REACH Implicit Bias Training Project

NCT03415308

4/20/2023

DUHS IRB Application (Version 1.59)

General Information

***Please enter the full title of your protocol:**

Development and pilot testing of an implicit bias training intervention for providers to advance equity in healthcare

***Please enter the Short Title you would like to use to reference the study:**

REACH Project 1
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Add Study Organization(s):

List Study Organizations associated with this protocol:

Primary Dept?	Department Name
◆	**DUHS** - Duke Default Department

Assign key study personnel (KSP) access to the protocol

*** Please add a Principal Investigator for the study:**

(Note: Before this study application can be submitted, the PI MUST have completed CITI training)

Svetkey, Laura

3.1 If applicable, please select the Key Study personnel: (Note: Before this study application can be submitted, all Key Personnel MUST have completed CITI training)
*** Denotes roles that are not recognized in OnCore. Please select an appropriate role that is recognized in all clinical research applications (iRIS, OnCore, eREG, etc.)**

A) Additional Investigators, Primary Study Coordinator (CRC), and the Primary Regulatory Coordinator (PRC):

Bennett, Gary
Co-PI
Wilson, Sarah
Co-PI

B) All Other Key Personnel

Alkon, Aviel
Computer Programmer*

Corneli, Amy
Collaborator
Corsino, Leonor
Collaborator
Davenport, Clemontina
Analyst*
Davis, Joseph
Analyst*
Falkovic, Margaret Barry
Interviewer/Surveyor
Fischer, Jonathan
Collaborator
Fish, Laura
Collaborator
Gonzalez-Guarda, Rosa
Interviewer/Surveyor
Hanlen, Emily
Collaborator
Johnson, Kimberly
Sub-Investigator
Liu, Evan
Other
Majors, Alesha
Study Coordinator (CRC/CRNC/RPL)
Matsouaka, Roland
Statistician
McKenna, Kevin
Collaborator
Mueller, Collin
Other
Olsen, Maren
Statistician
Perry, Brian
Collaborator
Redmond, Rebecca
Collaborator
Reese, Benjamin
Collaborator
Seidenstein, Judy
Collaborator
Stafford, Kamryn
Other
Steinhauser, Karen
Sub-Investigator
Svetkey, Laura
Sub-Investigator
Wood, Heather
Computer Programmer*
Wood, Heather
Other
Yang, Hongqiu
Statistician

***Please add a Study Contact:**

Majors, Alesha
Svetkey, Laura
Wilson, Sarah

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g., The study contact(s) are typically the Principal Investigator, Study Coordinator, and Regulatory Coordinator.)

Oncore

Please select the Library for your Protocol:

This field is used in OnCore. Determines the Reference Lists, Forms, Protocol Annotations, Notifications, and Signoffs available for the protocol. Protocols that require reporting to the NCI (National Cancer Institute), must select the Oncology library.

- ○ Oncology
- ◉ Non-Oncology

Protocol Application Type

Select the type of protocol you are creating:

Please see additional criteria and information in the policy titled "Reliance on the IRB of Another Institution, Organization, or an Independent IRB" on the **IRB web site**.

- ◉ Regular Study Application - Most common. The IRB will determine if the study is eligible for expedited review or requires full board review upon submission.
- ○ Application for Exemption from IRB Review - Includes Exempt, Not Human Subject Research, & Not Research.
- ○ External IRB Application - Any study using an external IRB as the IRB-of-Record.
- ○ Trainee Research While Away from Duke - Research conducted by medical students overseen by the Office of Curriculum & other student/trainee research away from Duke.
- ○ Individual Patient Expanded Access, Including Emergency Use - Use of an investigational product under expanded access, including emergency use of an investigational drug or biologic or emergency use of an unapproved device.

Conflict of Interest

Are any key personnel an inventor of any of the drugs, devices or technologies used in this research?

○ Yes ◉ No

Do any key personnel have a conflict of interest management plan issued by DOSI-COI related to this research?

○ Yes ◉ No

Oversight Organization Selection

CRU (Clinical Research Unit) or Oversight Organization Selection:

Please select the CRU.

Medicine

The Clinical Research Unit that takes responsibility for this study.

- Please select **Medicine** as the CRU **only** if the PI is in one of these Divisions or Institutes: Endocrinology, Gastroenterology, General Internal Medicine, Geriatrics, Hematology, Infectious Diseases, Nephrology, Pulmonary, Rheumatology & Immunology, Center for Applied Genomics and Precision Medicine, Center for the Study of Aging and Human Development, Duke Molecular Physiology Institute.
- More information on CRUs can be found on the Duke Office of Clinical Research (DOCR) website, **http://docr.som.duke.edu**
- Questions concerning CRU selection should be directed to docr.help@dm.duke.edu.
- For questions about the Campus Oversight Organization, please visit **Campus Oversight Organization**.

List all Key Personnel on the study who are outside Duke:

- **Note:** You will also need to attach the documentation of Human Subjects Certification for each individual, if they have completed the certification somewhere other than Duke.
- **If outside key personnel will have access to Duke PHI, a data transfer agreement AND external site IRB approval (or IRB authorization agreement) will be needed.** See HRPP policy **Use of Research Data by Former Duke Students or Former Duke Faculty and Employees**
- In the panel below, "PHI" is Protected Health Information.

Entry 1

Name	Brandy Sullivan
Study Role	Volunteer
Email Address	brandyhsullivan@yahoo.com
Institution / Organization	UNC
Will he/she have access to Duke P.H.I.?	(•) Yes ( ) No
Is he/she an unpaid volunteer at Duke on the study?	(•) Yes ( ) No

Entry 2

Name	Debra Rotor
Study Role	Trainer/Collaborator
Email Address	droter1@jhu.edu
Institution / Organization	Johns Hopkins University/RIASPrime
Will he/she have access to Duke P.H.I.?	( ) Yes (•) No
Is he/she an unpaid volunteer at Duke on the study?	( ) Yes (•) No

Entry 3

Name	Michele Massa
Study Role	Trainer/Collaborator
Email Address	mmassa1@jhmi.edu
Institution / Organization	Johns Hopkins Medical Institute/RIASPrime
Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	○ Yes ◉ No

Entry 4

Name	Ariel Domlyn, PhD
Study Role	Collaborator
Email Address	ariel.domlyn@duke.edu
Institution / Organization	Durham VA Medical Center
Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	○ Yes ◉ No

Entry 5

Name	Jessica Breland, PhD
Study Role	Collaborator
Email Address	Jessica.Breland@va.gov
Institution / Organization	VA Palo Alto Health Care System
Will he/she have access to Duke P.H.I.?	○ Yes ◉ No
Is he/she an unpaid volunteer at Duke on the study?	○ Yes ◉ No

Indicate the Protocol source below:

The protocol source is the author of the protocol. If the protocol is a joint authorship between multiple sources, select the primary author.

An IRB fee may be assessed for all research that is supported by for-profit entities and requires full board review. For additional information, see the **IRB fees section of the IRB web site**

- ◉ PI initiated
- ○ Commercial / Industry (for-profit entity) initiated
- ○ Federal Government initiated
- ○ Cooperative Group Initiated

○ Foundation (non-profit group) initiated
○ Other

Sponsor and Funding Source

Add all funding sources for this study:

View Details	Sponsor Name	Sponsor Type	Contract Type:	Project Number	Award Number
⊟	National Institutes of Health (NIH)	Externally Peer-Reviewed	Grant		

Sponsor Name:	National Institutes of Health (NIH)
Sponsor Type:	Externally Peer-Reviewed
Sponsor Role:	Funding
Grant/Contract Number:	1U54MD012530-01/3U54MD012530-05S2 (Supplement)
Project Period:	From:09/25/2017 to:06/30/2023
Is Institution the Primary Grant Holder:	Yes
Contract Type:	Grant
Project Number:	
Award Number:	
Grant Title:	
PI Name: (If PI is not the same as identified on the study.)	
Explain Any Significant Discrepancy:	

Is this a federally funded study?

◉ Yes ○ No

Does this study have any of the following?

- Industry sponsored protocol
- Industry funded Duke protocol
- Industry funded sub-contract from another institution
- Industry provided drug/device/biologic
- SBIR/STTR funded protocol

○ Yes ◉ No

As part of this study, will any samples or PHI be transferred to/from Duke to/from anyone other than the Sponsor, a Sponsor subcontractor, or a Funding Source?

○ Yes ◉ No

Is the Department of Defense (DOD) a funding source?

○ Yes ◉ No

For Federally funded studies:

Is your funding subject to, and does it comply with, the funding agency's policy for data sharing?

◉ Yes ○ No

Check all that apply:

- ☐ NIH Genome Sharing - dbGaP
- ☐ NIH Genome Sharing - GWAS
- ☐ NIH Genome Sharing - NCI databases
- ☐ NIH Genome Sharing - other
- ☐ Non-NIH Genomic
- ☑ General Data Sharing

Enter the Grant Number or Other Federal Agency Proposal or Application Number:

1U54MD012530-01 (Parent Project) and 3U54MD012530-05S2 (Admin Supplement)

Note: The Federal Funding Agency ID Number is the Sponsor's grant number assigned to your project and available on your Notice of Award (example: R01HL012345).

If known, enter the SPS (Sponsored Projects System) number if applicable:

231964

In the Initial Submission Packet, attach the following:
(1) The entire grant, or an explanation of why a grant is not needed.
(2) NIH institutional Certificate form related to data sharing (if applicable).

Mobile Devices and Software

Does this study involve the use of a software or a mobile application?

