ABSTRACT

Title of Thesis: "WHAT ARE YOU GOING TO TAKE FROM ME?" CONSIDERATIONS FOR DEVELOPING A TAILORED COMMUNITY CENTERED HUMAN SUBJECTS AND RESEARCH PROTECTIONS AND RESEARCH ETHICS WORKSHOP

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Research exploitation is a topic often relegated to history books and introductory ethics courses with the implication that these insidious practices could never thrive in today's enlightened and humanistic world. While much progress has been made in the standards and oversight of research projects, participation in research is not a risk-free endeavor, and every protection available to participants should be made readily accessible.

While many ethical consideration trainings exist for investigators and their teams, trainings that focus on the experience and rights of the participant are lacking. In this literature review and lesson plan development, the author outlines important considerations around research participation and best practices for building a workshop and provides a suggested lesson plan based on collected literature.

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by

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1. INTRODUCTION

1.1 Project Conception

Too often, the work of ethics is perceived as aloof and removed, and paradoxically uncaring of "real people". Much like the perception of philosophy as the antithesis of practicality and action, ethics too can seem impersonal, cold, and solely based on theory. The practice of ethics requires human centered thinking and genuine care for individuals impacted by top down decisions.

This project was built on the core issue of research ethics and the impact that these activities can have on the lives of participants. By designing the project with the participant in mind, the author hoped to create a community-oriented program that allows for rich conversations and understandings of research ethics. The program was made out of a desire to provide an opportunity for people to consider their feelings towards privacy and research so that they would be better prepared to answer questions from a recruiter in the future.

1.2 Project Overview

The goal of the project was to develop a community tailored workshop using existing literature. Training curriculum was adapted from existing modules on community engagement in research from the Maryland Center for Health Equity.

1.3 Project Rationale

The rationale for the Your Rights in Research (YRR) project is multidimensional. In terms of historic considerations, examples of exploitation in human subjects research, specifically in public health and medicine, have been well-documented in the literature (Scharff et al., 2015; Reverby, 2012). Given this context, it is necessary to make the

information clearly accessible to community members who may be vulnerable to future exploitation in research. From a public health perspective, prevention is one of the core tenets of the field and its practices (American Public Health Association, n.d.). Prevention is similarly embedded in the project goals to reach community members prior to involvement in human subjects research so that they are able to make the most informed and appropriate decisions for themselves. In terms of technology, rapid technological advancement and innovation are making large-scale data collection initiatives like ancestry tests and the National Institutes of Health's "All of Us" study possible, which present new challenges to protecting participants if they are not properly informed.

The aforementioned contexts paint a complex narrative, which is imperative for investigators to understand and navigate in order to effectively communicate training content to participants. As graduate students, the authors' involvement in academic research, their current status as residents of Prince George's County, and past participation in research uniquely position them to facilitate a nuanced training and reach community members effectively.

1.4 Research Questions

The following literature review was based on a series of research questions built using the generations of health disparity research theory, as outlined in the work of Thomas, Quinn, Fryer, and Garza, 2011. The stratification of generations allowed investigators to systematically analyze the issue and to evaluate gaps in discrete areas of interest. This review also serves as a tool to move forward toward fourth generation disparity research, which prioritizes the inclusion of community voices and solutions in the development of research paradigms.

First Generation

Goal: Describe the population that has previously participated in research

1. How many people engage in research programs?
2. What are the demographics of people currently engaging in research?

Second Generation

Goal: Identify and understand contributing factors to participation

1. What are the reasons that people choose to participate in research?
    a. What are the reasons people choose not to participate?
2. What is the comprehension level of research participant rights (and consent)?

Third Generation

Goal: Gather information concerning existing interventions/programs/resources

1. What kind of community trainings on research participant rights exist?
2. What are some effective methods or best practices for communicating training content?

Based on these research questions, the following literature review was generated.

2. LITERATURE REVIEW

2.1 First Generation Research: Demographics of Research participants

2.1.1 Global Participation

From a global perspective, one-third of all clinical trial participants are from the United States (U.S. Food and Drug Administration, 2017). Recent studies show that the demographic composition of US study participants is relatively comparable to that of the general US population (U.S. FDA, 2017). Males represent a slightly larger proportion of clinical trial participants than females (U.S. FDA, 2017). In terms of race, 81% of participants are white, 14.5% are Black or African American, 2.1% are Asian, and 2.3% identify as "other" (U.S. FDA, 2017). By urbancity, participants are more likely to reside in urban rather than rural areas (U.S. Food and Drug Administration, 2017). Regarding enrollment by study topic, participants are most commonly involved in research about cardiovascular disease (U.S. FDA, 2017).

2.1.2 National Participation

As seen in **Table 1**, participation in studies varies greatly by study type. For the purposes of this review, clinical trials and surveillance research were selected as they encompass a large portion of nationally conducted research and have demographic information about their participants readily available. At the current time, there are no publicly available national data about participation in social sciences or epidemiologic studies. The authors recognize that this is a limitation of research participation claims.

2.1.3 Participation in Surveillance and Epidemiologic Studies

To assess US participation rates by demographic categories, investigators examined data from the most recent Behavioral Risk Factor Surveillance System (BRFSS, 2018).

