We found research literacy score to be associated with race consciousness in the total sample. Specifically, as compared to those who reported never thinking about race, those who thought about it less than daily, daily, and greater than daily had higher research literacy scores. We define race consciousness in racial/ethnic minorities to be the cornerstone of experiencing discrimination, coping with discrimination, and anticipating future discriminatory encounters.<sup>133,151,153-155</sup> Considering its definition, it is likely that the gradient of race consciousness and its associations observed in our sample are driven by cultural contexts specific to the social and situational circumstances of individuals in society<sup>113,114,133</sup> and may influence the way potential research participants comprehend basic research information.

It is important to note that we did not find a statistical interaction between race and race consciousness in our sample. Perhaps race consciousness is an important factor which impacts research literacy across all of the racial/ethnic groups, not just racial/ethnic minorities. Contextualizing our results, perhaps the association between a

high level of race consciousness and a high research literacy score may speak to the fact that the heightened awareness of experiencing and coping with racial discrimination in minorities, and perhaps recognition of patterns of discrimination in socially conscious Whites, may drive the necessity to better understand research procedures. Since race consciousness was a term that was created and defined within the context of racial/ethnic minorities' experiences, deciphering its definition for non-Latino Whites is less straightforward. Recent studies have supported the notion that non-Latino Whites may experience race consciousness as recognition of strong white racial identity and white privilege,<sup>156,157</sup> or an anxiety provoking stressor for Whites socialized in areas that are predominately Black.<sup>151,156,158</sup> Thus race consciousness could have varied meaning and reflect polarized reactions among Whites of different backgrounds. If, for example, African-Americans who are familiar with the discriminatory practices that led to the historical injustices of the U.S. Public Health Service's Syphilis study conducted at Tuskegee University<sup>5,142,143</sup> also report a high level of race consciousness and a higher research literacy score, it may be because their previous exposure to and anticipation of discrimination may drive them to be vigilant about the research process. Alternatively, perhaps the same scenario in non-Latino Whites may lead to a higher research literacy score because of their knowledge of discrimination experienced by minorities as opposed to their personal experience of it. Thus the gradient of higher research literacy scores for individuals with increasing race consciousness could be driven by knowledge, previous experiences with discrimination, or fear of a repeated history of medical exploitation. In a society where racial/ethnic minorities continue to experience racial discrimination,

<sup>114,152,159,160</sup> and may have daily encounters with racial microaggressions <sup>152,160-163</sup>, it is plausible that these realities may impact the way African-Americans and Latinos, in particular, view and understand research. Though we did not observe this association in our sample, it is possible that regional differences in race-related experiences, and thus responses to the race consciousness question, may elucidate this as a finding in future studies. As such, race consciousness may be an important underlying driver as to how individuals understand, and may subsequently consent to participation in, research.

We also observed gender differences in the association of research literacy with race consciousness and perceived discrimination when seeking healthcare. Though we saw a gradient of increasing expected correct research literacy scale responses with increasing race consciousness across the board, the magnitude of these estimates were much stronger for women than men. This finding speaks to important differences in race consciousness in women versus men and is corroborated in other research studies on the intersectionality of race-based treatment and gender. <sup>164-166</sup> Intersectionality, the mutually constitutive relations among social identities specifically relevant in women's studies <sup>164-166</sup>, recognizes women's entangled experiences of both identity and oppression. <sup>164,166</sup> Research on intersectionality has found it to be an important factor in the interaction of patients with physicians and health care professionals, as well as an overarching driver of health disparities. <sup>167-169</sup> These findings may provide context for the particularly strong associations with race consciousness among women in our study—i.e., research literacy may be one of many concepts demonstrating the simultaneity of race and gender as a social process. Again, we observed a similar gradient of statistically significant findings

among men but with diminished magnitude as compared to women. We also observed marginally significant gender differences in the association of perceived racial discrimination when seeking health care with expected research literacy score—lower scores among men than women. These observed differences by gender are consistent with previous studies on discrimination in which men (specifically, men of color) reported experiencing racial discrimination more often than women.<sup>170,171</sup> Further, the association we observed may support findings emphasizing the experiences of discrimination as a factor underlying the limited interaction and engagement of men, and most poignantly men of color, with the health care system.<sup>172</sup> Given its connection to differences in healthcare utilization and engagement by gender,<sup>74,173-176</sup> it is plausible that experiencing racial discrimination when seeking health care could greatly influence gender differences in individual interpretation and understanding of research. The significant association between race consciousness and perceived racial discrimination when seeking healthcare with research literacy by gender thus provides credence to the notion that understanding of research may be shaped by the layered complexities of one's multiple identities and experiences in society.

