Title: TRANSLATE: Transgender and Gender Nonconforming Individuals' Access to Healthcare

Identifiers: NCT03808883

Unique Protocol ID: IRB-2018-2194

Last Update: 5/11/2018

[USE THIS SOCIAL, BEHAVIORAL, AND EDUCATIONAL PROTOCOL TEMPLATE IF YOUR PROJECT INCLUDES SURVEY, INTERVIEWS, FOCUS GROUPS OR EDUCATIONAL RESEARCH ACTIVITIES WITH NO BIOMEDICAL/CLINICAL COMPONENTS]

INSTRUCTIONS:

- *Use this template to prepare a document with the information from the following sections.*
- *Depending on the nature of what you are doing, some sections may not be applicable to your research. You may delete contents of sections, but will not be able to delete the headings of the sections*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *Consider using a different color font for your answers.*
- *Text in blue may be deleted or replaced by your answer(s).*

PROTOCOL TITLE:
Proposal for Understanding and Reducing Health Disparities Faced by Transgender and Gender Nonconforming (TGNC) Individuals in Cleveland through TGNC-Directed Advocacy

PRINCIPAL INVESTIGATOR:
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UH FACULTY ADVISOR:
If the principal investigator's primary role at UH is resident, fellow or student, identify a faculty advisor. N/A

OTHER DEPARTMENTS INVOLVED IN THIS STUDY (IF APPLICABLE):

VERSION NUMBER:
2.0

DATE:
5/11/2018

Indicate the origin of this protocol (who conceived of and leads the development of the protocol regardless of funding):

☒ Investigator initiated *(Investigator(s) developed protocol, regardless of funding)*
☐ Industry *(Pharmaceutical, Device, etc.) (Industry developed protocol)*
☐ Federal *(NIH, DOD, etc.)*
☐ Cooperative Group *(SWOG, GOG, etc.)*
☐ Other - *Please specify:*

Funding

NIH pass through grant from Centers for Reducing Health Disparities (MetroHealth)

Objectives

RESEARCH QUESTION: Do interactive dialogues between trans and gender nonconforming (TGNC) - trained in health literacy and advocacy - and healthcare providers and staff seeking cultural competency around TGNC primary care result in 1) more confidence on the part of TGNC in navigating the healthcare system, 2) more confidence on the part of providers in responding to the needs of TGNC patients, (sub question – is there a measurable difference between types of providers' responses to trainings, i.e., medical doctors compared to nurse practitioners) 3) person-to-person networks between the two populations resulting in ongoing, sustainable dialogue, 4) TGNC individuals prepared to train other TGNC in a peer-to-peer role to act as advocates on behalf of the TGNC population within the healthcare system, all of which ultimately result in increased access to and use of primary care services and reduce the health disparities faced by TGNC individuals?

Background

Research has shown repeatedly that transgender people are more at risk for poor health outcomes than the general population and even others with whom they share the LGBTQ+ moniker (Bradford, Reisner, Honnold, & Xavier, 2013; Grant, Mottet, Tanis, Herman, & Keisling, 2011; James et al., 2016; NPR, Robert Wood Johnson Foundation, & Harvard T.H. Chan School of Public Health, 2017; Whitehead, Shaver, & Stephenson, 2016). Although little data is available, Ohio is consistent with larger national trends of transgender people having negative interactions in healthcare settings (National Center for Transgender Equality, 2016; National Center for Transgender Equality & National Gay and Lesbian Task Force, 2011). The paucity of research of transgender health is a possible source of health disparities (Institute of Medicine (US) Committee on Lesbian, 2011; Shelton & Bond, 2017; Snyder, Burack, & Petrova, 2017; Stephenson et al., 2017) and researchers have become more cognizant of barriers faced by LGBT people to participate in research (Fisher & Mustanski, 2014; Murphy, 2014; Owen-Smith et al., 2016). Gender nonconforming individuals may face even greater challenges in receiving appropriate care, as they refute the gender binary so ingrained in medicine (Eckstrand, Ng, & Potter, 2016; Lykens, LeBlanc, & Bockting, 2018). Work done on the stigmatization of TGNC individuals broadly (Grant et al., 2011; James et al., 2016; NPR et al., 2017) and on the treatment of TGNC individuals medically (Bradford et al., 2013; Cruz, 2014; Shelton & Bond, 2017) recognizes their experiences are influenced by other aspects of identity, including race and class. TGNC individuals of color are even more likely to have negative experiences with healthcare providers than their white counterparts (Grant et al., 2011; NPR et al., 2017). The recent uptick in research specific to TGNC health needs (Imborek, Graf, & McCune, 2017; Thompson, 2017; Whitman & Han, 2017) was spurred in part by federal funding opportunities (Institute of Medicine (US) Committee on Lesbian, 2011) but mostly as a result of LGBTQ+ advocacy (Pandya,