Slightly more than half of BRFSS participants are female (51.3%) and the majority of the sample is between ages 18-65 years old (78.5%). Most participants identify as Non-Hispanic White (73.5%) followed by Hispanic (8.2%), Non-Hispanic Black/African American (7.1%), Asian (2.3%), and American Indian and Alaska Native (1.1%). Approximately 4.4% percent of the sample identifies as Lesbian, Gay, Bisexual, or Transgender (LGBT)(BRFSS, 2018). By educational attainment, 28.8% of respondents completed high school, 26.7% held a Bachelor's degree, and 10.8% had not completed high school. In terms of urbanicity, approximately one in seven participants resided in a rural area.

Table 1. US Population and Study Participation Statistics

Population	United States Population[1]	Participation in Clinical Trials[2]	Participation in Surveillance Research[3]
Sex	49.2% Male 50.8% Female	51% Male 49% Female	48.8% Male 51.3% Female
Age	55.5% age 18-65 16% age 65+	50% age 18-65 50% age 65+	78.5% age 18-65 21.5% age 65+
Race	76.5% White 13.4% African American/ Black 5.9% Asian 1.3% Alaskan Native/American Indian	75% White 8% African American/Black 10% Asian 7% Other	73.5% White 7.1% African American/Black 2.3% Asian 1.1% Alaskan Native/American Indian
Ability Status	8.7% report having a disability	Not available	Not standardized
Ethnicity	18.3% Hispanic	12% Hispanic	8.2% Hispanic
Educational Attainment	87.3% Graduated High School 30.9% Bachelor's Degree	Not available	10.8% less than High School 28.8% High School only 31.8% Some college 26.7% Bachelor's Degree or higher
Sexual Orientation and Gender Identity	4.5% LGB identified[4] .55% Trans identified[5]	Not available	4.4% LGBT identified
Urbanicity/ Rurality	19.3% live in a rural area	Not collected	15.1% Rural

1 U.S. Census Bureau QuickFacts: United States. (n.d.). Retrieved March 24, 2020, from https://www.census.gov/quickfacts/fact/table/US/PST045218

2 U.S. Food and Drug Administration. (2017). Clinical Trials: Participant Demographic Data (https://www.propublica.org/datastore/) [Text/html]. ProPublica Data Store.

3 Centers for Disease Control and Prevention. (2019). LLCP 2018 Codebook Report. Retrieved from https://www.cdc.gov/brfss/annual_data/2018/pdf/codebook18_llcp-v2-508.pdf

4 Rothwell, C. J., Madans, J. H., & Cynamon, M. L. (n.d.). *National Center for Health Statistics*. 32.

5 Baker, K. E. (2019). Findings From the Behavioral Risk Factor Surveillance System on Health-Related Quality of Life Among US Transgender Adults, 2014-2017. *JAMA Internal Medicine*. https://doi.org/10.1001/jamainternmed.2018.7931

2.1.3a Representativeness of US Population

Based on demographics reported in **Table 1**, participation rates in surveillance and epidemiologic studies are generally not representative of the US population. For instance, those who are male (48.8%) and older than 65 years of age (21.5%) are underrepresented while adults ages 18-65 years (78.5%) are overrepresented in surveillance studies (Centers for Disease Control and Prevention, 2019). Regarding race and ethnicity, people of color and those identifying as Hispanic/Latinx are underrepresented. In terms of educational attainment, individuals who had either completed less than high school or held a bachelor's degree were both underrepresented in surveillance and epidemiologic studies. Interestingly, participation rates by sexual orientation and gender identity are commensurate with national estimates of LGBTQ persons. Regarding urbanicity, individuals living in rural areas are underrepresented in surveillance studies. Representativeness by disability status could not be assessed overall because BRFSS variables were specific to particular disability statuses.

2.1.4 Participation in Clinical Trials

The Food and Drug Administration (FDA) reports that 40,835 people participated in a clinical trial in the United States from 2015-2016 (U.S. FDA, 2017). Recent data from FDA clinical trials reveals information about participants by demographic characteristics (see **Table 1**). Males represent 51% of clinical trial participants. Surprisingly, approximately 50% of participants were 65 years of age or older. The majority of the sample identifies as Non-Hispanic White (76%) followed by Hispanic (12%), Asian (10%), Non-Hispanic Black/African American (8%), and Other (7%). Collection of other populations of interest (Living with a disability, educational attainment, urbanicity, and sexual orientation

and gender identity) were not included in the demographic information of clinical trial participants.

2.1.4a Representativeness of US Population

In comparison to US Census statistics, clinical trial participation rates are not representative of the general population. Males, and particularly individuals older than 65 years of age, are overrepresented in clinical trials. In terms of race and ethnicity, people who identify as Hispanic or Non-Hispanic Black/African American are underrepresented while Asian American people are overrepresented (U.S. FDA, 2017). Representativeness by disability status, educational attainment, and urbanicity could not be assessed due to the lack of data on these demographic categories.

2.2 Second Generation: Reasons for Participation

2.2.1 Willingness

In order to examine potential sources of participation disparity in various types of research, it is important to consider willingness in the context of identity. There is a myth in the United States that minorities are less willing to participate in research than their non-minority counterparts; however, evidence to the contrary suggests that the problem may be with study aims and methodology rather than a lack of participant willingness (McElfish et al., 2018a; Wendler et al., 2006; Garza et al., 2017). An Institute of Medicine report revealed that recruitment efforts to obtain adequate minority representation in research continually fall short and that many studies fail to focus on factors that are specifically relevant to minorities' perceptions of their own health (Oh et al., 2015; Institute of Medicine, 2006).