Underrepresentation of minorities in research studies may, in turn, be propelled by a lack of understanding of the research process. Our results further support the fact that race and race-based treatment may be two of the many underlying factors shaping differences in individual understandings of research. Thus, acknowledging how the shared *and* unique experiences of minorities in America may contribute to gaps in understanding of research could be vital to better engaging minorities in research

participation. Recognition of race consciousness and the inequities that still persist in society for racial/ethnic minorities is important to contextualize the lens through which this population processes information about research studies. Because research participation serves as one pipeline through which advancements in health and wellness are made, the underrepresentation of minorities may be an important factor underlying health disparities. Accordingly, efforts to improve understanding of research processes in racial/ethnic minority communities, particularly within the context of race and race-based lived experiences, could be key to reducing health disparities. Previous studies on barriers and facilitators to research participation<sup>5,10,42,58</sup> do not take into account the ways in which race and race-based treatment may tie into one's understanding of research processes and, in turn, drive the underrepresentation of minorities in research participation. While the crux of previous inquiries on this topic have centered on mistrust as a significant deterrent to research participation in minorities, we focused on trying to better understand how well individuals understand the research process. Though trust is a foundational principle that is also paramount to the researcher-participant relationship, a level of knowledge and informed consumerism about research is just as vital for potential research participants, particularly minorities.

Synergistic with findings from another, prior study on barriers and facilitators to research participation,<sup>10</sup> we report strong associations between certain demographics (e.g., health literacy and previous experiences with research) with research literacy score. Since the concept of research literacy assumes, or fits within the context of, one's basic literacy skills, it is logical that health literacy and previous experiences with research are



associated with research literacy score. The complexities that come with understanding basic research concepts and procedures may require an advanced level of comprehension, characteristic of a higher health literacy level,<sup>177,178</sup> and could be enhanced as a result of previous experiences in research.

Enhanced engagement of racial/ethnic minorities in research participation may thus require a paradigm shift within the research community, as well as significant community empowerment initiatives focused on how to help individuals better understand research.<sup>16,58,128</sup> Introduction of the concept of research literacy as a tool for empowerment as a research consumer, as well as continued assessments of individual research literacy scores within diverse populations, could serve as the foundation for future intervention on this topic. The paradigm shift among researchers must also recognize the importance of 1) bi-directional communication with potential participants to enhance understanding of the research process<sup>91,179</sup> and 2) bi-directional understanding of the ways in which broader societal experiences may influence this understanding. Our results support the notion that there likely exists an inter-correlated nature between race-related treatment in broader society<sup>114,160,163,180</sup> and how one interprets and understands basic information about research. It is plausible, therefore, that this same notion extends to one's willingness to participate in research. The sooner health researchers acknowledge that individuals in society do not live in silos, and that each experience in greater society (even those of racial discrimination and race-based treatment) shapes one's perceptions and understanding of research, the sooner we can

make progress in developing and implementing methods to enhance research literacy among/within diverse individuals and communities.

The findings of our study should be viewed within the context of certain limitations. First, as a cross-sectional study, we are not able to draw temporal associations between Research literacy score and race or race-based treatment. More specifically, the responses regarding race-based treatment were only captured during the snapshot in time during which our survey was administered; accordingly, differences in the length of time between this study period and prior treatment (or other) experiences may have contributed to overestimates or underestimates. Second, reported experiences of race-based treatment may vary by community. For example, individuals who live and work in a racially homogenous community may be less apt to experience racial discrimination, be reminded of their race less often,<sup>181,182</sup> and report lower levels of race consciousness as compared to individuals who live in communities where they are among a small pool of racial/ethnic minorities. Since we did not collect data on neighborhood composition, we cannot rule out this possibility. Third, we recognize the use of single items to assess health literacy, and as a proxy for other sociodemographic variables such as education, as a limitation in our model. Given the complexity of research literacy and its relationship to other variables, future investigations warrant the use of more comprehensive measures of health literacy, education, and other socioeconomic measures/concepts. Finally, we acknowledge the fact that our research literacy survey does not cover all types of research studies or include all vocabulary terms pertaining to research. It is possible, for example, that racial/ethnic minorities are better informed about community-engaged research as

opposed to clinical trial research studies. While our goal in the research literacy survey was to capture the overarching concepts and terms that are the foundations of all types of research, future subscales should explore and perhaps delineate between different research study types and terms.