○ Yes ◉ No

List all software, including third party (non-Duke) and mobile apps, that will be utilized for ascertainment, recruitment, or conduct of the research/project: (eg, MaestroCare, DEDUCE):

Multi-site Research

Is this a multi-site study?

○ Yes ◉ No

Complete for each site if Duke is the Primary grant awardee or coordinating center:

Entry 1

Site Name:	
City:	
State/Province:	
Country:	
	Site Contact Information
Primary Contact Name:	
Primary Contact Phone:	
Primary Contact Email:	
	Site Details
Does the site have an IRB?	○ Yes ○ No
Site IRB approval expiration date:	
If date not provided, explanation of why:	
Has the site granted permission for the research to be conducted?	○ Yes ○ No
Does the site plan to rely on the DUHS IRB for review?	○ Yes ○ No
What is the status of the study at this site?	○ Open ○ Closed
Site approval letters or site personnel lists:	Attach site approval letters, site closure letterS (if applicable), or site personnel lists in the Initial Submission Packet.

Research Abstract

Please type your Research Abstract here:

The Research Abstract should summarize the main points of your study in one paragraph. The following guidelines may help you:

1. Purpose and objective (1-2 sentences)
2. Study activities and population group (2-4 sentences)
3. Data analysis and risk/safety issues (1-2 sentences)

The overall goal and theme of the Duke Center for Research to Advance Equity in Healthcare is to reduce racial and ethnic disparities in health through interventions that affect the clinical encounter. To achieve this goal, there is an urgent need for interventions that address implicit bias in healthcare. Implicit bias training is widely used to raise self-awareness and provide self-

management tools. Our overall objective is to test the hypothesis that implicit bias training for healthcare providers will reduce racial and ethnic disparities in patient- centered care. The proposed project will lay the groundwork for testing that hypothesis by using patient focus groups to garner a deeper understanding of perceptions of implicit bias in the clinical encounter; provider and health system stakeholder semi-structured interviews to inform refinement of the existing implicit bias training at Duke; and perform a pilot study of implicit bias training for providers. At the conclusion of this study, we will have the necessary preliminary data to propose a definitive trial to determine the impact of an implicit bias training intervention for providers on racial and ethnic disparities in patient-centered care. This research will ultimately lead to the delivery of equitable, evidence-based, patient-centered care for all.

Research Summary

State your primary study objectives

This project will lay the groundwork for testing that hypothesis by using patient focus groups to garner a deeper understanding of perceptions of implicit bias in the clinical encounter; provider and health system stakeholder semi-structured interviews to inform refinement of the existing implicit bias training at Duke; and perform a pilot study of implicit bias training for providers. At the conclusion of this study, we will have the necessary preliminary data to propose a definitive trial to determine the impact of an implicit bias training intervention for providers on racial and ethnic disparities in patient-centered care. This research will ultimately lead to the delivery of equitable, evidence-based, patient-centered care for all.

State your secondary study objectives

Administrative Supplement:

To preserve and increase the overall impact of this work and move it forward towards a clinical trial to determine effectiveness, in the administrative supplement we will: 1) Characterize outcomes for assessing clinicians' use of the implicit bias mitigation skills that are emphasized in the REACHing Equity curriculum by coding 80 existing audio-recorded new patient encounters using the Roter Interaction Analysis System (RIAS) to ascertain provider-level individuation and empathy skills. 2) Refine the REACHing Equity curriculum to facilitate implementation without compromising content and experiential learning, and 3) Develop a taxonomy of equity-focused implementation strategies by conducting the Implementation Strategies for Health Equity Delphi Panel.

These aims will complete the goals of this research project and set the stage for an effectiveness trial of curriculum for clinicians designed to mitigate implicit bias in clinical care.

Please select your research summary form:

Standard Research Summary Template

This is the regular (generic) research summary template which is required for all regular applications (unless your protocol fits under the other research summary templates in this category). Use of these instructions is helpful for ensuring that the research summary contains all necessary elements.

Standard Research Summary

Purpose of the Study

- Objectives & hypotheses to be tested

This project will lay the groundwork for testing that hypothesis by using patient focus groups to garner a deeper understanding of perceptions of implicit bias in the clinical encounter; provider and health system stakeholder semi-structured interviews to inform refinement of the existing implicit bias training at Duke; and perform a pilot study of implicit bias training for providers. At the conclusion of this study, we will

have the necessary preliminary data to propose a definitive trial to determine the impact of an implicit bias training intervention for providers on racial and ethnic disparities in patient-centered care. This research will ultimately lead to the delivery of equitable, evidence-based, patient-centered care for all.

Aim 1. Identify patient preferences for constructs, and related outcomes, that reflect the expression of implicit bias in clinical encounters. We will use qualitative methods to gather data on the elements associated with the patient perception of implicit bias (e.g. communication, respect, patient-centeredness) to ensure that our selected outcomes reflect the breadth of patients' concerns.

Aim 2. Refine an existing implicit bias intervention with input from providers, health system stakeholders and expert consultation. We will conduct a series of semi structured interviews to gather insights from stakeholders regarding how to best refine the design of our existing implicit bias intervention to ensure that we have addressed potential facilitators and barriers to uptake, use, and sustainability.

Aim 3. In a pilot trial, determine the feasibility of delivering the refined implicit bias reduction intervention and assessing patient centered outcomes. We will conduct a feasibility trial using the refined intervention emerging from Aim 2. These feasibility outcomes will prepare us for a future, fully-powered randomized trial of implicit bias training.

Administrative Supplement:

To preserve and increase the overall impact of this work and move it forward towards a clinical trial to determine effectiveness, in the administrative supplement we will:

Aim 1. Characterize outcomes for assessing clinicians' use of the implicit bias mitigation skills that are emphasized in the REACHing Equity curriculum by coding 80 existing audio-recorded new patient encounters using the Roter Interaction Analysis System (RIAS) to ascertain provider-level individuation and empathy skills.

Aim 2. Refine the REACHing Equity curriculum to facilitate implementation without compromising content and experiential learning.

Aim 3. Develop a taxonomy of equity-focused implementation strategies by conducting the Implementation Strategies for Health Equity Delphi Panel.

These aims will complete the goals of this research project and set the stage for an effectiveness trial of curriculum for clinicians designed to mitigate implicit bias in clinical care.

Background & Significance

- Should support the scientific aims of the research

Despite substantial improvements in the overall health of our nation, racial and ethnic disparities in health and healthcare remain ubiquitous. Disparities are apparent after controlling for access to care, insurance, income, patient preferences, and clinical need, suggesting that providers and health systems are important contributors to racial disparities in healthcare. In its landmark report, "Unequal Treatment," the Institute of Medicine concluded that providers contribute to disparities through the effects of implicit bias. Implicit bias occurs when thoughts and feelings outside of conscious awareness and control affect judgment and/or behavior. It is closely related to stereotyping, but not necessarily associated with explicit bias (i.e., prejudice). It leads to involuntary "blind spots" in virtually all of us. Implicit racial bias in providers is associated with Blacks (compared to Whites) experiencing lower patient-centered communication, worse doctor-patient relationships, lower confidence in the doctor, and poorer health outcomes. Therefore, to address health disparities, there is an urgent need for interventions that address implicit bias in healthcare.

Across society, implicit bias training is increasingly used in public service, business and healthcare settings to raise self-awareness and provide self-management tools for avoiding actions based on implicit bias. While such interventions are well-conceived and intuitively attractive, they have not been rigorously tested. In order to make optimal use and insure sustained support for such training, its effectiveness must be rigorously demonstrated. Our overall objective is to test the hypothesis that implicit bias training for healthcare providers will reduce racial/ethnic disparities in patient-centered care.

Administrative Supplement:

Although implicit bias is not the only factor leading to healthcare disparities and mitigating it will not dismantle or eliminate systemic racism in healthcare, it is reasonable to expect that successfully mitigating the effects of implicit bias can contribute significantly to health equity. However, although implicit bias training programs are widespread in medical education and in healthcare settings, evidence of best practice and impact is lacking.

In the parent project (Development and feasibility testing of an implicit bias training intervention for providers to advance equity in healthcare), we sought to fill this evidence gap. We obtained qualitative input from patients, clinicians, and health system leaders; developed an implicit bias educational curriculum for clinicians that is based on evidence linking attitudes and behaviors to racial disparities in care; and pilot-tested the curriculum for feasibility and acceptability. Successfully completing these steps led to the identification of specific needs for preserving and advancing this science, namely the need to identify and characterize appropriate outcomes for implicit bias training; refine the REACHing Equity curriculum to optimize content and delivery and to facilitate successful implementation without compromising its comprehensive scope and experiential learning; and establish an empirical equity-focused approach to implementation science to inform strategies for program dissemination and implementation

Design & Procedures

- Describe the study, providing detail regarding the study intervention (drug, device, physical procedures, manipulation of the subject or the subject's environment, etc.). Discuss justifications for placebo control, discontinuation or delay of standard therapies, and washout periods if applicable. Identify procedures, tests and interventions performed exclusively for research purposes or more frequently than standard of care. Include alternative therapies, concurrent therapies discontinued per protocol, risk benefit ratio, and use of tissue/specimens. Discuss monitoring during washout periods if applicable. Include brief description of follow-up, if any.

This project consists of 3 smaller projects that correspond to each aim.

Aim 1 Focus Groups: There will be 1 group for each of the race/education combinations: Black/high education; Black/low education; White/high education; White/low education; Hispanic/high education; Hispanic/low education (6 groups total). The focus groups will be conducted by an experienced focus group facilitator, who is race-concordant with the group, accompanied by a co-facilitator, and audio-taped.