2014; The Fenway Institute, 2017). Studies on reducing LGBTQ+ health disparities have included restructuring electronic health records and data collection methods (Cahill et al., 2014; Callahan, Hazarian, Yarborough, & Sánchez, 2014), addressing myths and establishing best practices (McNamara & Ng, 2016), and macro-analysis of intersectionality between institutions providing transgender healthcare (Stroumsa, 2014). More in line with our proposal are studies that focus on direct, personal intervention with healthcare providers (Lelutiu-Weinberger et al., 2016), advocacy led by community members (Cartwright, Desiderio, Green, Persson, & Tescher, 2012), and based directly on self-assessed patient needs (Alpert, CichoskiKelly, & Fox, 2017; Bevan, 2013). The annual Philadelphia Trans Wellness Conference includes a professional track for medical providers on issues such as primary care management and gender affirming medical procedures, exemplifying both a community need for improved quality of care and interest within in the medical field (Mazzoni Center, 2018).

Inclusion and Exclusion Criteria

Directions: Describe how individuals will be screened for eligibility. Using the tables below, describe the inclusion and exclusion criteria that will define who will be included and excluded in your final study sample.

	Inclusion
1.	Age range: 14 years old and up
2.	Self-identifies as transgender or gender non-conforming
3.	
4.	

	Exclusion
1.	Under the age of 14
2.	Non-English speaking
3.	
4.	

Number of Research Participants

We will enroll 20 participants in the transgender/gender non-conforming cohort, 12 medical providers, and 12 clinic staff.

Vulnerable Populations

1. *Indicate specifically if you will include each of the following special populations by checking the appropriate box:*
   - ☐ **Adults unable to consent**
   - ☒ **Minors (infants, children, teenagers)**
     - ☐ Wards of the state
     - ☐ Foster Children
   - ☐ **Pregnant Women**
   - ☐ **Neonates**
   - ☐ **Neonates of Uncertain Viability**
   - ☐ **Employees of CWRU or UHHS**

- ☐ **Prisoners**
- ☐ **Illiterate Individuals**
- ☐ **Non-English Speaking**
- ☐ **University Students**
- ☐ **None**

2. If the research involves individuals that are included in a vulnerable population, describe the additional safeguards included to protect the rights and welfare of the individuals for each population indicated. Minors (aged 14-17) will be invited to participate in the study with their parent's permission. Assent forms with appropriate language will be provided and youth will be invited to take them home to discuss with trusted individual. It will be emphasized that participation is voluntary and can end at any time and that a decision to participate will not result in negative consequences (including loss of services through the LGBT Community Center).

3. If excluding pregnant women, illiterate or non-English speaking individuals, provide a scientific rationale for the exclusion. Inconvenience or cost is not an acceptable rationale.
   Non-English speakers will be excluded from this study because the primary intervention is a discussion-based group that requires a grasp of English.

Recruitment Methods

Note: Attach all applicable recruitment materials to the last section of the Smart form under "Recruitment Materials."

1. Which of the following methods will be used to recruit research participants. *– Select all that apply*
   - ☒ Email
   - ☒ Phone call
   - ☐ Letter
   - ☒ Advertisement (e.g., poster, flyer, etc.)
   - ☒ Social media
   - ☐ Other. *Please specify:*

2. Describe when, where, and how potential research participants will be recruited.
   Research participants will be recruited from the LGBT Community Center's existing database of people who attend meetings at the Center or have participated in events such as TRANS in the CLE. Flyers will go up about 1 month before the beginning of the program. Emails and phone calls will be sent out about 3 weeks prior. Social media posts on the LGBT Community Center's accounts (Facebook, Instagram, Twitter) will begin about 3 weeks prior. Coordinators at the Center may refer people to flyers at other meetings. Similar contact schedules will follow for medical providers and staff.