2.2.1a Participation in Surveillance and Epidemiologic Studies

Willingness to participate in research is not a commonly collected variable in surveillance studies. In 2015, the BRFSS had an optional module addressing the topic, and the state of Arkansas participated. A study analyzing the results of this module revealed that individuals who are younger, African American, have fewer years of education, live below the federal poverty level, are unemployed, or are unable to afford health services are more willing to participate in research when compared with their respective counterparts. In fact, those who are between the ages of 18-24 years have nearly six times the odds of willingness to participate in research compared with those who are at least 65 years of age (AOR, 5.68; 95% CI, 2.6-12.25) (McElfish et al., 2018b). Those living at 300% of the federal poverty level (FPL) have half the odds of willingness to participate when compared with their counterparts living below 100% FPL (AOR, 0.48; 95% CI, 0.26-0.88) (McElfish et al., 2018b). Interestingly, individuals who are unable to work have twice the odds of past participation in research than those who are employed (AOR, 1.98; 95% CI, 1.21-3.23) but these groups do not differ in their willingness to participate in research (McElfish et al., 2018b). The willingness and participation history of individuals conflict with the belief that African Americans are less likely to want to participate in research.

2.3 Motivation

2.3.1 Altruism

Participating in research requires an individual to devote some of their own resources to the research project. Participants can be asked for their time, personal information, opinions, medical information, genetic samples, or a combination of these. Studies investigating the reasons that participants choose to enroll identified altruism as a

top factor. One mixed methods study of people who donated genetic samples were asked about their motivations. The most common reason across race and education level (70% of all participants) is a sense of altruistic desire to help the study or to help others who might benefit from the study's findings (Michie, Henderson, Garrett & Corbie-Smith, 2011). In the qualitative section, people stated that they wanted to help out their neighbor, and expressed that others would do the same for them (Michie, Henderson, Garrett & Corbie-Smith, 2011). This pattern is not specific to genetic research. Altruism was the top priority of cardiac patients who participated in a psychological study and was also the second most commonly cited reason in a study of adults who participated in research after visiting the Emergency Room (Irani & Richmond 2015; Soule et al., 2016).

2.3.2 Other Reasons

Another reason for participation was the perception that the individual is contributing to a body of scientific knowledge. Advancement of research and an understanding of the importance of DNA samples from a scientific perspective was another common factor; however, this level of motivation was related to the amount of education the individual completed. Those who completed college or more were 1.67 times as likely to specify scientific advancement as a motivation factor (Michie, Henderson, Garrett & Corbie-Smith, 2011).

Other sources of motivation include the potential for direct participant benefit, financial compensation, curiosity, interest in the research outcome, interest in learning more about one's own health, and simply because the person who enrolled them seemed earnest or trustworthy (Soule et al., 2016; Irani & Richmond, 2015). Individual's perception of the trustworthiness of the researcher, their institution, and the subject of the study can also

increase or decrease a person's likeliness to participate (Passmore et al, 2019). A study focusing on African American participants found that when an individual cares about the topic of study or when the researcher was racially concordant, their willingness to participate in a theoretical study increased (Passmore et al, 2019). Willingness to participate is optimized when the research conducted has a study question that participants are interested in, the benefit to others is clear, and there is a sense of trust in the researcher and their institution.

2.3.3 Reasons for Non-Participation

While individuals demonstrated strong altruistic motivations, some had reservations for the true use of their samples, feeling that they simply had to trust that the researchers would do the right thing with the information (Michie, Henderson, Garrett & Corbie-Smith, 2011). Genetic samples are often collected using generic consents, in which a participant does not agree to specific studies that their samples will be used for, sometimes called a 'blanket consent' (Kerasidou, 2017). Giving samples for unspecified research or biobanking is an act of trust that depends on the participant's perception of the researcher or their institution. These differences in participant trust can be related to other cultural factors, which will be discussed in following sections.

Individuals can also choose not to participate based on either a lack of time or understanding of the study demands (Irani & Richmond, 2015). The research project also might not be relevant to that individual, or other priorities might be more relevant at the time of recruitment (Irani & Richmond, 2015). While a research project can be of the utmost importance to the research team, the participant might not be similarly motivated to

complete the study. Information about study refusal is difficult to capture however, as individuals who do not wish to participate often do not wish to discuss why they refused.

2.3.3a Historical abuses

Considerable attention has been paid to several famous studies that perpetrated abuses on research participants who were exploited due to particular vulnerability or identity-based power imbalance. While ethical standards and protocols have evolved in response to exposure and discussion of these studies, there are serious cases of historical abuse that cannot be ignored in the perceptions and knowledge of research practice (Grady, 2015).

African American/Black Communities

The United States Public Health Service's study at Tuskegee on untreated syphilis is a commonly cited reason for non participation among African American populations (Scharff et al., 2010). Legacies of exploitative research, or other medical movements perceived as research, have influenced public perception of research which can be prohibitive to current participation. One such example is the development and continued use of a cell line from a biological sample taken from an African American Baltimore resident, Henrietta Lacks, for diagnostic purposes that was later used for research without her consent or compensation. Another critical example is the exploitation of enslaved men and women for medical experimentation and demonstration. In this period, new medical procedures and advances in the fields of anatomy, gynecology, and medical education were developed through purposeful selection of those who did not have the power to refuse participation (Savitt, 1982). So strong was the fear of medical experimentation and death that slave owners created songs to reinforce slave's perceptions of doctors as tormentors

(Savitt, 1982). While individuals might not directly mention one of these experiments by name, a lingering distrust of research and medical organizations has been well documented.