The focus group guide will direct the facilitator to begin with open-ended questions about the participants' personal experience of the healthcare encounter (i.e., a grand tour question). We expect that open-ended questioning will elicit responses reflecting some or all of the domains addressed in the Interpersonal Processes of Care (IPC) survey and give us insight into patient perceptions of these domains. However, if not spontaneously elicited, we will ask follow up probe questions regarding the importance of each of the domains. In addition, we may learn from participants that there are other relevant domains that are not included in this survey instrument, but which should be assessed. We also will probe areas in which validated measures exist to receive feedback on their importance (e.g., patients' overall trust of the provider and perception of the provider's respect). Patient responses will help us prioritize these domains, and identify any missing dimensions that should be measured.

We will conduct follow-up interviews with up to 20 participants. We will pool from both existing focus group participants and new participants. Former participants will be emailed to assess their interest in participation. If interested, participants will be enrolled in the same way as the focus groups. After consenting online via RedCap, they will be scheduled for a time to talk one on one with a race-concordant member of the study team. These interviews will be up to 60 minutes conducted by telephone or in person. The interview guide will be based on the gaps in knowledge from the focus groups. Participants will be paid $50 for their participation in these interviews.

Aim 2 Stakeholder Interviews.

Expert consultation: The nascent scientific literature on implicit bias interventions has not yet established guidelines to inform program design. In lieu of such guidelines, we believe it critical to expose our intervention to expert review. Early in the first year of funding, Howard Ross of Cook Ross Inc. will spend a day at Duke. Cook Ross Inc. is a consulting firm that provides training in the areas of diversity, inclusion, cultural competency, leadership development, and organizational change management. Howard Ross is a founding partner who leads implicit bias workshops for health professionals. During his visit, we will review with Ross our current intervention and potential innovations, and get his input on potential adaptations that might increase impact, feasibility and/or acceptance.

Provider and health system stakeholder perspectives: We will conduct semi-structured interviews of providers and health system stakeholders to determine an implicit bias training design that optimizes engagement and impact. The primary purpose of these interviews is to identify barriers and facilitators to conducting implicit bias training for providers. A secondary goal will be to review the logistical considerations associated with conducting the planned implicit bias training intervention trial in the clinical setting.

Interview methods: To inform our understanding of intervention uptake and implementation, we will recruit approximately 30 providers to participate in telephone-based or Zoom-based semi-structured individual interviews to identify potential facilitators and barriers to use and implementation of implicit bias training. Exact sample size will be dictated by thematic saturation.

Interview questions are based on Weiner's Theory of Organizational Readiness for Change (ORC), which refers to the extent to which organizational members are prepared to make changes in organizational policies/practices that are necessary to implement and support innovation use (change commitment) and their perceived ability to do so (change efficacy). Attributes impacting ORC include change valence (perceived value of the innovation) and information about perceived task demands, resource availability, and situational context (e.g., competing demands). This framework combined with health system experience will allow us to create a guide to explore issues such as: specific cultural and health system practices that serve as barriers and facilitators to addressing implicit bias, potential prior experience with training or bias awareness, and facilitators and barriers to translating training into practice. The team has extensive experience creating interview guides that allow participants to speak directly from their experience to address study questions, in an interviewee centric manner. We will also administer a brief questionnaire to characterize our sample and assess background demographic characteristics. We will ask previously-interviewed participants one additional demographic question by email.

Interviews will last approximately 30-40 minutes, will be digitally recorded, transcribed by Datagain and coded using qualitative research data management software (i.e., Atlas.ti software). Participants will be informed that their supervisors will not have access to individual participant audio-recordings or transcripts.

Training new trainers: In the final year of this project, we will create a training guide and certification process based on a train-the-trainer model.

Implicit Bias Academic Medical Centers (AMC) Survey: To give a more complete picture of what is out there and where we should focus our efforts in this trial, we will survey leadership of other institution's Offices of Diversity and Inclusion. This survey will poll their specific strategies and populations in reference to implicit bias training.

Aim 3: Implicit Bias Training

Design overview: This is a pre-post feasibility trial design, for which we will recruit up to 50 providers from Duke Health affiliated clinics. Provider participants will be exposed to the refined implicit bias intervention that emerges from our Aim 2 activities. Our primary outcomes will include measures of feasibility, acceptability, and intervention fidelity; these will be assessed immediately following training. If successful, the resulting data will position us well to test a fully powered, health system-wide trial of the implicit bias reduction intervention. We will conduct the proposed feasibility trial via three interactive Duke Zoom sessions (Knowledge, Awareness/Skills Part 1, and Skills Part 2). Each session will be offered more than once to accommodate providers' schedules. Providers will be eligible if they provide care at a Duke-affiliated facility, and we will recruit all providers at DUHS. Dr. Adia Ross, the Chief Medical Officer of Duke Regional Hospital, and Tracy Killette, Administrative Director at Duke Raleigh, will provide mailing lists that contain the name, title, status, department, and email address of all providers at Duke Regional and Duke Raleigh hospital. We will use these mailing lists to recruit providers via email for the intervention. Angie Cain, Interim Director of the Office of the Chief Medical Officer for DUHS, will also include the recruitment email in the weekly clinical operations update email and the weekly PDC provider newsletter to help us recruit all providers at DUHS. We will also share the recruitment email information through department and divisional newsletters with endorsements from willing leaders. These leaders will not have access to study data. Dr. Adia Ross, Tracy Killette, and Angie Cain will also not have access to any of the study data.

Potential participants will receive a duke secured introductory email with study details and a Redcap consent and baseline survey link. All eligible providers will be recruited and enrolled, with IRB-approved informed consent and baseline survey by using Redcap. In summary, participants will be asked to complete an e-consent and baseline survey in Redcap; attend three interactive sessions via zoom (2-3 hours each, conducted over 4-12 weeks), complete an end of session evaluation form after each session, and complete two evaluation surveys at the end of the program. Participants will be asked to complete the end of session evaluation form for each session if they attend at least part of the session. They will also be asked to complete the two evaluation surveys at the end of the program if they attend at least one session. Study team members will lead the training.

We will communicate with participants using 4 IRB-approved emails:

1. Scheduling Confirmation/Knowledge Session email: This email will be used to confirm availability for each session based on the participant's responses in the baseline survey. This email will also include the pre-work for the Knowledge session. To prepare for the Knowledge session, participants will be asked to watch a 1 hour video of Dr. Jeff Baker's Grand Rounds Presentation, "Forgotten Voices: Confronting Duke Hospital's Racial Past", at this link: **https://trentcenter.duke.edu/race-and-health**.

2. Awareness/Skills Part 1 Session email: This email will be used to send each participant a link and unique code to their end of session evaluation survey for the Knowledge session, provide a list of resources from the Knowledge session (resources will be submitted in a future amendment before the scheduled session), and provide details about the pre-work for the Awareness/Skills Part 1 session. To prepare for this session, participants will be asked to complete the Harvard Implicit Association Test (Race IAT and another IAT of their choice) at this link: **https://implicit.harvard.edu/implicit**.

3. Skills Part 2 Session email: This email will be used to send each participant a link and unique code to their end of session evaluation survey for the Awareness/Skills Part 1 session, provide a list of resources from the session (resources will be submitted in a future amendment before the scheduled session), and provide details about the pre-work for the Skills Part 2 session. To prepare for this session, participants will be asked to practice skills discussed during the Awareness/Skills Part 1 session. A list of the skills and details about the exercise will also be provided (list will be submitted in a future amendment before the scheduled session).

4. End of Program email: This email will be used to send each participant a link and unique code to their end of session evaluation survey for the Skills Part 2 session, provide a list of resources from the session (resources will be submitted in a future amendment before the scheduled session), and send the link and unique code to their program evaluation surveys (program evaluation survey and self-efficacy assessment).

We would also like to conduct follow-up interviews with participants who enrolled in Aim 3 of the study. Interviewees will consist of providers who enrolled but did not participate in any of the sessions and providers who enrolled and participated in at least one session. Providers who enrolled but did not participate in any of the sessions will also have the option of completing a three question survey instead of participating in the follow-up interview. Since the interview and survey is optional, we will not amend the main consent and will use an implied consent (standalone and language in the scheduling survey) for the interviews and the three question survey. Providers will be recruited via email and the interview will be conducted according to the interview guide. Participants will receive a $25 gift card for their participation in the interview or survey.

Provider training: We will deliver the implicit bias training that results from our Aim 2 activities; the complete intervention package will incorporate both: 1) the changes to the training content, and; 2) the information garnered from semi-structured interviews about training logistics that will make it most feasible for the providers to participate.

Outcomes and measures: Our primary outcomes include feasibility and acceptability, which will be assessed as described below. Secondary outcomes include change in implicit racial attitudes. We will also gather provider data (age, sex, race, practice characteristics, time in practice, etc.) via self-report.

Feasibility. Consistent with best practices, we will judge the trial as feasible if at least 50% of eligible providers agree to participate; at least 80% of those enrolled complete the trial; and if we achieve at least 75% adherence to all intervention activities and exercises.

Acceptability. We will assess acceptability using a 12-item adapted measure scored with Likert-type response options. The measure assesses overall program satisfaction, perceived content quality, perceived content usefulness, perceptions of trainer quality, appropriateness of training timing and logistics, desire to participate in future sessions, and behavioral reactivity to intervention content. In analysis, we will use the summary index as well as responses to the 12 individual items that comprise the index. Participants will also be asked to offer suggestions regarding how to improve the training session.