3. Describe the source (e.g., from what department, EMR, etc.) of the research participants.

LGBT Community Center, Preterm, Planned Parenthood, MetroHealth, Neighborhood Family Practice

4. Describe the methods that will be used to **identify** potential research participants.

Potential research participants will be asked to fill out a screening tool so that we can create a sample that is reflective of the diversity in Cleveland.

5. Describe the feasibility of recruiting the required number of suitable research participants within the agreed recruitment period. For example, how many potential research participants do you have access to? The LGBT Center regularly sees over 100 unique TGNC individuals each month for their transgender programming, with an additional list of 300 individuals in Cleveland who participate less regularly. Recruiting 20 from that list is feasible. We have the support of several clinics to recruit medical providers and staff.

Setting

Research (in the form of cohort meetings and facilitated discussions) will occur at the LGBT Community Center. Recruitment for the TGNC cohort will occur in the same location. Recruitment for medical providers and staff will be done via email and phone.

Consent Process

1. Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes, answer the following questions:

1. Describe where the consent process will take place:
   When an individual first expresses interest in the study by filling out an application, the consent form will be provided. When an individual is confirmed, the PI or Research Associate will review the consent form in detail at the LGBT Center and then the person will sign, if they so choose.
2. The time that will be devoted to the consent discussion:
   At least 5 minute discussion, with the individual able to review the document at their leisure beforehand. When the cohort begins, consent will be reviewed and then revisited periodically.
3. Any waiting period available between informing the prospective subject and obtaining the consent:
   Yes – consent form given when screening tool filled out
4. Steps that will be taken to ensure the research participants' understanding:
   Consent form will be written in age appropriate language and investigators will set time aside to answer any questions
5. Any process to ensure ongoing consent:
   Check in at the beginning of meetings
6. The role of the individuals listed in the application as being involved in the consent process:
   Misty Luminais and Margaret McGuire
7. Steps that will be taken to minimize the possibility of coercion or undue influence to the subjects:

Reiteration of the voluntary and on-going ability to end participation at any time without negative effects

2. Indicate if you will be asking for a waiver or alteration of consent process or documentation (consent will not be obtained, written consent will not be documented)

☐ Yes ☒ No

If yes, indicate which part of the consent process you are requesting be waived or altered and the rationale for requesting the waiver or alteration:

☐ I will obtain consent, but not participant's signature

☐ I will obtain consent, but request a waiver for pre-screening purposes

☐ I will obtain consent, but request a waiver of some of the elements of consent (e.g. use of deception)

☐ I will not obtain consent, and I am requesting a full waiver of consent

1. Give the rationale for the request of a waiver or alteration of the consent process or documentation:

2. Explain how the research involves no more than minimal risk

3. Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants:

4. Explain why the research could not practicably be carried out without the waiver or alteration of consent.

5. If you will obtain consent, but not document consent in writing (e.g. over the phone, verbally, electronic survey, etc.), please describe and provide a rationale.
   ☐ N/A

6. Describe how you will be documenting that a research participant has consented

**Be sure to upload a consent script or information sheet with your study protocol*

Additional Considerations for Consent Process with Adults

Non English Speakers *(Please select one)*

☒ I am **not** enrolling non-English speaking individuals in this research study. The following is justification for why non-English speaking individuals cannot be enrolled:

The intervention is based on participation in ongoing, fast paced discussion groups that require a good grasp of spoken English.

☐ I will be targeting non-English speaking adults

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study.

2. List the language(s) other than English that will be targeted:

☐ I am **not** targeting non-English speaking individuals. If a non-English speaking individual is eligible for the trial, we will use the following procedures to enroll:

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study.

2. List the language(s) other than English that will be targeted:

Adults Unable to Consent

☒ I am **not** enrolling adults unable to consent in this research study – *please leave the rest of this section blank.*

☐ There is an anticipated direct benefit to the subject. Explain:

☐ There is NOT an anticipated direct benefit to the subject. Explain:

1. Describe the process to determine whether an individual is capable of consent.

2. List the individuals from whom permission will be obtained in order of priority (e.g. durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child).

3. For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in the research.
   ☐ N/A

4. Describe the process for assent of the research participants. Indicate:
   - Which subjects that are unable to consent will be required to give assent? If not all, explain why.

   - Describe whether assent of the research participants will be documented and the process to document assent.

   ☐ The subject will be informed about the research to the extent compatible with the subject's understanding.
   ☐ Subjects will be closely monitored.
   ☐ The subject will be withdrawn if they appear unduly distressed.