Psychological Studies

Perceptions of research have also been influenced by famous psychological studies such as the Milgram Obedience Study and the Zimbardo Prison Experiment. In both of these studies, researchers designed conditions that were intensely stressful and of questionable ethical standards. While the impact of these controversial studies have not been directly measured, these stories have permeated introductory psychology classes and popular culture. The legacy of many of these controversial studies can distort the public perception of the goals and methods of research. Long term harm can also result from unethical psychological studies, as seen in the unpublished 1939 Tudor study, more commonly known as the Monster Study. The study was an attempt to determine the long term linguistic effect of being labeled as disfluent or a "stutterer". Twenty-two children were selected from an orphanage to participate: some who stuttered and some who did not. Six children with normal speech were told they were stutterers and were severely criticised for any errors or hesitations in their speech. Over time, the children spoke less and showed greater amounts of shame when they made a speech error (Silverman,1988). While it is unclear whether these children had lifelong changes in their speech pattern, as adults, several participants felt that their mental health had been affected by their involvement in early life (Monster Study Still Sings).

Native American Communities

Indigenous American Nations have been the subject of a countless number of atrocities perpetrated by the American government. This long and violent history has

resulted in a greatly diminished population of people who have legitimate concerns about the motivations of health departments and researchers. Genetic research in various Native communities has resulted in major miscommunication and misuse of samples. One of the more well known examples is the case of the Havasupai tribe in Arizona. Elders of the tribe were concerned about the high prevalence of diabetes in the community, and asked a trusted anthropologic researcher at the University of Arizona to recommend a colleague to investigate the health issue. Upon collection, instead of genetic analysis for diabetes, samples were used for a variety of other work without the consent of the tribe. These samples were used to investigate topics that were highly stigmatized, including schizophrenia, that the tribe states they would not have agreed to have been studied. The cultural implication of DNA samples was also not respected by the research team, as the members view the genetic materials as deeply spiritual and see them as a "part of the essence of a person" (as cited in Garrison, 2013). In response to the collection of genetic samples on Native people, an organization titled Indigenous Peoples Council on Biocolonialism has published a guide on genetic research for Native people that explains both the process of collection and cautions people of the historic risks (Indigenous People, Genes and Genetics What Indigenous People Should Know About Biocolonialism).

People with Disabilities

Individuals vary greatly in their ability status; as such, cultural groups concerning ability are diverse in their experiences, needs, and perceptions of people outside their ability group (e.g. the cultural experiences of being blind versus having an intellectual disability differ greatly). Individuals who differ from a culture's ability norm have been opportunistically targeted by medical practitioners and research groups, not always for the

benefit of the individual. Examples of this include the infamous 1955 Willowbrook hepatitis experiment, where institutionalized young children with disabilities were infected with hepatitis (National Institutes of Health, 2009). Though this case study has been explained as a natural experiment, as children at the facility were already exposed to a high rate of hepatitis, taking advantage of the situation to leverage study results was inappropriate. Children in this study were unable to fully assent to the study, and parents were coerced to take part in order for their child to have a space available at the facility (National Institutes of Health, 2009). When research practices have implications about access to care this creates a major ethical concern. Before working with individuals from varying ability, care needs to be taken to ensure that the researcher is not jeopardizing their health or access to care.

Queer Populations

Research concerning the health and life of Lesbian, Gay, Bisexual, and Transgender (LGBT) populations has largely occured within the last few decades. Early work was limited to sociological and anthropological representations of the community, but has since expanded to include psychological and medical research. LGBT populations have also encountered significant discriminiation and medicalization of their identity, which has created systematic distrust in medical or psychological settings.

An example of dubious research ethics in gay communities is an anthropological text titled “Tearoom Trade” published in 1970 which detailed the sexual activities and culture of homosexuality in men. In his work, the researcher, Laud Humphreys, made these observations using deception, including lying about his orientation and using disguises to later interview the men (The Tearoom Trade). He also took notes which included the license plates of the men which he used to track them down one year later (The Tearoom Trade).

He posed as a health researcher and asked them a set of questions, not revealing that he had previously met them (The Tearoom Trade). At the time of publication, the book was highly controversial, as the notes the researcher took described illegal activities (The Tearoom Trade). If subpoenaed, his records could have been evidence against the participants (The Tearoom Trade). The use of deception and the publication of illegal activity could have created serious implications for the people detailed in the book and other individuals in the Queer community.

2.3.4 Implications for Sampling

Studies that have employed dubious research methods have left an impression on public opinion of research, particularly in the affected communities. The reputation of research organizations, universities, and individual researchers can be tarnished by these practices, and create further conversations on how best to include populations in health research. Recruitment of diverse samples creates more nuanced and appropriate conclusions for the broad population (Medin and Lee, 2012). Inclusion is central and crucial to achieving health equity and improving health disparities (Medin and Lee, 2012). However, historical and community context is critical to take into account before selection of population and enrollment in a study. Before embarking on a new project, research teams should review available literature about their study populations.