Implicit attitudes. We will ask participants to complete an implicit association test (IAT) at baseline and immediately following training. We will use the Brief IAT measure, which can be administered in under 5 minutes on a laptop computer. The Brief IAT provides comparable findings on implicit racial attitudes tests, when validated against the longer IAT measure.

Administrative Supplement

We plan to address additional needs during the administrative supplement by achieving the following Specific Aims:

Aim 1. Characterize outcomes for assessing clinicians' use of the implicit bias mitigation skills that are emphasized in the REACHing Equity curriculum by coding pre-existing audio-recorded new patient encounters using the Roter Interaction Analysis System (RIAS) to ascertain provider-level individuation and empathy skills. We will address the need to identify an objective measure of impact of our curriculum on clinicians' behavior by evaluating potential outcome measures in audio-recorded clinical encounters that are available to us from another REACH Equity parent study, led by co-investigator Pollak[27] (**Pro0009169 1)**.

Procedures: During the supplement period, we will build the capacity of the REACH Equity team by training study staff and faculty to use RIAS. The creator of RIAS, Dr. Debra Roter, will provide five 4-hour training sessions with staff at the Duke Qual Core (a resource for high-quality qualitative research within Duke University) and a small number of REACH Equity faculty (e.g., Qual Core Director Dr. Corneli and Dr. Wilson). In between and during training sessions, coders will use audio recordings of patient encounters to practice and reconcile codes.

Outcome Measures: In evaluating these encounters, we seek to identify a measure of impact of an implicit bias curriculum that a) reflects implicit bias; b) has demonstrable racial differences; c) links to the educational goals of the REACHing Equity curriculum; and d) is potentially mutable. We propose to use the Roter Interaction Analysis System (RIAS) to ascertain clinician-level individuation and empathic communication skills.

Aim 2. Refine the REACHing Equity curriculum to facilitate implementation without compromising content and experiential learning.

Procedures: To achieve this Aim, we will reconvene the Advisory Group that assisted with initial curriculum development. The Advisory Group includes investigators, clinicians, faculty, diversity/equity experts, and stakeholders. The members provide expertise in implementation science, medical education, doctor-patient communication, racial disparities research, diversity/equity/inclusion training, intervention design and health system management. The Advisory Group will review:

- Results of program assessments completed by participants in the pilot study (data analysis in progress)
- Summaries of informal post-program interviews of pilot study participants (interviews in progress)
- Qualitative results of structured interviews of clinicians and health system leaders from of the parent project (data available)
- Continuously updated literature review

We anticipate that 12-15 Advisory Group members will participate in 4-6 meetings over the course of the supplement year. In group discussions, members will be asked to provide input on possible refinements to the curriculum. As suggestions are reviewed, refined and selected, we will ask them to respond to prototypes of refinements (e.g., self-study resource for Knowledge domain). We will return to the Advisory Committee in an iterative manner until no further significant modifications are suggested.

After iterations are complete, we will ask clinicians who have not been previously involved in the project to help us finalize the refined curriculum. We engaged in a similar process in the initial development of the curriculum before launching the pilot test. In an informal setting, we invited clinicians to a "dress rehearsal" followed by a discussion in which they provided extremely valuable feedback. In the current proposal, we will invite 10 clinicians to preview the refined curriculum and ask them to identify areas to fine-tune. Our intent is to identify aspects of the presentation that can be easily adjusted by altering the style in which the content is presented.

Aim 3. Develop a taxonomy of equity-focused implementation strategies by conducting the Implementation Strategies for Health Equity Delphi Panel.

We will address the need to establish an equity-focused empirical approach to codifying implementation strategies by convening a scientific working group of expert consultants and using Delphi panel methods. We will follow best practices for healthcare-related Delphi panels. For this process, we will define "implementation strategies" as any action designed to increase uptake, carrying and sustainability of evidence-based interventions or health innovations. We define "promote health equity" as any of the following: a) implementation strategies to promote uptake of an evidence-based intervention, program, or practice to reduce health inequities, b) implementation strategies designed to ensure that clinicians and health systems equitably deliver evidence-based care, or c) implementation strategies designed to increase organizational or programmatic emphasis on health equity.

Consultants: In order to promote inclusion in our process, we will use purposive sampling to identify expert consultants for membership in an online panel of N = 40. Consultants will be experts in either

health equity or equity-related implementation science who are diverse with respect to race, ethnicity, and other identities underrepresented in sciences. This panel size is similar to panels used in prior implementation science Delphi panels. We will run an asynchronous (i.e., no group meetings), three-round Delphi panel focusing on three key tasks (one task for each round): 1) create a comprehensive list of equity-focused implementation strategies, 2) achieve consensus on definitions of implementation strategies, and 3) distill the list to unique, non-redundant equity-focused implementation strategies and finalize definitions.

Procedures: Expert consultants for the Implementation Strategies for Health Equity Delphi Panel will be identified via purposive sampling and snowball sampling. Consultants will be sought via invitations sent to email lists for scholarly and practice-based organization focusing on health equity and/or equity-focused implementation science, for example: National Association of Diversity Officers in Higher Education, National Diversity Council, Research in Implementation Science for Equity (RISE) fellowship past instructors and fellows, Implementation Research Institute (IRI) fellowship past instructors and fellows, Academy Health Disparities Interest Group, Society for Implementation Research Collaboration, NIMHD Specialized Centers of Excellence on Minority Health and Health Disparities, the American Medical Association Center for Health Equity, Society for Community Research and Action, Society for Prevention Research, and editorial boards for key journals (*Health Equity*, *International Journal for Equity in Health*, *Im plementation Science*). Postings on social media sites (e.g., Facebook, Twitter) will also be used. For snowball sampling, applicants will be invited to recommend up to 2 colleagues who may be interested in being contacted for representation on the Panel.

At the time of application, prospective consultants will be asked to self-identify professional role(s), membership in underrepresented group(s) in medicine, and degree of experience in the following: health equity practice, health equity research, using group- or system-level strategies to improve health inequities, and equity-focused implementation science research, and equity-related implementation science practice.

We will use Qualtrics software to electronically program each round of the Delphi Panel, similar to previously used methodology. If consultants agree, we will also use either Slack (slack.com) or Mighty Networks (mightynetworks.com) as a virtual networking platform to facilitate asynchronous discussion among the scientific working group in between Delphi Panel Rounds. Using virtual, asynchronous strategies for engagement on the scientific working group Delphi panel can improve participation and speed the process, thus enabling us to complete the panel within the proposed timeline. Time commitment for each consultant is approximately 2 hours per round (6 hours total).

Compensation/Benefits for Consultants: Consultants who are not employed by Duke who are on the working group Delphi panel will be compensated with a $50 digital Target or Etsy gift card (choice selected by the member) following participation in each of the three Delphi Rounds. For consultants who complete all three rounds, they will receive a bonus $50 digital Target or Etsy gift card. This would yield a total compensation for panelists of up to $200. All digital gift cards will be emailed to the Delphi panel consultant. Consultants (within and outside of Duke) will also be offered acknowledgement in any resulting manuscripts from this Delphi panel.

Delphi Round 1: The purpose of this round is to gather diverse expert opinions on the breadth of implementation strategies that are used to promote health equity, as defined above. Consultants will complete asynchronous nominations of implementation strategies. Every time an expert partner nominates a new strategy, they will be asked to construct a preliminary definition of the strategy. Strategies nominated to date will be visible by all partners. At this phase, we prioritize quantity of uniquely brainstormed strategies rather than paring down and finalizing definitions.

After Delphi Round 1, the research team will undertake a process of cataloguing each strategy, and identifying potentially overlapping strategies.

Delphi Round 2: The purpose of this round is to establish preliminary consensus on including and defining identified implementation strategies. Consultants will be asked for initial consensus on a) agreement with overlapping strategies identified by the research team, b) definitions of strategies, and c) nominating additional strategies.

Delphi Round 3: The purpose of this final round is to finalize labels, names, and definitions of implementation strategies designed to improve health equity. Consultants will be asked to provide final consensus decisions on: a) inclusion of each strategy, and b) definition of each strategy. Consensus for each definition will be defined as high (≥ 70% agreement), moderate (between 50% to 69.9%), or low (< 50%). All consensus results will be reported.

This protocol will be amended at a later date to include more details and requirements for carrying out the administrative supplement aims, such as consent forms, surveys, and key personnel information.

Selection of Subjects

- List inclusion/exclusion criteria and how subjects will be identified.

Aim 1: Our recruitment goals are feasible in the context of the demographics of this area and the number of non-urgent healthcare facilities. There will be 1 group for each of the race/education combinations: Black /high education; Black/low education; White/high education; White/low education; Hispanic/high education; Hispanic/low education (6 groups total). The focus groups will be conducted by an experienced focus group facilitator, who is race-concordant with the group, accompanied by a co-facilitator, and audio-taped. We will recruit up to 15 participants for each focus group to account for no-shows.

Aim 2: We will recruit providers for this Aim. We will email providers from:

_____ Nephrology

_____ Orthopedics

_____ Pediatrics

_____ Primary Care

_____ GI

_____ Cardiology

_____ General Surgery

_____ Emergency

as well as specific hospital leaders and administrators. Participants will be invited to participate via email and scheduled for either in-person or telephone interviews.