Research Participants Who Are Not Yet Adults (infants, children, teenagers)

☐ I am not enrolling participants who are not yet adults in this research study. *– please leave the rest of this section blank*

1. Will parental permission be obtained from:
   - ☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child
   - ☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child
   - ☐ Waiver of parental permission

2. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's participation in research. Legal guardians will be asked for consent if the child is under their care. If a youth wants to participate with the permission of the legal guardian, the guardian will be asked to provide proof of guardianship.

3. Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. Assent will be obtained from all children participating.

4. When assent of children is obtained, describe how it will be documented. Because all children must be at least 14 years old, assent will be written.

5. For children who are pregnant, describe how assent and permission are obtained.
   ☒ N/A

6. Describe how the risk is justified by the anticipated benefit to the subjects.
   Although minimal, the risks of embarrassment, stigma, or group stereotyping are present. Many TGNC individuals already face these issues in their everyday lives. Working as an advocacy team working with healthcare providers, subjects may experience those feelings. We will employ a trained facilitator who understands the challenges faced by TGNC individuals and can redirect the conversation with healthcare providers to a productive dialogue rather than a rehashing of stereotypes. Discussing health disparities may bring up these feelings as well. We will have access to the full complement of services provided by the LGBT Center, including support groups for TGNC individuals and referrals for counseling if anyone becomes so distressed that this is necessary.
   There may be the perception that lack of participation could result in the loss of services offered by the LGBT Center since they are the community partners and the events will occur in their space. We will make it abundantly clear in all written and

spoken communication that this is not the case and will convey the information at the time an individual calls to get more information when recruited through the flyer. However, because the LGBT Center offers a number of these types of groups, either for support or advocacy, the culture supports the belief that participation in such a project is completely voluntary.

There is the possibility that someone may not be "out" as transgender or gender non-conforming in some aspects of their lives. Participation in this group may expose them to the risk of disclosure because it is a public group in which the researchers cannot guarantee complete confidentiality. At the beginning of the program and periodically throughout, we will discuss the importance of maintaining confidentiality. We will be upfront about the possibility of breach of confidentiality and encourage those who feel it could adversely impact their lives severely not participate. As far as the data collection goes, we will store all fieldnotes, audio recordings, surveys, and any other data collected on Box, a secure, encrypted server. Access to the data will be limited to the PI, co-PI, community partner (to be hired), and the RA (Margaret McGuire).

At the heart of this project is addressing the ways that stigma can result in disparate healthcare outcomes. Therefore, a forthright discussion of what constitutes stigma and how it impacts healthcare decisions is necessary. We believe it is important for healthcare providers to actually hear the concerns of TGNC people from those people directly in order to increase their cultural competency. By employing a trained facilitator to moderate the discussion, we hope that both groups will benefit from the discussion, ultimately resulting in a more welcoming atmosphere for TGNC people at clinics and more knowledge and comfort on the part of TGNC people in seeking healthcare. This is a relatively low-cost intervention that has the potential to greatly increase access and use of health care by a population that suffers great disparities. If successful, it could be reproducible in other locations.

7. Describe how the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
   There are no available alternatives.

Sharing of Results with Research Participants

- ☐ Results will not be shared with research participants
- ☐ Results will not be shared with research participants' doctors

Results will be co-created and shared with participants over the course of the study through constant feedback. Final results will be presented at the LGBT Center, probably through TRANS in the CLE conferences and other LGBT-directed gatherings. Final reports will be available at the Center. Medical providers and staff will have access to all final reports.

Study Design

Non-random participatory action research consisting of discussion groups and facilitated meetings

Study Procedures

Over the course of the grant year, each step of the project is divided into three month portions. The first quarter will be dedicated to recruiting and forming a