To our knowledge, this is the first study to assess the association between race, race-based treatment, and research literacy. Our findings indicate that there may be important distinctions and particularities, rooted in cultural and social contexts, that shape the ways in which ethnic/racial minorities process and understand research. These findings also suggest, and may hold significant implications in the efforts to address/combat, the connection between low research literacy and the underrepresentation of minorities in research studies. With a growing U.S. minority demographic, the intentional inclusion of minorities in research has particular importance. Life-saving treatments specific to conditions that drive health disparities in minority communities may be overlooked and understudied as a result of low participation of racial/ethnic minorities in research studies. As disparities in these communities continue to widen, it is imperative that researchers recognize the broad experiences and perspectives that shape how racial/ethnic minorities understand research in order to identify appropriate strategies to increase their inclusion.

**Table 4.1. Sample characteristics, by race/ethnicity, Research Literacy survey: non-Latino White, African-American, and Latino respondents. (n=401)**

<b>Demographic Characteristic</b>	<b>Total sample (%) (n=401)</b>	<b>Non-Latino White (%) (n=143)</b>	<b>African-American (%) (n=188)</b>	<b>Latino (%) (n=70)</b>
<b>Race consciousness</b>				
Never	32.3	47.7	18.5	34.0
<Daily	30.5	39.2	23.2	30.2
Daily	13.8	10.0	17.2	13.2
>Daily	23.4	3.1	41.1	22.6
<b>Discrimination seeking healthcare</b>				
Yes	24.2	7.0	35.7	29.9
<b>Age category, years</b>				
18-34	41.5	26.2	46.4	60.6
35-49	30.4	36.9	26.5	27.3
50-64	21.1	24.8	22.1	10.6
65+	7.0	12.1	5.0	1.5
<b>Gender, women</b>	59.1	59.9	56.7	63.8
<b>Education</b>				
<College	45.4	34.3	47.6	62.3
<b>Employment</b>				
Unemployed	29.2	25.9	35.6	18.6
<b>Perceived income</b>				
Not enough	40.7	30.9	47.4	43.6
<b>Health literacy</b>				
Low	19.4	11.2	19.4	36.2
<b>Previous experience with research</b>				
Yes	23.9	22.4	24.7	24.6

Table 4.2: Mean Research Literacy score by sample characteristics in the overall sample and by race/ethnicity (n=401)

Demographic characteristic	Overall Sample (n=401)			Non-Latino White (n=143) $\alpha=0.80$			African-Americans (n=188) $\alpha=0.78$			Latinos (n=70) $\alpha=0.77$													
	Research Literacy Mean Score M (SD)	ANOVA		Research Literacy Mean Score M (SD)	ANOVA		Research Literacy Mean Score M (SD)	ANOVA		Research Literacy Mean Score M (SD)	ANOVA												
		F-statistic	P-value		F-statistic	P-value		F-statistic	P-value		F-statistic	P-value											
<b>Race/Ethnicity</b>																							
Non-Latino White													12.3 (3.3)										
African-Americans													11.3 (3.4)	12.15	<0.01								
Latinos													9.9 (3.6)										
<b>Race consciousness</b>																							
Never	10.8 (3.8)			11.8 (3.6)			10.3 (3.5)			8.1 (3.8)													
<Daily	12.0 (3.5)			12.8 (3.1)			11.3 (3.9)			10.8 (3.0)													
Daily	12.1 (2.9)			13.1 (2.2)			11.6 (3.2)			12.0 (2.9)													
>Daily	11.9 (3.3)	3.26	0.01	14.0 (1.4)	1.30	0.27	11.8 (3.3)	1.04	0.39	11.8 (3.5)	3.70	<0.01											
<b>Discrimination seeking healthcare</b>																							
No	11.7 (3.2)			12.4 (3.2)			11.5 (2.9)			10.2 (3.5)													
Yes	10.8 (4.1)	6.02	<0.01	11.3 (4.8)	1.04	0.31	11.1 (4.1)	1.99	0.14	9.7 (3.8)	0.94	0.41											
<b>Gender</b>																							
Female	11.6 (3.3)			12.1 (3.2)			11.7 (3.1)			10.3 (3.5)													
Male	11.2 (3.8)	1.64	0.20	12.5 (3.5)	0.31	0.58	10.8 (3.7)	3.23	0.07	9.2 (3.7)	1.38	0.24											
<b>Age, years</b>																							