Aim 3: We will conduct the proposed feasibility trial via three Duke Zoom sessions over the course of 4-12 weeks. Providers will be eligible if they provide care at a Duke-affiliated facility, and we will recruit all providers at DUHS. Dr. Adia Ross, the Chief Medical Officer of Duke Regional Hospital, and Tracy Killette, Administrative Director at Duke Raleigh, will provide mailing lists that contain the name, title, status, department, and email address of all providers at Duke Regional and Duke Raleigh hospital. We will use these mailing lists to recruit providers via email for the intervention. Angie Cain, Interim Director of the Office of the Chief Medical Officer for DUHS, will also include the recruitment email in the weekly clinical operations update email and the weekly PDC provider newsletter to help us recruit all providers at DUHS. Dr. Adia Ross and Angie Cain will not have access to any of the study data. All eligible providers in these clinics will be recruited and enrolled with an IRB-approved introductory email, e-consent form, and baseline survey that determines availability for the sessions and demographics. The e-consent form and baseline survey will be completed through Duke REDCap. We will aim to recruit a sample that is roughly 20% comprised of racial/ethnic minority providers. Compensation will not be provided for participation in the pilot curriculum. Providers who enroll in the study by completing the e-consent and baseline survey (indicating that they provide care at a Duke facility and confirming availability for all three sessions), may be withdrawn if they no show or cancel the first session (Knowledge session). Some providers may also remain in the study, at the PI's discretion, if they no show or cancel the first session (Knowledge session). Any providers who were ineligible or withdrawn due to availability will be able to participate in any future sessions if they become available to attend all three sessions and confirm that they still provide care at a Duke affiliated facility.

Administrative Supplement

Aim 1:

Study Population (Audio-recorded encounters): We will address the need to identify an objective measure of impact of our curriculum on clinicians' behavior by evaluating potential outcome measures in audio-recorded clinical encounters that are available to us from another REACH Equity parent study, led by co-investigator Pollak. [27] In Pollak's study (The effect of a clinician communication coaching intervention on racial disparities in the quality of communication in cardiology encounters), 40 clinical cardiologists participated in a trial of communications coaching. The cardiologists' clinical encounters (N= 161, 81 Black and 80 White patients) were audio-recorded and transcribed. Of the available audio-recordings, we will code the 88 new patient encounters, which are the longest, most comprehensive and most interactive of all cardiology encounters, and thus most likely to provide opportunities for using implicit bias mitigation

skills. Approximately half of these new patient encounters involve Black patients. Of note, of the 40 participating cardiologists, only 2 are Black providers (63% are White providers, 28% Asian providers, and 5% another race). Therefore, the vast majority of encounters with Black patients will include non-Black providers consistent with clinical practice.

Aim 2: Not Applicable

Aim 3: No human subjects will be included in this study aim. This is a scientific working group of expert consultants being asked to report based on their content area expertise.

Subject Recruitment and Compensation

- Describe recruitment procedures, including who will introduce the study to potential subjects. Describe how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a) (3)). Include information about approximately how many DUHS subjects will be recruited. If subjects are to be compensated, provide specific prorated amounts to be provided for expenses such as travel and/or lost wages, and/or for inducement to participate.

Aim 1: Participants will be recruited using a multi-pronged strategy: 1) direct marketing; 2) local media; 3) social media, and; 4) community organizations. We will advertise in local newspapers, television, and radio. We will also work with local websites and bloggers to advertise the study and place geographically targeted advertisements via Facebook and Google, and at several community organizations. We will recruit a sample that is 44% racial/ethnic minority (similar to the demographics of Durham, N.C.).

Inclusion criteria:

1. Had at least 2 non-urgent ambulatory care visits any Healthcare facility in the past year (via self-report),
2. Proficient in English,

Those who respond to study marketing will undergo preliminary eligibility screening via a RedCap eligibility survey. If deemed eligible via the online screening, participants will be invited to complete the study's informed consent process and choose a focus group. Each of the 6-focus group will have approximately 8 participants (48 total focus group participants). The focus groups will be conducted by an experienced focus group facilitator, who is race-concordant with the group, accompanied by a co-facilitator, and audio-taped. Participants will receive a $50 incentive for their focus group participation.

Aim 2: Identified providers will be recruited via e-mail invitation. Participants will be consented via a Redcap consent with obtained waiver of informed consent documentation. We will compensate providers ($25 Starbucks giftcard) for their participation.

Implicit Bias Academic Medical Centers (AMC) Survey: We will send an invitation message that includes a Qualtrics survey link to known GDI regional representatives, based on a list from the Association of American Medical Colleges (AAMC), and request for them to forward our invitation to their region of chief diversity officers (CDOs) or equivalent officers. If this is unsuccessful, we will send an invitation message directly to the CDOs using emails obtained from public websites. We will send follow-up messages for non-responders.

Aim 3: We will conduct the proposed feasibility trial via three Duke Zoom sessions over the course of 4-12 weeks. Providers will be eligible if they provide care at a Duke-affiliated facility, and we will recruit all providers at DUHS. Dr. Adia Ross, the Chief Medical Officer of Duke Regional Hospital, and Tracy Killette, Administrative Director at Duke Raleigh, will provide mailing lists that contain the name, title, status, department, and email address of all providers at Duke Regional and Duke Raleigh hospital. We will use these mailing lists to recruit providers via email for the intervention. Angie Cain, Interim Director of the Office of the Chief Medical Officer for DUHS, will also include the recruitment email in the weekly clinical operations update email and the weekly PDC provider newsletter to help us recruit all providers at DUHS. Dr. Adia Ross and Angie Cain will not have access to any of the study data. All eligible providers in these clinics will be recruited and enrolled with an IRB-approved introductory email, e-consent form, and baseline survey that determines availability for the sessions and demographics. The e-consent form and baseline survey will be completed through Duke REDCap. We will aim to recruit a sample that is roughly 20% comprised of racial/ethnic minority providers. Participants will not be compensated for their participation in this training. However, CME credit will be available to providers who participated in at least one session of the program. To earn CME credit, a roster for each session including first name, last name, and email address will be provided to Brandie Jones, a program specialist with Duke Joint Accreditation.

The learners will then be imported into the system and will receive email instructions on how to login, complete an evaluation, and obtain their certificate.

Aim 3 Follow-up Interview and Survey: Participants will receive a $25 gift card for their participation in the interview or survey.

Administrative Supplement Aim 3: No human subjects are included in this aim.

Consent Process

- Complete the consent section in the iRIS Submission Form.

Subject's Capacity to Give Legally Effective Consent

- If subjects who do not have the capacity to give legally effective consent are included, describe how diminished capacity will be assessed. Will a periodic reassessment occur? If so, when? Will the subject be consented if the decisional capacity improves?

We will not include subjects that do not have the capacity to give legally effective consent.

Study Interventions

- If not already presented in #4 above, describe study-related treatment or use of an investigational drug or biologic (with dosages), or device, or use of another form of intervention (i.e., either physical procedures or manipulation of the subject or the subject's environment) for research purposes.

N/A

Risk/Benefit Assessment

- Include a thorough description of how risks and discomforts will be minimized (per 45 CFR 46.111(a) (1 and 2)). Consider physical, psychological, legal, economic and social risks as applicable. If vulnerable populations are to be included (such as children, pregnant women, prisoners or cognitively impaired adults), what special precautions will be used to minimize risks to these subjects? Also identify what available alternatives the person has if he/she chooses not to participate in the study. Describe the possible benefits to the subject. What is the importance of the knowledge expected to result from the research?

There are few potential risks associated with any of the measures or data to be collected. Participants may feel uncomfortable talking during the interviews or focus groups. Participants do not have to answer any question that they do not wish to answer, as will be explained during the consent process. The implicit bias training is not mandatory. They can refuse participation or stop at any time. Participants may benefit from the implicit bias training by learning self-awareness and the effects implicit bias has on patients.

Costs to the Subject

- Describe and justify any costs that the subject will incur as a result of participation; ordinarily, subjects should not be expected to pay for research without receiving direct benefit.

There will be no costs to subjects.

Data Analysis & Statistical Considerations

- Describe endpoints and power calculations. Provide a detailed description of how study data will be analyzed, including statistical methods used, and how ineligible subjects will be handled and which subjects will be included for analysis. Include planned sample size justification. Provide estimated time to target accrual and accrual rate. Describe interim analysis including plans to stop accrual during monitoring. Phase I studies, include dose escalation schema and criteria for dose escalation with definition of MTD and DLT.

Focus Groups: Each focus group will be digitally recorded and transcribed by Datagain Services for coding using qualitative research data management software (i.e., Atlas.ti). We will use directed content analysis, organizing the data in response to the a priori questions contained in the interview guide. Two coders will examine transcripts for common and emergent themes as well as a priori themes. Open coding will be used to identify manifest and latent content, followed by axial coding to identify patterns between code categories. A codebook of definitions and exemplars will be developed and presented to the team for feedback. The team will maintain an audit trail of coding and analytic decisions. A systematic process of mutual consensus will be used. We will also employ theme matrix techniques to facilitate data analysis and presentation. Initial matrices will be developed and refined. We will separately aggregate quotes and present them in matrices with columns identifying critical quote dimensions. We will develop separate matrices for each stakeholder category.

Stakeholder Interviews: Interviews will last approximately 30-40 minutes, will be digitally recorded, and transcribed by Datagain Services for coding using qualitative research data management software (i.e., Atlas.ti software). We have a contract with Datagain for these services. Participants will be informed that their supervisors will not have access to individual participant audio-recordings or transcripts. To analyze the resulting data, we will use directed content analysis, organizing the data in response to the a priori questions contained in the interview guide. Two coders will examine transcripts for common and emergent themes as well as a priori themes. Open coding will be used to identify manifest and latent content, followed by axial coding to identify patterns between code categories. A codebook of definitions and exemplars will be developed and presented to the team for feedback. The team will maintain an audit trail of coding and analytic decisions. A systematic process of mutual consensus will be used. We will also employ theme matrix techniques to facilitate data analysis and presentation. Initial matrices will be developed and refined. We will separately aggregate quotes and present them in matrices with columns identifying critical quote dimensions. We will develop separate matrices for each stakeholder category.