cohort of TGNC individuals, drawn mostly from the LGBT Center's extensive contact lists and centrality within the TGNC population. We plan on recruiting 20 individuals to ensure we meet the minimum retention of 12 subjects throughout the study needed for qualitative saturation (Guest, Bunce, and Johnson 2006), and individuals between 14-18 years of age will be able to participate with guardian permission. Interested individuals will fill out applications to identify their interests and ability to commit to the project and will allow us to create a cohort that reflects the diversity of the TGNC community in Cuyahoga County, including gender identity, types of gender-affirmative care required (including whether or not someone is considering, in the process of, or completed physical transition), racial and ethnic identity, age (over 14), and socio-economic class. Upon accepting the invitation to participate, each member of the cohort will complete a pretest that will elicit data on their experiences in the healthcare system, their knowledge of basic and transgender-specific medical terminology, their familiarity with healthcare providers in Cuyahoga County, and the likelihood of seeking care under a number of conditions (acute, chronic, moderate, severe). We expect this to take one month. The following two months will consist of meeting as a cohort twice a month. The first two meetings will be dedicated to understanding the group's collective experiences with health care, what they would like to see change, and what strategies can be used to accomplish those ends. We recognize that TGNC people come from a variety of backgrounds and each will bring their own strengths, networks, and perspectives to the table which will allow us to make full use of the indigenous expertise of the group. In consultation with the Nursing School of CWRU, we will develop a health literacy training that meets the expressed needs of the cohort and Jesse Honsky will present it during the 3rd meeting. The goal here is not to provide all possible health education but rather to arm the cohort with the skills and language to empower them to act as advocates on their own behalf when navigating the healthcare system. The final meeting (the 4th) in this first quarter will be with a trained facilitator (Shemariah Arki) who will, under the direction of the TGNC cohort, plan a series of three interactive dialogues between the TGNC cohort and the healthcare providers. By meeting with the TGNC cohort first, without the healthcare providers, the TGNC cohort will have the opportunity to ensure the dialogues are designed to meet their objectives. Individual healthcare practitioners and medical staff will be recruited during the first quarter from the aforementioned clinics. We will recruit at least twelve providers and twelve staff members, who will attend one meeting each. All of the clinics we have documented support from and those we are in current dialogue with have previously reached out to the LGBT Center for training in this area, and CMEs may be available through MetroHealth. In the second quarter, we will

conduct a pretest that will collect data on attitudes towards TGNC individuals, TGNC-specific healthcare concerns, depth and breadth of referral networks for TGNC providers. Once the healthcare provider group is solidified, the LGBT Center will host three evening meetings (once per month) with the trained facilitator wherein TGNC individuals lead a conversation about what they see as barriers to their care, how they would like to be treated, and what they want healthcare providers to know about them as people. The first two meetings will be with healthcare practitioners and the final meeting will be medical staff so that the meetings can be more specific and without the interference of power dynamics within the provider groups. Healthcare providers and staff will only attend one meeting each. During this second quarter, the TGNC cohort will continue to meet on its own once a month to debrief from meetings, respond to what they have learned so far, and possibly refine the strategies for future meetings with healthcare providers as the series goes forward. At the end of the three months of dialogue, each participant, from both the TGNC cohort and healthcare provider, will be given a post-test to measure changes in attitude, practice, and knowledge. Participants will also have the opportunity to engage in a reflective interview.
The third quarter will diverge onto two different paths: the LGBT Center project coordinator will continue to engage with the cohort as they shift into the role of peer educators and advocates with other members of the TGNC community that interact at the LGBT Center. Luminais will conduct follow-up interviews with any TGNC cohort member that notifies the researchers that they have sought medical care and with any healthcare provider that notifies the researchers that they have had a clinical interaction with a TGNC individual. We will not be seeking any protected medical information or the identity of patients, in the case of healthcare providers, but rather a discussion of the ease or difficulty in communication, levels of comfort, and comparison with other interactions in general.
Throughout the process, both Luminais and the LGBT Center coordinator will be engaged in participant observation (Bernard, 2002; Denzin & Lincoln, 1994) and keep detailed field notes on all the meetings. All participant observation will take place during the scheduled cohort meetings which will not be recorded except through note-taking. All interviews will be transcribed unless the participant chooses not to be recorded; interviews and field notes will be coded with a priori codes (Bernard & Ryan, 2010) derived from the literature on reducing health disparities and TGNC-specific health care by a research assistant. Participants may choose to participate in an optional reflective interview where they are asked to reflect on the appropriateness and effectiveness of the project in meeting their expectations. Pre- and post-tests will be analyzed to determine the success of facilitated dialogue in improving confidence and knowledge by both the TGNC

cohort and the healthcare providers, and depending on sample size, we will determine if there are any statistically significant changes. This analysis and write up will encompass the last quarter of the project.