2.4 Trust

The role of trust in relation to research participation is a complex question. In order to determine aspects of trust in research, these must be understood.

Trust can be seen as an act of accepting a certain amount of vulnerability to another person and having the belief that they will act in a way you expect for the reasons you wish

them to (Kerasidou, 2017; Gambetta, 2000). When an individual trusts another, they ask something of the other, whether it be tangible or emotional. This request leaves a person vulnerable to rejection or failure if the trusted party does not follow through, and has an impact on their future relationship. The act of trust is performed when the trusting individual has assessed the motivations of the other party and views them as aligned with their own moral justification. Using this lens, the relationship between the participant and the researcher can be viewed and issues of mistrust defined.

In the design of a research project, motivations and goals of the study are defined. There are a variety of reasons an investigator might decide to embark on a project: intellectual curiosity, a desire to understand a phenomenon they witness or experience personally, a great perceived need for information, a community request, or prestige or recognition. These motivations have an impact on every element of the project as a philosophical alignment to research including the research questions, design of the study, recruitment methods, communication methods, and dissemination of the results. The act of trust takes place in the researcher from the conception of every project involving human subjects research, as the investigator is reliant on participants to provide information for analysis. This is their core vulnerability: without participants, their work cannot be completed.

When an individual is asked to give information to a research study, they are made vulnerable by their consent. The information, once given, is out of the control of the original owner and can be used in ways that the individual would never approve. This can be amplified in people who are marginalized or stigmatized, as their information can be misinterpreted to justify their continued oppression. The motivations of an individual, as

previously discussed, are varied as well, and have an impact on the length of time and attention paid to the research task. The open honesty or biological specimen given to the project improves its reliability and validity.

Mistrust can arise when either party suspects the motivations of the other. As discussed, suspicion or negative perceptions about researchers can lead to a lack of trust. In order to determine the role of trust in the decision to participate in research, several studies have interviewed participants of past studies. Trust in the researcher was found to be a significant predictor of willingness to participate (Hall, 2006). Trust in the researcher was also significantly lower in populations that were African American or had a health status rated as 'poor'. Lower trust of research and physicians by African American populations has been corroborated by other studies concerned with this topic.

In order to conduct high quality, ethical research, the investigator needs to consider the balance between the motivations and goals of their team and those of the community asked to participate. Communication of the study goals and methods is a crucial component to trust and participation.

2.5 Workshop Development

2.5.2 Existing Programs and Curriculum Development

Currently, very few programs focus specifically on empowering and equipping community members with the knowledge they need to make informed decisions about research participation (Cadman et al., 2014; Coats, Stafford, Thompson, Javois & Goodman, 2015; Goodman, Dias & Stafford, 2010). Thus, there is a need for initiatives that educate individuals who may be approached to participate in research to facilitate equitable

relationships between researchers and community members and to protect potential participants' quality of life.

Community oriented research ethics training programs that have been documented in the literature use a variety of methods to reach individuals and facilitate their ability to become informed research participants. One commonly used method employs a combination of didactic lecture sessions where participants acquire knowledge and skills, and experiential workshops where participants are then able to apply skills learned during lecture (Coats, Stafford, Thompson, Javois & Goodman, 2015; Goodman, Dias & Stafford, 2010). Another programmatic feature of interest is the inclusion of community feedback throughout the curriculum development process (Coats, Stafford, Thompson, Javois & Goodman, 2015).

2.5.3 Teaching Methods

It is important to emphasize the lack of literature on effective training methods for the current populations of interest. Most of the literature focuses on effective methods for recruiting members of minority groups to participate in community trainings. While recruitment is a crucial part of the training process, cultural and linguistic adaptations must be carried forward beyond recruitment and integrated into the methods instructors use to deliver training content. Increasing representation by inviting vulnerable populations to participate in community trainings is neither sufficient nor effective if the content is not presented in an accessible manner.

2.6 Strengths and Limitations

In the literature review, investigators synthesize a wide variety of topics, perspectives, and contexts that converge to create a complex foundation while accounting

for intersecting vulnerabilities in the population of interest. The review also explores a range of research studies rather than limiting the focus to one type of study such as clinical trials. Regarding training development, proposed methods align with identified best practices in the literature.

The investigators also acknowledge the limitations of this project. For the literature review, there was a lack of centralized information on study participation in research other than clinical trials and selected surveillance research. Given the lack of available information, the conclusions drawn might not be representative of the current research field.

3. METHODS

3.1 Workshop Development

3.1.1 Planning and Logistics

Each workshop session was designed to be three hours long. This duration was selected based on guidance from a community best practices toolkit, which emphasizes that a three-hour workshop is best for teaching new concepts and skills while still remaining considerate of individuals' time (University of Kansas, n.d.). The workshop was broken into three modules to appropriately chunk the relevant information. Workshop modules were limited to no more than one hour each to ensure content remained concise and accessible to participants (University of Kansas, n.d.). The plan includes varied workshop activities including roleplay, lecture, group discussions, and partner discussions to reinforce concepts and skill mastery and to maximize participant engagement.