Implicit Bias intervention: We will calculate the feasibility and acceptability outcomes along with 95% confidence intervals. We will examine whether there is variability in any trial outcomes by provider-related characteristics. We will also calculate change in IAT outcomes from baseline to immediately post-intervention. Given that this is a pilot study with primary feasibility and acceptability outcomes, a power calculation is not performed.

Data & Safety Monitoring

- Summarize safety concerns, and describe the methods to monitor research subjects and their data to ensure their safety, including who will monitor the data, and the frequency of such monitoring. If a data monitoring committee will be used, describe its operation, including stopping rules and frequency of review, and if it is independent of the sponsor (per 45 CFR 46.111(a) (6)).

This is a minimal risk study so the potential for serious adverse events related to the study is low. The study consist of only focus groups, interviews and training so a data and safety monitoring board is not required.

Privacy, Data Storage & Confidentiality

- Complete the Privacy and Confidentiality section of the iRIS submission form.

Describe Role of External Personnel:

Brandy Sullivan, an MD completing her MPH at UNC, will serve as a volunteer this study. She will be primarily coding Aim 2 provider interviews. She will have access to PHI. No PHI/data will leave Duke.

The creator of RIAS, Dr. Debra Roter, and her master coder, Michele Massa, will provide five 4-hour training sessions with staff at the Duke Qual Core (a resource for high-quality qualitative research within Duke University) and a small number of REACH Equity faculty (e.g., Qual Core Director Dr. Corneli and Dr. Wilson). In between and during sessions, coders will use audio recordings of patient encounters to practice and reconcile codes.

Jessica Breland, PhD and Ariel Domlyn, PhD are implementation science experts that will assist us with Aim 3 of our supplement: developing a taxonomy of equity-focused implementation strategies by conducting the Implementation Strategies for Health Equity Delphi Panel. They will have access to study data but no data will leave Duke. Access to study data will be provided to them through Duke Box only after an agreement has been finalized and fully executed.

Study Scope

Does this study have a cancer focus? Cancer focus includes studies that enroll >50% oncology or malignant hematology patients; or, preventing, detecting, and diagnosing cancer or understanding the impact of cancer on patients and their caretakers.

○ Yes ◉ No

Are you using a drug, biologic, food, or dietary supplement in this study?

○ Yes ◉ No

Are you using a medical device, an algorithm (whether computer based or not), an in vitro diagnostic test, or using samples to look for biomarkers in this study?

○ Yes ◉ No

Does this study employ magnetic resonance, including imaging (MRI), spectroscopy (MRS), angiography (MRA) or elastography (MRE) beyond the standard of care?

○ Yes ◉ No

Does this study specify or require the performance of diagnostic procedures using ionizing radiation (x-rays, DEXA, CT scans, nuclear medicine scans, etc.) that are beyond the standard of care?

○ Yes ◉ No

Does this study specify or require the performance of therapeutic procedures using ionizing radiation (accelerator, brachytherapy or systemic radionuclide therapy) that are beyond the standard of care?

○ Yes ◉ No

Does this study specify or require the use of a laser system for diagnosis or therapy that is beyond the standard of care (excludes the use of lasers as a standard surgical instrument)?

○ Yes ◉ No

Will the participant be subjected to increased or decreased ambient pressure?

○ Yes ◉ No

Do you plan to recruit subjects from Duke Regional Hospital (DRH)?

○ Yes ◉ No

Do you plan to recruit subjects from Duke Raleigh Hospital (DRAH)?

○ Yes ◉ No

Are you using the Duke logo in any advertisements?

◉ Yes ○ No

Is this study retrospective, prospective, or both?

"Retrospective" means that data or samples already in existence (collected prior to the study submission) will be used.
"Prospective" means there will be data or samples collected in this study for research purposes.

○ Retrospective
◉ Prospective
○ Retrospective and Prospective

If the study is both retrospective and prospective: Is this a review solely of information collected for non-research purposes (i.e. a review of medical records)?

○ Yes ○ No

Does this protocol include any research using botulinum toxin, including the FDA-approved clinical product (Botox)?

○ Yes ◉ No

Does this protocol involve the administration of any of the following materials to humans?

- Any viral vector or plasmid
- Any cells that have been modified by a viral vector
- Any other genetically-modified cells
- Any genetically-modified virus, bacterium, or other agent
- Any other recombinant or synthetic nucleic acid

○ Yes ◉ No

Subject Population Groups and Enrollment

Population Groups (Select targeted population groups only):

☑ Adults
☐ Minors who are Wards of State
☐ Minors
☐ Duke Patients
☐ Pregnant Women
☐ Fetuses

- [ ] Prisoners
- [ ] Adults incapable of giving consent
- [ ] Adults with diminished capacity
- [ ] Handicapped subjects
- [ ] Students
- [x] Employees
- [ ] Healthy Controls
- [ ] Deceased subjects
- [ ] Blanket Protocol

Students and Employees over whom Key Personnel have a supervisory role may not be enrolled in this study.

Please select any population groups excluded from participation in this study:

- [ ] Pregnant women

Maximum number of subjects to be consented at Duke:

Enter a single number. If you anticipate consenting a range of subjects, enter the **upper** limit of the range. The number should represent the maximum number of subjects for the life of the study.

368

Maximum number of subjects to be consented at all sites:

Enter a single number. If you anticipate consenting a range of subjects, enter the **upper** limit of the range. The number should represent the maximum number of subjects for the life of the study.

368

Subject Procedures and Costs

Biobank - Does this study involve the collection, use, tracking, banking (storage) or distribution of human biological specimens?

Human biological specimens include blood or its components, healthy or diseased tissue, bodily fluids, DNA /RNA or human stem cells.

- ○ Yes
- ◉ No

Procedures

Check all that apply:

- [ ] Genetic Testing
- [ ] Gene Transfer
- [ ] DNA Banking
- [ ] Testing for Reportable Infectious Diseases
- [ ] Human Cell Banking
- [ ] *Use of Human Embryonic Stem Cells
- [ ] *Use of Human-induced Pluripotent Stem Cells
- [ ] *Use of Other Cells Derived from Human Embryos
- [ ] *Use of Human/Animal Chimeric Cells
- [ ] *Specialized Cell Populations for Cell Therapy
- [ ] Use of Human Tissue
- [ ] Use of Bodily Fluids

☐ Use of Blood (or its components)
☑ Not Applicable

Will blood be drawn in this study for research purposes?

○ Yes ◉ No

Will the Operating Room be used in this study?

Include only research time, not clinical care time.

○ Yes ◉ No

Will there be extra costs to subjects or insurance as a result of the research (e.g. tests, hospitalization)?

○ Yes ◉ No

Will there be Subject Compensation?

◉ Yes ○ No

Compensation for Travel / Lost Income (in USD):

0

Other Subject Compensation:

Aim 1: $50
Aim 2: $25 gift card
IB AMC Survey: Raffle for 1- $250 giftcard
Aim 3: No compensation
Supplement: $200 for Delphi Panel Consultants

Subject Recruitment Materials

For each document to be reviewed, use the table below to provide the following information:

Attach a copy of each advertisement that you will be using with this study in the Initial Submission Packet. If any Ad will have multiple wording variations, attach a copy of each version of the Ad.
All materials that will be used to advertise the study in order to recruit subjects must be approved by the IRB.

Types of subject recruitment materials include, but are not limited to, the following:

Direct Advertising
Posters
Billboards
Flyers
Brochures

Media Advertising
Newspaper Ads
Magazine Ads

Radio Ads
TV commericals / Video
Internet website
Social Media

Other Types of Advertising
Newsletter
Email
Postcards / Letters

(Note: Doctor-to-Doctor letters do not require IRB approval)

Document name	Material category	Location material displayed	Has this material previously been approved by the IRB?
Flyer	◉ Billboard / Flyer / Poster ○ Brochure ○ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. Waiting rooms of Duke, Wake Med, Rex and UNC healthcare facilities, restaurants, community centers	◉ Yes ○ No
Online Advertisements	○ Billboard / Flyer / Poster ○ Brochure ○ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. Facebook, twitter, intsagram, next door	◉ Yes ○ No
Aim 3 Introductory email	○ Billboard / Flyer / Poster ○ Brochure ○ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. Aim 3 Introductory email will be sent out to the colleague	◉ Yes ○ No

Consent Process

Attach draft consent forms in the Initial Review Submission Packet.

Consent forms must be MS Word documents and follow the specific format outlined by the IRB. **Click here** to download a copy of the consent form template.

Note: Please do not edit the section of the footer that contains the Protocol ID, Continuing Review and Reference Date fields. Those fields will be used to stamp the final consent form when it is approved by the IRB. If you want to add an internal version date, please put it in the header.

Who will conduct the consent process with prospective participants?

Give the person's role in this study (PI, Study Coordinator, etc.):

The PI, study coordinator, research assistant or co-investigator. For Aim 3, the e-consent process will be conducted electronically via RedCap. We will also use implied consent for the Aim 3 follow-up interview and survey.

Who will provide consent or permission?

(Select all that apply):

- [x] Participant
- [ ] Parent(s) or Legal Guardian(s)
- [ ] Legally Authorized Representative (LAR)

How much time will the prospective participant (or legally authorized representative) have between being approached about participating in the study and needing to decide whether or not to participate?

If you are not giving the person overnight to consider whether or not to participate, please justify.