18-34	11.4 (3.4)			12.5 (3.0)			11.6 (3.3)			10.2 (3.5)		
35-49	11.1 (3.7)			12.4 (3.6)			10.4 (3.5)			9.3 (3.7)		
50-64	12.1 (3.3)			12.6 (3.2)			11.8 (3.2)			11.0 (3.7)		
65+	12.0 (3.2)	3.31	0.01	11.3 (3.5)	0.49	0.74	12.2 (2.5)	3.16	0.02	12.0 (2.2)	0.99	0.42
<b>Health Literacy</b>												
High	11.9 (3.3)			12.6 (3.2)			11.6 (3.4)			10.8 (3.3)		
Low	9.7 (3.5)	15.70	<0.01	10.0 (3.4)	9.5	<0.01	10.4 (3.3)	2.60	0.08	8.5 (3.5)	5.0	<0.01
<b>Previous participation in research</b>												
No	11.1 (3.5)			11.9 (3.4)			11.2 (3.5)			9.4 (3.4)		
Yes	12.5 (3.1)	6.87	<0.01	13.8 (2.3)	9.18	<0.01	11.9 (3.0)	1.30	0.27	11.5 (3.8)	2.65	0.08

**Table 4.3: Adjusted incidence rate ratios of Poisson regression models of the association between sample characteristics and Research Literacy score, in non-Latino White, African-American, and Latino Research Literacy Survey respondents, (n=401)**

	<b>Adjusted* IRR (95% CI)</b>
<b>Race/Race-based characteristics</b>	
<b>Race</b>	
Non-Latino White	---
African-American	0.90 (0.84-0.96)
Latino	0.82 (0.75-0.89)
<b>Race consciousness</b>	
Never	---
<Daily	1.18 (1.06-1.31)
Daily	1.24 (1.08-1.43)
>Daily	1.27 (1.12-1.43)
<b>Discrimination when seeking healthcare</b>	
No	---
Yes	0.92 (0.85-1.00)
<b>Socio-demographic characteristics</b>	
<b>Gender</b>	
Women	---
Men	1.09 (0.97-1.25)
<b>Age, years</b>	
18-34	---
35-49	0.93 (0.87-1.00)
50-64	0.99 (0.92-1.07)
65+	0.99 (0.90-1.10)
<b>Health Literacy</b>	
High	---
Low	0.85 (0.78-0.92)
<b>Previous experience in research</b>	
No	---
Yes	1.11 (1.04-1.17)

\*Interaction term between gender and race consciousness included in model

**Table 4.4: Adjusted incidence rate ratios of Poisson regression models of the association between race/ race-based treatment and Research Literacy score, in non-Latino White, African-American, and Latino Research Literacy Survey respondents, by gender, (n=401)**

	<b>Women (n=257)</b> <b>Adjusted* IRR</b> <b>(95% CI)</b>	<b>Men (n=144)</b> <b>Adjusted* IRR</b> <b>(95% CI)</b>
<b>Characteristic</b>		
<b>Race</b>		
Non-Latino White	---	---
African-American	0.90 (0.83-0.98)	0.89 (0.80-0.99)
Latino	0.83 (0.74-0.92)	0.80 (0.68-0.94)
<b>Race consciousness</b>		
Never	---	---
<daily	1.17 (1.06-1.30)	1.01 (0.89-1.15)
daily	1.24 (1.08-1.41)	1.04 (0.90-1.21)
>daily	1.24 (1.09-1.41)	1.05 (0.90-1.23)
<b>Discrimination when seeking healthcare</b>		
No	---	---
Yes	0.97 (0.88-1.07)	0.84 (0.73-0.97)

\*Model adjusted for gender, age in years, health literacy level, and previous experience with research; estimates derived using multiple imputed data.