3.1.2 Title of the Workshop

The project was originally titled "Nobody's Guinea Pig: Your Rights in Research". The title was in reference to the common perception that researchers 'experiment' on participants, much like "lab rats" or "guinea pigs". The author selected this name to be attention grabbing and to have an immediate message. An important aspect that the author wanted to emphasize is that this project was not an attempt to recruit people to other studies, make people more willing to participate in studies, or even assess how willing they are to participate in research. The author recognized that since the populations they are working with might be vulnerable, any information produced could be used against the community. The title was an attempt to clearly position the workshop against exploitative research, so that the spirit of the project was immediately and unequivocally conveyed to participants. It is understood that the name can be seen as inflammatory.

3.2 Curriculum

3.2.1 Information Source and Tailoring

In 2013, the Maryland Center for Health Equity created a website titled "Building Trust between Minorities and Researchers" which serves as a toolkit of resources for researchers and research participants to facilitate mutually beneficial, collaborative partnerships and to provide ethical practices that honor the rights and responsibilities of both parties in research (Maryland Center for Health Equity, n.d.-b). The resources, which include modules for engaging community members in research, were used as foundational material for the training curriculum to ensure that the content, despite its tailoring to the population of interest, is grounded in evidence-based practice.

In order to be relevant to the population of interest, workshop presentations and handouts were modified in compliance with the Office of Minority Health's Cultural and Linguistic Access Standards, particularly in reference to the Principle Standard (U.S. Department of Health and Human Services Office of Minority Health, 2016). Materials used in the training, including all surveys, were written at an 8th grade readability level and were checked using a Composite Readability scoring system (Automatic Readability Checker, n.d.). This scoring system uses a composite score from seven different readability scoring tests, including the The Flesch-Kincaid tests, the SMOG Index, and the Linsear Write Formula (Automatic Readability Checker, n.d.).

3.2.2 Rationale for Concepts

The author designed a lesson plan based on the information and material provided by the "Building Trust" website (see **Appendix A. Lesson Plan and Activities**) Concepts for the lesson plan were split into three modules that build on each other to support the

specific aims of increasing knowledge and self-efficacy about decision-making in research. The first module provides a broad overview and aims to increase participants' understanding of research and its goals. The second module equips individuals with useful questions to ask researchers should they be approached to participate; the third module discusses important aspects of research such as the meaning of true informed consent and what to look for in terms of data storage and privacy.

3.2.3 Rationale for Materials

Workshop materials included a sample consent form from the University of Maryland IRB and the "Questions to Ask a Researcher" handout from the "Building Trust" website. These materials were selected to reinforce key takeaways and skill mastery so that individuals knew how to read a consent form and could refer back to questions they could use to protect themselves as research participants (see **Appendix A.**).

3.3 Strengths and Limitations

The project has several strengths in design and methods. Workshop content is grounded in evidence-based practice as presented on the "Building Trust" website. Workshop modules help to break up information into manageable pieces. Instructors also varied teaching methods to maximize participant engagement.

The material in the lesson plan required further tailoring and evaluation to determine effectiveness of the proposed plan. Future iterations of the workshop should be evaluated and

4. CONSIDERATIONS FOR IMPLEMENTATION

4.1 Literacy

Little information was available in the literature about Prince George's County residents preferences for workshops and other interventions. The author instead based program needs on literature that addresses the preferences of populations with low literacy. This is evident in the survey materials and the limited amount of proposed in-class written materials. Teaching methods using a powerpoint presentation were also ruled out, as it would require reading quickly or taking notes for participants. A conversational workshop style was selected to engage people and to allow space for them to share their experiences with research. The author also considered how a formal presentation might be appropriate for some audiences and alienating for others. A powerpoint can serve as a symbol that activates the power dynamic of the presenter as a voice of authority and the participant as a passive receiver of information. This method was rejected for these reasons.

Alternative methods for making all workshop materials should also be explored, including reading survey questions out loud or assisting people in filling out forms or worksheets. If more feasible, implementation should include flexibility of written materials.

4.2 Language

The proposed workshop and all materials were developed exclusively in English. Neither of the investigators have Spanish proficiency, and were not able to hire an interpreter for the workshop due to limited funding. Based on the community the project was built to serve, materials and information in Spanish would be appropriate. This is an area of expansion for the program, and would benefit from a subject matter expert for cultural tailoring and delivery.

5. SIGNIFICANCE AND INNOVATION

At its core, public health is about prevention. Prevention is inherent in the study's goal to reach community members prior to involvement in human subjects research so that they are able to make the most informed and appropriate decisions regarding research participation. This project is innovative because it attempts to balance accountability in research. It is necessary to educate researchers so that they may uphold ethical standards within their own work; however, in placing sole responsibility on this party, it creates a power imbalance and assumes less capability of those who enroll as participants. Thus, making research ethics accessible to participants fosters equitable accountability in a way that prior research ethics trainings have not because they focus on the researcher.

6. CONCLUSION

The conception of the project and final product have a key element of the philosophy of the work: collaboration. This project utilizes academic resources in the academic literature already available, the university specific resource of the Building Trust website, and the values and feedback of the community. By combining them into one final workshop, content has the benefit of academic integrity and community tailoring. Future iterations of this project can further refine the important components of each, strengthening each time through evaluation measures.