Study Timeline

	Pre-Screening	Meetings 1-18	Facilitated meetings	Optional interviews
Estimated time requirement of visit for TGNC cohort	Fill out on own	1.5 hours		1.5 hours
Estimated time requirement of visit for medical providers			2 meetings, 1.5 hours each	1.5 hours
Estimated time requirement of visit for medical staff			1 meeting, 1.5 hours	1.5 hours

Devices

If the research involves device(s), describe your plans to use the device(s).

☒ N/A

ClinicalTrials.gov Information

Case Western Reserve University Protocol Record IRB-2018-2194, TRANSLATE: Transgender and Gender Nonconforming Individuals' Access to Healthcare, has been reviewed and will be made public on ClinicalTrials.gov.

List of Data to be Collected

Note: If using REDCap, all selected identifiers below must be indicated as PHI.

1. *Indicate what identifiers you will collect*

☒ Name
☐ Address *(e.g., Zip code, other geographical designation, etc.)*
☐ Dates related to an individual *(e.g., Date of admission, birth, surgery, etc.)*
☐ Telephone number
☐ Fax number
☐ Email address
☐ Social security number
☐ Medical record number
☐ Health plan beneficiary number
☐ Account number
☐ Certificate/license number
☐ Any vehicle or other device serial
☐ Device identifiers or serial numbers
☐ Web URL
☐ Internet protocol (IP) address
☒ Finger or voice prints

☐ Photographic images

☐ Other: Any characteristic that would uniquely identify the individual

2. List all other data to be collected for the research study *(e.g. laboratory values, physician notes, length of stay, etc.)*

Data Analysis Plan

Pre and post tests will analyze knowledge gained. Qualitative data analysis with atlas.TI will be performed on field notes based on meeting observations and any optional interviews completed.

Confidentiality of Data

1. To maintain the confidentiality of the data:

   ☒ I will use a unique study identifier (not derived from the participants personal identifiers) to code individuals' data and I will store this ID log separate from study data.

   ☒ Other (please explain) Upon completion of the study, identifiers will be destroyed, leaving only the unique coded identifier in fieldnotes and transcripts. Voice recordings will be destroyed as soon as interviews are transcribed.

   Screening data will be collected by LGBT team member (Gulnar Feerasta, CREC certified) on paper and scanned to an electronic file that will be uploaded to Box, after which the paper and local file will be destroyed. People who choose to answer the screener online through Qualtrics will have their data exported to Box. After the sample is composed, all electronic documents will be destroyed.

2. How are you storing your electronic data?

   ☐ UH Redcap

   ☐ CWRU Redcap

   ☐ Secure Research Environment (SRE)

   ☒ CWRU Box

   ☐ OnCore

   ☐ UH Secure Network Drive

   ☐ CWRU Secure Network Drive

   ☐ Other - List storage method and provide justification:

3. ☒ I acknowledge that paper research data and documents will be stored in a double-locked secure environment in the following location:
   Location: ☒ Misty Luminais's office (MSASS 375J)

4. Will data be shared?

   ☒ Yes

   - List the exact data elements that will be shared:
     1. Code books will be shared with NIH

2. Fieldnotes (deidentified) may be shared with researchers at LGBT Community Center

- Describe how data will be sent: via CWRU Box

☐ No

☐ N/A

(Please note: if sharing data, please contact your Grants and Contracts Specialist to ensure the proper contracts are in place.)

HIPAA Authorization

If you are going to be accessing PHI (Protected Health Information), indicate how HIPAA authorization will be obtained (check all that apply): N/A

☐ HIPAA authorization is in the consent form

☐ Requesting a full or partial waiver of HIPAA for prescreening

☐ Requesting a full or partial waiver of HIPAA

1. Describe why the study cannot be completed without the specified identifiable information.

2. If the identifiable information will be used or disclosed by anyone other than the research team, please state who those individuals/entities are and provide justification for the disclosure.
   ☐ Identifiable information will **not** be used or disclosed by anyone other than the research team
   ☐ Identifiable information will be used or disclosed to:

3. Describe how long identifiers will be kept for in relation to study length and data collection and analysis.

☐ I assure that protected health information collected for purposes of this research study will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512

Devices

☒ This is **not** device study. The protocol is considered non-therapeutic (non-therapeutic is defined as research not intended to diagnose, prevent, cure, mitigate, treat, etc. a disease or condition) by the FDA. – *You may delete the rest of this section.*

OR

☐ This is a device study. The protocol is considered therapeutic (research intended to diagnose, prevent, cure, mitigate, treat a disease or condition) by the FDA.