Aim 1: After completing the initial screening questionnaire via REDCap, participants will be able to read the consent online and email or call us if they have any questions. The participant could choose to consent at that time or if desired, could wait and return to the form at a later time, including overnight. They will also have an option to check that they would prefer to talk with a study staff before signing the online consent form.

Aim 2: Participants will have a REDCcap consent. Participants will be able to read the consent online and email or call us if they have any questions. The participant could choose to consent at that time or if desired, could wait and return to the form at a later time, including overnight. They will also have an option to check that they would prefer to talk with a study staff before signing the online consent form.

Aim 3: Participants will be approached initially via email at least a week prior to the set training dates. They will have that time to think before they come to the sessions and consent.

Where will the consent process occur?

Aim 1: The consent process will occur at the participants preferred location since they will be reviewing the consent form online via REDCap.

Aim 2: The consent process will occur at the participants preferred location since they will be reviewing the consent form online via REDCap.

Aim 3: The consent process will occur at the participants preferred location since they will be reviewing the consent form online via REDCap.

What steps will be taken in that location to protect the privacy of the prospective participant?

Aim 1: Participants will be encouraged to find a private location to review the online consent form. Since the location is based on participant preference, we can not guarantee full privacy protection.

Aim 2: Participants will be encouraged to find a private location to review the online consent form. Since the location is based on participant preference, we can not guarantee full privacy protection.

Aim 3: Participants will be encouraged to find a private location to review the online consent form. Since the location is based on participant preference, we can not guarantee full privacy protection.

How much time will be allocated for conducting the initial consent discussion, including presenting the information in the consent document and answering questions, with each prospective participant?

Aim 1: After completing the initial screening questionnaire via REDCap, participants will be able to read the consent online and email or call us if they have any questions. The participant could choose to consent at that time or if desired, could wait and return to the form at a later time. There is no set time limit.

Aim 2: Participants will have consent via REDCap. Participants will be able to read the consent online and email or call us if they have any questions. The participant could choose to consent at that time or if desired, could wait and return to the form at a later time. There is no set time limit.

Aim 3: Participants will be consented via REDCap. They will be asked to review the electronic consent and contact the study team if they have questions. There is no set time limit, and participants will be able to consent at the time of initial review or return to the form at a later time.

What arrangements will be in place for answering participant questions before and after the consent is signed?

Aim 1: Participants can call or email study staff before or during the online consent to answer questions. They will be able to ask questions before the focus group as well, in-person.

Aim 2: Participants can call or email study staff before or during the online consent to answer questions. They will be able to ask questions before the interview as well, in-person or by phone.

Aim 3: Participants may call or email study staff before, during, and after the online consent with any questions. They will also be able to ask questions during each of the three Zoom sessions.

Describe the steps taken to minimize the possibility of coercion or undue influence.

The study staff obtaining consent will make it very clear that the subject does not need to participate. They will state the following:

"You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled."

Payment is kept at a rate that will not be coercive but will compensate participants for their gas. We also send letters out before we call and give participants plenty of chances to decline.

Before consented we will give ample time to ask questions and decline participation.

They will also be given Dr. Svetkey's phone number and email, so they can call or email her with any questions or concerns.

What provisions will be in place to obtain consent from participants who do not read, are blind or who do not read/understand English?

We will not consent participants who do not read, are blind or do not read/understand English.

Do you plan to obtain written consent for the conduct of research?

(•) Yes ( ) No

Protected Health Information (PHI)

Indicate how you intend to use potential subjects' Protected Health Information (PHI):

( ) I will review, but not record, PHI prior to consent.
(•) I will record PHI prior to consent.
( ) I do not intend to use PHI prior to consent.
( ) I will record PHI without consent. (decedent research, database repository, chart review)

Request for Waiver or Alteration of Consent and/or HIPAA Authorization

Will the population include deceased individuals?

( ) Yes (•) No

This waiver request applies to the following research activity or activities:

[ ] Scheduling of research activities in MaestroCare and/or the recording of PHI via telephone for screening purposes prior to obtaining written consent for the research. Scheduling of research activities in MaestroCare and/or the recording of PHI via telephone for screening purposes prior to obtaining written consent for the research.
[x] Ascertainment (identification, selection) and/or recruitment of potential subjects while recording identifiable private information, such as protected health information (PHI), prior to obtaining the subject's consent.
[x] Conduct of the research project without obtaining verbal or written consent and authorization.

Note: Answer the questions below as they pertain solely to PHI collected prior to consent.

Provide the following information:

List the elements of informed consent and/or HIPAA authorization for which waiver or alteration is requested:

- Provide the rationale for each.

We request to waive all elements of the informed consent and HIPPA authorization for screening and recruitment purposes. We will access PHI submitted by potential participants for screening.

For AMC Survey: We request a waiver to conduct of the research survey without obtaining verbal or written consent and authorization.

For Aim 3 Follow-Up Interview and Survey: We request a waiver to conduct of the interview and survey without obtaining verbal or written consent and authorization.

Administrative Supplement Aim 3 (Scientific Working Group Delphi Panel): We request a waiver to conduct of the scientific working group Delphi panel without obtaining verbal or written consent and authorization.

List the specific protected health information (PHI) to be collected and its source(s):

- (Note: PHI = health information + identifiers)

1. Name
2. Address
3. Date of Birth
4. Phone #
5. E-mail addresses
6. Health information related to blood pressure

7. All of the information will be self-submitted by participants via RedCap survey for recruitment and eligibility screening and stored in a RedCap database.

For AMC Survey: Participant's emails (used for recruitment) will be entered to win a $250 giftcard. The winning participant will fill out a IRB disclosure form for payment purposes. IRB disclosure forms require:

- Name
- Address
- SSN

For Aim 3 Follow-Up Interview and Survey: Email addresses will be used for recruitment. Participants will receive a $25 giftcard for completing the follow-up interview or survey and must provide name, address, SSN/DUID per IRB disclosure form.

Administrative Supplement Aim 3: Information such as name and email address will be self-submitted and stored in a Qualtrics database.

Criteria for Waiver: The DUHS IRB may waive the requirement for informed consent and authorization if all of the following criteria are met:

- Please respond to each item in the space below using protocol-specific language to provide justification:

a) The research or clinical investigation involves no more than minimal risk to subjects:

Identification process for potential participants involves no more than minimal risk to participants.

For AMC Survey raffle winner, an IRB disclosure form for payment purposes. The participant can decline to disclose this information if they feel uncomfortable doing so.

The Aim 3 Follow-Up Interview and Survey will be completed virtually and all data will be securely stored in RedCap and Duke Box.

Administrative Supplement Aim 3 (Scientific Working Group Delphi Panel): No human subjects will be included in this aim. This is a scientific working group of expert consultants being asked to report based on their content area expertise.

b) The waiver or alteration will not adversely affect the rights and welfare of the subjects. Include a description of any measures to be taken to ensure that the rights and welfare of subjects will be protected:

Identifying information submitted by the subject for recruitment will be stored within a REDCap database. This data is password protected and only available to approved study staff and investigators. Participant welfare and rights are not negatively affected by this process.

For AMC survey: We will send a qualtrics survey link to AMC chief diversity officers or equivalent. Since this survey is institution based, and not person based, participant welfare and rights are not negatively affected by this process. For AMC Survey raffle winner, an IRB disclosure form for payment purposes. The participant can decline to disclose this information if they feel uncomfortable doing so.

Aim 3 Follow-Up Interview and Survey: To protect the rights and welfare of participants, language describing the procedures, rights, and contact information for the study team/IRB will be provided at the beginning of the interview scheduling survey and three question survey. Participants will also be informed of their right to withdraw participation. We will also store data securely in RedCap and Duke Box.

Administrative Supplement Aim 3 (Scientific Working Group Delphi Panel):
No human subjects will be included in this aim. This is a scientific working group of expert consultants being asked to report based on their content area expertise. We will use Duke Qualtrics for the application and each round of the Delphi panel survey to keep their information confidential.

c) Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

Whenever appropriate, subjects will be provided with additional pertinent information.

d) If this research activity relates to research involving deception, explain how subjects will be provided with additional pertinent information after study participation and what information will be provided. Otherwise indicate "not applicable":

N/A

e) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements (e1. and e2.)

Demonstrate that the use or disclosure of PHI involves no more than minimal risk to the privacy of subjects by describing the plans requested below:

**e1) An adequate plan to protect the identifiers from improper use and disclosure.
Describe the plan (how protection will be accomplished) and indicate where the PHI will be stored and who will have access:**

PHI identifiers will be stored within a REDCap database (stored on Duke servers) and RedCap Surveys with access restricted to approved study staff. Data will be stored with a corresponding study ID.

AMC Survey: No PHI will be stored for most participants. For AMC Survey raffle winner, an IRB disclosure form is required for payment purposes. The participant can decline to disclose this information if they feel uncomfortable doing so. The form will be uploaded to the geriatrics box folder for payment purposed only. After payment, all PHI will be purged as required.

Aim 3 Follow-up interview and survey: PHI identifiers will be stored within Duke RedCap and only approved key personnel will have access to data. We will also securely store any notes from the interview in Duke Box.

Administrative Supplement Aim 3 (Scientific Working Group Delphi Panel):
No human subjects will be included in this aim. This is a scientific working group of expert consultants being asked to report based on their content area expertise. We will use Duke Qualtrics for the application and each round of the Delphi panel survey to keep their information confidential.

e2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Describe the plan (how and when identifiers will be destroyed and by whom). If there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, provide the reason to retain identifiers:

Identifiers will be maintained for 6 years after the completion of the study in accordance with Duke policy. After this date, electronic records will be destroyed.

e3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity except (i) as required by law, (ii) for authorized oversight of the research study, or (iii) for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule. By electronically signing this submission, the PI provides this written assurance:

True.

f) The research could not practicably be conducted or carried out without the waiver or alteration:

- Explain why informed consent/authorization can not be obtained from subjects.