The history of research practice is undeniable. Incredible strides in research ethics have already been implemented and disseminated, greatly reducing the risk of harm to participants. This work aims to build on these advancements and alter the research paradigm. The hope of the authors is that this work is used to benefit the community and that they are able to use the knowledge and skills gained in the workshop to be active and informed decision makers about research participation. The future of research includes a diversification of research recruitment and involvement. The aim of this is based in justice- to create scientific results that are accurate for the nation. The authors hope that this work contributes to the methods being just as well, to offer resources and information equitably to those who need it.

For the companion piece to this work, please see Deane-Polyak, 2020 for the implementation and evaluation methods for the proposed workshop: Nobody's Guinea Pig: Your Rights in Research.

7. APPENDICES

7.1 Appendix A . Lesson Plan and Activities

7.1 Lesson Plan Outline

Lesson Plan (3 hours)

PRE-SURVEY (*20-25 minutes*)

INTRODUCTION/ICEBREAKER (*Discussion ~ 5-10 minutes*)

Discussion question: What do you think of when you hear the word "research"?

MODULE 1: What is research? (*Lecture ~ 35 minutes*)

Objective: To create a mental image of research.

a. Overview of research types (*~15 mins*)
    i. What is research? (Maryland Center for Health Equity, n.d.-b)
        1. Research definition: The practice of studying some subject (i.e. person, animal, object, weather pattern, phenomenon) to discover or learn new information about that particular subject
        2. Aspects of research:
            a. Research question: Based on a topic or phenomenon that a person would like to know more about
            b. Hypothesis: An educated guess about the outcome of the research based on existing knowledge or evidence (i.e. Predicting that if you increase the amount of books in a classroom, the students will read more)
            c. Experiment: A procedure that is used to test a hypothesis, make a new discovery, or show evidence of some fact. Sometimes this includes a set of conditions that the researcher puts in place (i.e. giving a new medication to mice in a laboratory setting to see how their body systems react). Other times, the researcher may observe something that occurs naturally (i.e. weather patterns and how they affect plant growth).
    ii. Where might they encounter research?
        1. Places where your information is taken for research already
            a. Legal records (i.e. birth and death certificates)
            b. Census Records
            c. Medical records
        2. Places where you might be enrolled
            a. Doctor's office
            b. Recruitment Flyer
            c. Community center

d. University campus

iii. Why is research needed and what is it used for?

1. Generally
   a. To find out more information about a topic
      i. More detail about a specific topic (disease, ect)
      ii. Find support for other studies that have studied a topic
2. Depends on the type of research (GIVE, TAKE, DO)
   a. Health research **improving the health of people**
      i. To try out a new type of medical service (e.g. having interpreters available by telephone vs in person)
         1. Demographic information
         2. Opinion
         3. Medical records
      ii. To monitor changes in a new procedure (A new method comes out, they want to see the health status of patients on the old procedure vs the new one- not always an 'experiment' on patients, sometimes you just compare naturally occurring situations)
         1. Demographic information
         2. Medical records
      iii. Health disparities research: to compare the health of different groups of people to see if there are differences in people (so that we can try to change the situations that create these differences)
         1. Demographic information
         2. Health history
         3. Genetic Sample
      iv. Making new medicines and vaccines (sometimes need genetic samples)
         1. Demographics
         2. Genetic sample
         3. Medical readings

b. Activity: Give, Take, Do - What are You Comfortable Sharing? (~*10min*):
Question: What kinds of information are you comfortable giving away?
Instructors will have a list of potential pieces of information that people may be asked for in research (e.g. demographic information, medical history, genetic samples, public social media (internet searches, twitter), medical records, opinions, etc.). Participants will pick a few topics from this list, write them on separate post-it notes and place them on one of three posters displayed around the room that indicate their feelings on sharing this information in a research setting (Comfortable Sharing, Not Comfortable Sharing, No Opinion). After everyone has placed their post-it notes,

participants will be asked if they would like to elaborate or discuss the placement on the posters.

c. Discussion (*~10min*) -- If activity 1b runs long, discussion will be skipped.

Questions

i. What kind of research do you think is valuable or important to you?

ii. Is there something you would like the researcher to know about the way they conduct projects, talk with people, recruit, or contact people? What would you want a researcher to know as a participant?

MODULE 2: Knowledge is power - (*Experiential ~ 20 minutes*)

Objective: To provide participants with tools they can apply to make informed decisions about research participation

a. Explanation of activity (*~5 minutes*)

b. Partner activity (*~15 minutes*): Pick and share your three most important questions from the list: 10 key questions to ask a researcher. Report back to the group.(Maryland Center for Health Equity, n.d. -a)

---------- BREAK (*~10 min*) ----------

MODULE 3: Protections today - (*Lecture ~35 minutes*)

Objective: To increase knowledge about research protections and increase participant confidence if they ever participate in research

a. Informed Consent: Role play** (*~5 mins*) Overview of research protections (*~30 mins*)

b. Informed consent break down

i. What does "informed consent" mean?

a. A process of communication between the researcher and the participant in which a participant learns about the risks, benefits, and alternatives to what they are being asked to give/take/do in the study.

b. Given voluntarily

c. Can be given by signing a form or verbally agreeing to participate in the research

1. Activity: Reading a consent form. Instructors will review a template consent form from the University of Maryland IRB with participants. They will cover the following aspects in detail:

a. Explanation of the study- what participants will be asked to do in the study

b. Risks - any consequences of the study (i.e. emotional distress, loss of time etc.)