1. Is there an IDE (Investigational Device Exemption) for the proposed study?

   ☐ Yes, provide an official letter of support or proof of approval which identifies the IDE holder and IDE number. Please attach this in the SpartaIRB smartform

   ☐ No, see question below:

2. Is the device (and its use) a non-significant risk device for the proposed study design?

   ☐ Yes, please identify the authorized party who made the determination and provide supporting documentation as applicable.

   ☐ No *NOTE: either an active IDE or an exemption would be required for investigational product use in a therapeutic protocol.*

   ☐ N/A

3. If the research involves device(s), describe your plans to store, handle, administer and track those device(s) to ensure that they will be used only on research participants and be used only by authorized investigators.

Risks to Research Participants

1. List the reasonably foreseeable risks such as breach of confidentiality, discomforts, hazards, or inconveniences to the research participants related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Include the physical psychological, social, legal, and economic risks.
   Although minimal, the risks of embarrassment, stigma, or group stereotyping are present. Many TGNC individuals already face these issues in their everyday lives. Working as an advocacy team working with healthcare providers, subjects may experience those feelings. We will employ a trained facilitator who understands the challenges faced by TGNC individuals and can redirect the conversation with healthcare providers to a productive dialogue rather than a rehashing of stereotypes. Discussing health disparities may bring up these feelings as well. We will have access to the full complement of services provided by the LGBT Center, including support groups for TGNC individuals and referrals for counseling if anyone becomes so distressed that this is necessary.
   There may be the perception that lack of participation could result in the loss of services offered by the LGBT Center since they are the community partners and the events will occur in their space. We will make it abundantly clear in all written and spoken communication that this is not the case and will convey the information at the time an individual calls to get more information when recruited through the flyer. However, because the LGBT Center offers a number of these types of groups, either for support or advocacy, the culture supports the belief that participation in such a project is completely voluntary.
   There is the possibility that someone may not be "out" as transgender or gender non-conforming in some aspects of their lives. Participation in this group may expose them to the risk of disclosure because it is a public group in which the researchers cannot guarantee complete confidentiality. At the beginning of the program and periodically throughout, we will discuss the importance of maintaining confidentiality. We will be

upfront about the possibility of breach of confidentiality and encourage those who feel it could adversely impact their lives severely not participate. As far as the data collection goes, we will store all fieldnotes, audio recordings, surveys, and any other data collected on Box, a secure, encrypted server. Access to the data will be limited to the PI, co-PI, community partner (to be hired), and the RA (Margaret McGuire).

2. If applicable, indicate which experimental procedures may have risks to the research participants that are currently unforeseeable.
   ☒ N/A
3. If applicable, describe the risks to others who are not research participants.
   ☒ N/A
4. Describe the availability of medical or psychological resources that research participants might need.
   ☐ N/A
   The LGBT Community Center maintains contacts with May Dugan for crisis intervention and other community support, so if someone needs assistance, that connection can be made quickly.

Provisions to Protect the Privacy Interests of Research Participants

We will encourage confidentiality among participants in group settings but also be upfront about the fact that this is not a guarantee of confidentiality. We will not use identifiable information in any reports or publications. Interviews will be held privately.

Potential Benefit to Research Participants

☒ There is potential benefit to research participants.

1. Describe the potential benefits that individual research participants may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits.
   TGNC participants will be offered training on medical literacy to increase their own knowledge of the medical system. Medical providers will be offered training on cultural competency to increase their own knowledge of how to treat TGNC patients. These benefits could make navigating the space easier for each set of individuals.

☐ There is **no** direct benefit to research participants.

2. If no direct benefit, state the potential benefit to society or others. By reducing stigma and increasing knowledge about TGNC concerns, the medical profession can reduce the health disparities faced by TGNC people.

Withdrawal of Research Participants

Directions: Describe the anticipated circumstances under which research participants will be withdrawn from the research without their consent. Also include the procedures that will be followed when a research participant withdraws or are withdrawn from the research, including partial withdrawal from procedures with continued data collection.

☐ N/A If participants cannot continue to participate in bi-monthly meetings, they will be withdrawn after discussion. The data collected up to that point will continue to be used; field notes will not have participants' names and it would be very difficult to remove individuals' contributions. If the person had decided to give an interview, they would have the choice of whether or not that interview would be used.