Participants are self-screening for eligibility for the study. The information is necessary to identify eligible participants. We are recruiting from the community and potential participants would not have the opportunity to participate without first self-screening.

AMC Survey: We will send a qualtrics survey link to AMC chief diversity officers or equivalent. Since this survey is institution based, and not person based, participant welfare and rights are not negatively affected by this process. For AMC Survey raffle winner, an IRB disclosure form is required for payment purposes. The participant can decline to disclose this information if they feel uncomfortable doing so.

Aim 3 Follow-up interview and survey: Participants previously signed the Aim 3 consent form. The follow-up interview and survey are additional ways to evaluate participants' decision to enroll in the study and participate or not participate in the session. Participants will still receive an informative descriptive of procedures before participating in the interview or survey with an explanation that continuation implies consent.

Administrative Supplement Aim 3 (Scientific Working Group Delphi Panel):
No human subjects will be included in this aim. This is a scientific working group of expert consultants being asked to report based on their content area expertise.

g) The research could not practicably be conducted or carried out without access to and use of the protected health information:

Since we are recruiting from the community, there would be no way to contact/screen potential participants without this information.

AMC Survey: No PHI will be obtained for most participants. For AMC Survey raffle winner, an IRB disclosure form is required for payment purposes. The participant can decline to disclose this information if they feel uncomfortable doing so.

Aim 3 Follow-Up interview and survey: In order to recruit participants for the interview and survey, we will need access to this information. This information is also necessary to schedule them for the interview and to conduct the interview.

Administrative Supplement Aim 3 (Scientific Working Group Delphi Panel): Information such as name and email address is necessary to recruit for and conduct each round of the panel.

h) For research using biospecimens or identifiable information, the research could not practicably be carried out without access to and use of the protected health information:

In order to identify potential participants, name and contact information is required to follow up for screening, consent and enrollment.

AMC Survey: No PHI will be obtained for most participants. For AMC Survey raffle winner, an IRB disclosure form is required for payment purposes. The participant can decline to disclose this information if they feel uncomfortable doing so.

Aim 3 Follow-Up interview and survey: Name and email address is required in order to recruit participants and schedule them for interviews.

Administrative Supplement Aim 3 (Scientific Working Group Delphi Panel): Information such as name and email address is necessary to recruit for and conduct each round of the panel.

Privacy and Confidentiality

Explain how you will ensure that the subject's privacy will be protected:

Consider privacy interests regarding time and place where subjects provide information, the nature of the information they provide, and the type of experience they will be asked to participate in during the research.

We will use Duke RedCap and Qualtrics for all survey data as this is behind the Duke firewall. Study records that identify patients will be kept confidential as required by law. All data will be marked with a unique code number for storage at Duke University Health System in accordance with Duke's Institutional Review Board's guidelines and policies. All data collection will occur in private settings where patient survey responses cannot be seen or heard by others. Patients are able to refuse to answer any of the questions or stop participation in this study at any time.

During the screening process, each potential participant will be assigned a study participant number for tracking purposes. Participant identifying information will be recorded only at the time of screening and will be kept separate from data forms and in a locked file cabinet in the research offices of the PI. Potential participants who decline participation or are ruled ineligible during the screening process will have their identifying information destroyed. All other case report forms will be identified by study participant number only.

AMC Survey: We will send a qualtrics survey link to AMC chief diversity officers or equivalent. Since this survey is institution based, and not person based, participant privacy will not be violated. No PHI will be obtained for most participants. For AMC Survey raffle winner, an IRB disclosure form is required for payment purposes. The participant can decline to disclose this information if they feel uncomfortable doing so.

Describe how research data will be stored and secured to ensure confidentiality:

How will the research records and data be protected against inappropriate use or disclosure, or malicious or accidental loss or destruction? Records and data include, for example, informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheets, screening logs or telephone eligibility sheets, web based information gathering tools, audio/video/photo recordings of subjects, labeled specimens, data about subjects, and subject identifiers such as social security number.

Electronic study data storage: A RedCap database will be created and shared with key personnel on this study. Using encrypted study computers, a trained research assistant will administer/send surveys to consented subjects in order to enter that data directly into the database. At the time of analysis and after data cleaning, we will export the data from RedCap into secured statistical software as above. All output analyses will be stored on a secure Box folder created for the purpose of this study and with access restricted to key personnel.

All hard copies of data will be stored in the office or lab space of either PI. Electronic data files will be password-protected and maintained on a password-protected Duke server, with access only available to approved study staff and investigators. This includes the study database, which contains the link of study identification numbers to identifying information. All data will be retained for at least 10 years and will be destroyed according to Duke guidelines.

Focus group discussions and transcripts, as well as notes from cognitive interviews, will be stored in a secure Box study folder.

AMC Survey: Results will be exported from Qualtrics into a secure Box study folder. No PHI will be obtained for most participants. For AMC Survey raffle winner, an IRB disclosure form is required for payment purposes. The participant can decline to disclose this information if they feel uncomfortable doing so. All data will be retained for at least 10 years and will be destroyed according to Duke guidelines.

Administrative Supplement Aim 3 (Scientific Working Group Delphi Panel): We will use Duke Qualtrics to collect and store information for each round of the Delphi panel.

Application Questions Complete

Please click Save & Continue to proceed to the Initial Submission Packet.

The Initial Submission Packet is a short form filled out after the protocol application has been completed. This is an area to attach protocol-related documents, consent forms, and review the application.

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Development and Feasibility testing of an implicit bias training intervention for providers to advance equity in healthcare: Aim 3
Version 3.0

CONCISE SUMMARY

The purpose of this study is to implement a refined implicit bias reduction intervention. Implicit bias occurs when thoughts and feelings outside of conscious awareness and control affect judgment and/or behavior. Training can minimize the effects of implicit bias by raising awareness.

If you decide to participate, you will be asked to complete a baseline survey to assess eligibility and demographics, attend three interactive sessions via zoom (2-3 hours each, conducted over 4-12 weeks), and complete post-session surveys and two evaluation surveys at the end of the program. Study team members will lead the training. Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

The greatest risk of this study is the possibility of loss of confidentiality.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you provide patient care at a Duke-affiliated facility. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Laura Svetkey, MD will conduct the study and it is funded by the National Institute of Health (NIH). The sponsor of this study, NIH, will pay Duke University to perform this research, and these funds may reimburse part of Dr. Svetkey's salary.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to determine the acceptability and feasibility of delivering an implicit bias educational program to providers.

There is a large body of empiric evidence indicating that all humans make implicit associations. This is a process in which we make unconscious associations about members of certain groups that can lead to stereotyping. There is further evidence that these associations affect our clinical care, decision-making, patient's experience of our care, and health outcomes,

contributing to disparities in healthcare. Consequently, there are many implicit bias training programs, but little evidence of impact and best practices. This REACH Equity research project aims to fill that evidence gap by developing and pilot-testing an implicit bias educational program for providers that can be more definitively tested and ultimately disseminated. The ultimate goal of this research is to mitigate the impact of provider implicit bias on clinical care with a particular focus on racial and ethnic minority patients who experience healthcare disparities.

We have developed an implicit bias educational program using a conceptual framework, literature review, qualitative research methods, and our own internal and external experts. We are asking you to participate in pilot-testing this educational program to determine feasibility and acceptability among providers.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
We will recruit up to 50 to will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
If you decide to join the study, you will be asked to sign and date this consent form. You will then be asked to complete a baseline survey to assess eligibility and demographics, attend three interactive sessions via zoom (2-3 hours each, conducted over 4-12 weeks), and complete post-session surveys and two evaluation surveys at the end of the program. Study team members will lead the training. Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

HOW LONG WILL I BE IN THIS STUDY?
Participants will participate for three implicit bias training sessions which will last up to 3 hours each for a total of 9 hours. There will also be follow-up questionnaires for you to complete through RedCap at the end of the program. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may

take a break at any time during the study. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be no direct benefit to you, but you may find the educational program useful and interesting. We hope that in the future the information learned from this study will benefit other providers and patients.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

The Department of Health and Human Services (DHHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information.
This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.
Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be

assigned a unique code number. The key to the code will be kept in a locked file in Dr. Svetkey's office.

This information may be further disclosed by the sponsor of this study, the National Institute of Health. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed. Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS?
There will be no additional costs to you as a result of being in this study.

WHAT ABOUT COMPENSATION?
You will not receive compensation for participating in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Svetkey (919) 681-6386 during regular business hours or text Dr. Svetkey at 919-819-0238 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

DUKE UNIVERSITY HEALTH SYSTEM

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You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision to not participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Svetkey in writing (via email: laura.svetkey@duke.edu) and let her know that you are withdrawing from the study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Svetkey by email (laura.svetkey@duke.edu), or by phone at 919-681-6386 during regular business hours or on her cellphone (919-819-0238) after hours and on weekends and holidays. For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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Development and Feasibility testing of an implicit bias training intervention for providers to advance equity in healthcare: Aim 3
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STATEMENT OF CONSENT
The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form.

- ○ I have read the consent document and I wish to participate in this study.
- ○ I have read the consent document and I DO NOT wish to participate in this study.

_____
First Name of Participant

_____
Last Name of Participant

_____
Email Address of Participant

_____
Consent Review Date/Time