i. Information on resources for support (i.e. counseling services)

c. Benefits - what participants will gain from being in the study (i.e. knowledge, skills)
d. Compensation (optional) - some studies will offer compensation in the form of cash, food, vouchers, giftcards, coupons, etc. for participating
e. Researcher's contact information

2. Why is informed consent important to you?
   a. Tells what will be asked of you

ii. Data Safety
1. De-identifying participants
2. How will your information be stored during the study? (should say in consent form)
3. What can your information be used for? (should say in consent)

iii. IRB protections
1. Oversight committee that assesses all projects that involve human subjects
2. You can contact them, need the number on the consent form

iv. Right to leave a study
1. At any time
   a. You might not get the compensation
2. Should not affect your **non study related** medical care

POST-SURVEY (*20-25 minutes*)

7.1a Activity: Give, Take, Do - What are You Comfortable Sharing?

Inputs:	Comfortable Sharing	No Opinion	Not Comfortable Sharing
- Biological sex - Age - Socioeconomic status - Education level - Annual income - Religion - Spirituality - Gender identity - Sexual orientation - Citizenship status - Preferred language - Medical history - Genetic sample (i.e. cheek swab, blood sample) - Social media name/link - Medical records - Political party affiliation			

7.1b Activity: Questions to Ask a Researcher

BUILDING TRUST
BETWEEN MINORITIES AND RESEARCHERS

A Program of the Maryland Center for Health Equity
at the University of Maryland School of Public Health
www.buildingtrustumd.org

Key Questions to Ask a Researcher

Here are some key questions that experts recommend you ask a researcher before joining any study, whether it involves an interview, focus group, a study of a new program, or a clinical trial.

1. **What is the main purpose of the study?**
2. **What will I be asked to do during the study?**
3. **How will I benefit from participating in this study?**
4. **What are the possible risks?**
5. **How will the results be shared?**
6. **How will my personal information be kept confidential?**
7. **How long is the study going to last?**
8. **Are there any reimbursements or incentives offered?**
9. **Who is funding the study?**
10. **What are the credentials of the researcher and the researcher's institution?**

In addition, if you are considering a clinical trial, here are some additional questions:

If I am asked to take a drug or treatment, how will it be given to me (pill, injection, surgically)?
Do I have to pay for any part of the study? Will my insurance cover these costs?
If the treatment works, can I keep using it after the study has ended?
If I have a bad reaction to the treatment, how can I get medical care?
Will I receive any follow-up care after the trial is over?

Finally, here are some general tips and suggestions to help you during the informed consent process:

Consider bringing a family member or friend along.
Ask questions whenever you need more information.
Do not hesitate to ask if something is unclear.
Bring a list of questions with you that you would like answered.
Write down the answers so you can review them later.
Ask if you can record the conversation.
Take time to make your decision.

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7.1c Activity: Reading a Consent Form

CONSENT TO PARTICIPATE

Project Title	*Project Title*
Purpose of the Study	*This research is being conducted by **[Principal Investigator]** at the University of Maryland, College Park. We are inviting you to participate in this research project because you _____. The purpose of this research project is _____.*
Procedures	*The procedures involve __.*
Potential Risks and Discomforts	*There may be some risks from participating in this research study.*
Potential Benefits	*There are no direct benefits from participating in this research. However, possible benefits include_____.* ***OR** The benefits to you include_____ . We hope that, in the future, other people might benefit from this study through improved understanding of ___.*
Confidentiality	*Any potential loss of confidentiality will be minimized by_____. **[storing data in a secure location such as: locked office, locked cabinet, password protected computer, etc].*** *If we write a report or article about this research project, your identity will be protected to the maximum extent possible. Your information may be shared with representatives of the University of Maryland, College Park or governmental authorities if you or someone else is in danger or if we are required to do so by law.*

Medical Treatment **[*If Necessary]**	*The University of Maryland does not provide any medical, hospitalization or other insurance for participants in this research study, nor will the University of Maryland provide any medical treatment or compensation for any injury sustained as a result of participation in this research study, except as required by law.*
Compensation **[*If Necessary]**	*You will receive _____. You will be responsible for any taxes assessed on the compensation.* *If you will earn $100 or more as a research participant in this study, you must provide your name, address and SSN to receive compensation.* *If you do not earn over $100 only your name and address will be collected to receive compensation.*
Right to Withdraw and Questions	*Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.* *If you decide to stop taking part in the study, if you have questions, concerns, or complaints, or if you need to report an injury related to the research, please contact the investigator:* ***[Principal Investigator]*** ***[Address]*** ***[Email]*** ***[Telephone Number]*** ***[*Co-Investigator information may be listed as well.]***
Participant Rights	*If you have questions about your rights as a research participant or wish to report a research-related injury, please contact:* University of Maryland College Park

	Institutional Review Board Office 1204 Marie Mount Hall College Park, Maryland, 20742 E-mail: irb@umd.edu Telephone: 301-405-0678 *For more information regarding participant rights, please visit:* https://research.umd.edu/irb-research-participants *This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human subjects.*	
Statement of Consent	*Your signature indicates that you are at least 18 years of age; you have read this consent form or have had it read to you; your questions have been answered to your satisfaction and you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.* *If you agree to participate, please sign your name below.*	
Signature and Date	**NAME OF PARTICIPANT [Please Print]**	
	SIGNATURE OF PARTICIPANT	
	DATE	

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