**CHAPTER V**  
**DISCUSSION AND CONCLUSION**

## Summary of Findings

The purpose of this dissertation was to 1) define and conceptualize the domains, determinants, and impacts of research literacy through the development of a multi-component comprehensive framework, 2) operationalize research literacy by developing and psychometrically testing the Research Literacy Scale, and 3) quantify differences in research literacy, measured by the Research Literacy Scale, by race/ethnicity, race-related factors and other socio-demographic factors.

First, we defined and conceptualized research literacy. We created a framework outlining domains of research literacy and the multi-faceted influences of societal, community, researcher, and participant factors that may influence an individual's level of research literacy. The eight domains of research literacy were determined to include: 1) goals of research, 2) human subjects protections, 3) ethical conduct, 4) randomization & experimentation, 5) understanding research versus treatment, 6) confidentiality, 7) research as a choice, and 8) researcher responsibility.

Second, we created, administered, and psychometrically tested a culturally responsive measure of research literacy through the creation of a Research Literacy scale. The cross-sectional survey was administered to a purposive community-based sample (n=430) using a web-based data collection system and via paper. The Research Literacy Scale created is comprised of 16 items, with a KR-20 estimate of 0.81 and test-retest reliability 0.84. We found differences in mean scale scores by race/ethnicity, age, education, income, and health literacy (all  $p < 0.01$ ).

Third, we examined the associations of race and race-based treatment on Research Literacy score. African-Americans and Latinos had a lower expected Research Literacy score as compared to non-Latino Whites. Race consciousness was associated with an expected higher Research Literacy score. Perceived racial discrimination when seeking healthcare was marginally associated with an expected lower research literacy score.

In summary, we defined research literacy as the capacity to obtain, process and understand basic information about research in order to make an informed decision about participation. We also emphasized and explored the multiple variables/domains underlying and shaping this broader concept. Preliminarily, the Research Literacy scale we created was psychometrically sound. Race and race-based treatment (both race consciousness and perceived racial discrimination when seeking healthcare) were associated with Research Literacy score. Gender differences in the association between race consciousness and Research Literacy score was observed, with women having a lower expected score as compared to men. An additional gender difference in the marginal association between perceived racial discrimination and Research Literacy score was observed, with men having a lower expected score as compared to women.

### **Study Strengths and Limitations**

Study strengths include: the diverse sample, the use of both former research participants and researchers for survey development, and the exploration of research literacy as a novel concept towards the empowerment and equitable inclusion of minorities in clinical research participation. The results of this study will inform future

research on methods to potentially educate and engage minority and low SES populations in/on clinical research participation. Further, the results could offer direction on methods of culturally relevant recruitment that will directly impact the current dismal rates of research participation among African-Americans and Latinos. In the future, it is possible that research literacy messaging could be disseminated through a number of targeted social media outlets to spark a paradigm shift in the understanding and potential benefits of clinical research participation in minority populations.

This study is limited, providing only one particular angle/perspective in the development of a research literacy framework and survey. While designed with this limitation in mind—to inform only a part of the picture regarding research participation in minority populations—it does provide insight into a critical and neglected piece of the convoluted puzzle of factors influencing individual research literacy and participation. We acknowledge that, by only enrolling 430 participants via purposive sampling, the individual participant perspectives may not be representative of the population at large. It is plausible, however, that the insights gained from this study could provide the tools for expanded research exploring clinical research understanding in minority populations *outside of* individual awareness. Our goal was to assess the validity and utility of the Research Literacy survey by examining the extent to which it explains research literacy variance among participants. A pilot survey seemed adequate for this purpose. Future work, however, must focus on understanding the additional and/or expanded roles of systems and researchers in the experience and engagement of minority participants. It must also be noted that the administration of this survey on a purposive sample will not

ultimately define its efficacy. However, the purpose of this thesis was to conduct a comprehensive pilot study in order to inform future inquiries into this topic.