Alternatives to Participation

Directions: List other available clinical treatments, what would be included if a subject continued on standard of care therapy. If this is not a clinical trial, you may select the box indicating that the alternative is not to participate. If there is a viable alternative you must list it in the consent.

☒ The alternative is for research subjects not to participate.

Costs to Research Participants

☒ There are **no** costs to research participants or their insurance companies (there are no clinical visits or billable procedures.) – *You may delete the rest of the section.*

1. Describe what costs research participants will be responsible for as a result of their participation in the research, including but not limited to: clinical services required by the protocol deemed billable to insurance, transportation to study visits, parking, costs of drugs, cost of therapy, lost broken or stolen devices, etc.

2. Explain who will be responsible for payment of provided services in the event of insurance denials.

3. List what procedures, drugs, devices, supplies will be paid by the study sponsor or covered by other funding. List the other funding source.

Research Participant Compensation

☐ There is no compensation for research participants

☒ There is compensation for research participants.
TGNC individuals will receive a $25 gift card for each meeting (up to 18 meetings) they attend in full at the end of that meeting. Medical providers will be offered CME credits and medical staff will be offered professional development credits.

☐ There will be reimbursement for research participants.
Describe the schedule, payment method, and payment total of any reimbursement that research participants will receive for participation in the research (e.g., gift cards or cash with amount, etc.)

Compensation for Research Related Injury

Describe who will pay for the costs of medical treatment and/or compensation in the event of a research related injury:

☐ Funding agency is providing some/all payment for injury

☐ Funding agency is providing no payment for injury

☒ N/A

Provisions to Monitor the Data to Ensure the Safety of Research Participants

1. Describe how often the data will be monitored for completeness, accuracy and adherence to the protocol.

Every quarter, the PI will review protocols to make sure they are being adhered to and spot check data collection.

2. Indicate if there will be a Data and Safety Monitoring Board or Committee:

☒ There will **not** be a formal Data and Safety Monitoring Board/Committee.

☐ There will be a formal Data and Safety Monitoring Board/Committee.

Provide information about the DSMB/C including the contact information of the committee member(s) (as applicable); whether it is independent from the study sponsor; how often it meets; the type of data that will be used; written reports, etc.

Community-Based Participatory Research

☐ This is **not** a community-based participatory research project – please leave the rest of this section blank

☒ This is a community-based participatory research project

The LGBT Center has been integral in the development of this design and will be a full partner in carrying out the work. Their staff is currently training on CREC and will be added when that is complete. A coordinator is being hired with the expectation they will also be a research partner. They will be involved in analysis and dissemination.

Note: Community based research is research that is conducted as an equal partnership between academic investigators and members of a community. In Community Based Participatory Research (CBPR) protects, the community participates fully in all aspects of the research process.

MULTI-SITE RESEARCH (when UH or CWRU is the IRB of Record)

Does this project have multiple sites?

☐ **Yes**

☒ **No** – please leave the rest of this section blank

Non-Local Site Information for Multi-Site Studies

*If this is a multi-site study where you are the **lead investigator,** list the following information for each relying site:*

1. Name of site:
2. PI of relying site:
3. Name of IRB contact:
4. Phone number of IRB contact:
5. Email address of IRB contact:

Non-Local Recruitment Methods for Multi-Site Studies

*If this is a multi-site study and research participants will be recruited by methods **not under the control of the local site** (e.g. call centers, national advertisements) describe those methods. Local recruitment methods are described above.*

1. *Describe when, where, and how potential research participants will be recruited.*

2. *Describe the methods that will be used to identify potential research participants.*

3. *Describe the materials that will be used to recruit research participants.*

Multi-Site Research Communication Plan (when you are the lead investigator)

*If this is a multi-site study where you are the **lead investigator**, describe the processes to ensure communication among sites including:*

☐ *All sites will have the most current version of the protocol, consent document, and HIPAA authorization*

☐ *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record)*

☐ *All modifications have been communicated to sites, and approved (including approval of the site's IRB of record) before the modification is implemented*

☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*

☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*

☐ *All local site investigators conduct the study in accordance with applicable federal regulations and local laws*

☐ *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy*

*If this is a multi-site study where you are the **lead investigator,** describe the method for communicating to engaged participant sites the following:*

1. *Problems:*
2. *Interim results:*
3. *The closure of the study:*

Additional Information

If you have any additional information regarding your study not covered in the template, please include it here.

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Please reference the Investigator Manual for local institutional requirements.