### **Discussion and Future Research Directions**

The U.S. demographic continues to become increasingly more diverse. Underrepresented populations make up a significant portion of the U.S. population, shoulder a disproportionate burden of disease, and receive inadequate care.<sup>2</sup> Members of minority populations (in particular African-Americans and Latinos) and individuals of low socioeconomic status disproportionately fall victim to markedly dismal health outcomes as compared to their white counterparts.<sup>24</sup> Clinical research aims to identify strategies to treat and prevent diseases through the use of human subjects. Despite the advances in health and life expectancy as a country, population specific black-white gaps continue to persist in areas such as access to care, quality of care, chronic disease risk factors, and disease incidence and related mortality.<sup>24,33</sup> These examples of inequity have seeped into multiple tiers of the healthcare system from which implementation research is not exempt. Individuals from minority populations are underrepresented in clinical research that could alleviate this inequity. To reach wider applicability, a diverse pool of participants in research studies is necessary.

Low research participation from minority populations stems directly from historical inequities and power imbalances that have created a lack of trust between the community and academic medical institutions.<sup>5,183</sup> In the past two decades, mandates for federally funded clinical trials have aimed to address the concerns of distrust in these communities. However, racial and ethnic minorities remain marginalized in research participation and,

despite these mandates, challenges in the recruitment of minorities still exist. The above-proposed project sought to investigate an approach to addressing the disparity in clinical research participation in minorities while empowering and equipping minority communities with the understanding of research processes in order to make truly informed decisions about clinical research participation.

A plethora of knowledge stands to be gained from this dissertation. First, the project offers a definition and conceptual framework for *research literacy*. This is a new concept, adding to the current literature introduced and defined through this project. The concept of research literacy could offer insight into the layered complexities of research participation in minorities. Second, the proposed study implemented a community-engaged approach to this issue. Few studies have attempted to investigate this topic from a community-based and research literacy-rooted perspective. Finally, the knowledge gained from this dissertation could inform the platform for future research in this arena-- leading to additional knowledge about the bi-directional system- and researcher-level interactions influencing research participation in minorities. These potential outcomes could serve as the catalyst for increased research participation in minority populations and directly impact the health and well-being of these communities and the wellness of the greater U.S. population.

Overall, the findings of this dissertation further our understanding of the concept of research literacy and its association between socio-demographics and race-based treatment characteristics. This dissertation provides useful information to improve

research understanding within diverse populations, which may in turn lead to increased research participation.

Given the results gleaned from this dissertation, the next steps in expansion on this topic should include the consideration of targeted interventions to enhance research literacy in diverse patient populations. Ms. Powell, the doctoral candidate who conducted this project, recently spent four weeks (February 2016) as a Visiting Research Fellow at the Office of Health Disparities Research at the Mayo Clinic Scottsdale to explore potential approaches to such interventions. During the fellowship, Ms. Powell created and implemented an interactive workshop to enhance research literacy among underrepresented participants in research. She conducted a workshop with parishioners at a Phoenix area African-American church (n=20) and with a community-based organization called The Coalition for Blacks Against Breast Cancer (n=18). The workshop covered topics including: an overview of research gone wrong, why minorities don't participate in research, an overview of basic research lingo, myths vs. facts about research, why #blacklivesmatter in research too, and where to learn more about being informed about research. Pre- and post- surveys were administered to workshop participants assessing demographics (age, gender, education), one race-based treatment variable (discrimination when seeking healthcare), attitudes towards research, and feedback on the presenters. On average, workshop participants tended to be African-American, female, and in the 50s age range. , Following the workshop facilitated by Ms. Powell, participants indicated a 20% increase in willingness to participate in research, a 12% increase in trust in medical researchers, and an 18% increase in the belief that

minorities should participate in research to improve health of the minority community. The majority of participants (92%) indicated more clarity and understanding about medical research as a result of the presentation. They also emphasized that the information presented had particular influence coming from a researcher (100%) and a presenter of the same race/ethnicity (92%). This small pilot workshop, which sought to help African-American community members better understand basic principles of research, could be expanded for future broad implementation to enhance research literacy in communities of color.

Future studies are needed to explore how research literacy is correlated with the type of research study individuals elect to participate in, as well as related variation by race/ethnicity. For example, it may be that certain racial/ethnic groups are open to non-invasive studies such as surveys and focus groups but not open or as open to clinical drug trials. The work contributed through this dissertation should serve as the foundation by which the concept of research literacy can be further investigated and implemented, as a resource to potentially improve individual understanding of health related research.



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