

Clinical Trial Consent Form Cover Sheet

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Project Title: Development and Evaluation of an Indigenized Family Acceptance Project for Lakota LGBTQ2S+ Youth

Principal Investigator: Dr. Katie M Edwards, PhD, University of Michigan

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U-M General Human Research Protocol Template

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1. Study Information

1.1 Protocol Title and Version Information

Indigenized Family Acceptance Project Open Pilot Trial

Study ID #: HUM00264029

Current Version Number: v. 4

Current Version Date: 3/23/2025

1.2 PI Information

Principal Investigator: Katie M. Edwards, Ph.D.

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PI Department Affiliation: School of Social Work

PI Responsibilities

Dr. Edwards conducts research on prevention of violence and related mental and behavioral health problems. Much of her work is with SGMY (sexual and gender minority youth) and/or Indigenous youth, predominantly Indigenous youth and she has a wealth of experience with program development and evaluation including family-based interventions and interventions for SGMY. Dr. Edwards has published more than 200 peer-reviewed publications, and her research is currently funded by NIH, CDC, NSF, CIHR, and DOJ. She will oversee and directly contribute to all programmatic and research aspects of the project. More specifically, with support from senior lab leadership, she will be responsible for staff hiring/training, maintaining IRB protocols and strict adherence to IRB protocols, refinement and implementation of research protocols, recruitment/retention, qualitative data analyses, and dissemination efforts. She will provide input to Dr. Lorey Wheeler (Co-I, UNL) on quantitative data analyses and work closely with Dr. Caitlin Ryan (Director, Family Acceptance Project) on programming and Dr. Gayle Beck (licensed clinical psychologist) on ensuring participant safety.

Specialized Skills Required (as applicable)

Community-based participatory research, program development and evaluation, content expertise in prevention and family-based programming, cultural humility, excellent working relationships with Indigenous peoples on Pine Ridge Reservation and in Rapid City SD, and a frequent presence in the communities.

1.3 Sponsor Information

Study Sponsor: NIMH

Grant Title: Development and Evaluation of an Indigenized Family Acceptance Project for Lakota 2SLGBTQ+ Youth and their Caretakers

Grant Number: 25-PAF04373

1.4 Statement of Compliance

This study will be conducted in compliance with the protocol, the federal regulatory requirements of United States (US) Code of Federal Regulations (CFR) 45 CFR Part 46, and applicable state and local laws.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent forms will be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent forms will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

All personnel involved in the conduct of this study will have completed Human Subjects Protection training prior to the initiation of this project. Please note that a number of individuals working on this study will be U of M staff but are not yet in the system given their start dates are on January 1, 2024. We will also have a reliance agreement for the work of Dr. Lorey Wheeler and her team at UNL. We will do an IIA agreement with Dr. Caitlin Ryan (FAP) and Ms. Antonia Barba (independent consultant), both of whom will train facilitators in delivering IFAP.

2. Protocol Summary

2.1 Study Description

Description. Indigenous 2SLGBTQ+ (Two Spirit Lesbian Gay Bisexual Transgender Queer/Questioning) youth experience disproportionately high rates of mental health problems including depression, anxiety, and suicidality as well as related issues such as alcohol and drug initiation/use and dating and sexual violence.[1-4] There is little research on how to prevent mental health and related problems among Indigenous 2SLGBTQ+ youths. Our research demonstrates that these deleterious outcomes are rooted in family rejection as well as internalized homo/trans/bi phobia.[5] Our previous research also shows that Indigenous 2SLGBTQ+ youth and their adult caretakers perceived the Family Acceptance Project (FAP)—a family support approach that seeks to reduce family rejecting behaviors and increase family accepting behaviors in the context of the family’s cultural world—as highly acceptable and likely to be impactful in reducing mental health and related problems of Indigenous 2SLGBTQ+ youth. [5, 6] To date, despite its promise for reducing mental health and related problems among

2SLGBTQ+ youth, FAP has not been rigorously evaluated. The purpose of this larger R34 grant is to develop/refine and evaluate the acceptability, feasibility, safety, and preliminary efficacy of a Lakota-adapted FAP for Indigenous 2SLGBTQ+ youths and their caregivers.

Objectives. The purpose of this specific IRB protocol is to conduct an open pilot trial (OPT) with 7 families in Rapid City, SD and 7 families on the nearby Pine Ridge Indian Reservation. This OPT is part of a larger NIH R34 grant that includes theatre testing (completed under a UNL IRB and OST RRB fall 2024) and a pilot randomized control trial (RCT) to be conducted in the future (summer 2025). Please note that in the pilot RCT there will be three arms: wait-list control, traditional FAP (FAP delivered by Indigenous program facilitators individually to families), and I-FAP (FAP delivered by Indigenous, mostly Lakota, program facilitators to groups of families with deep structural adaptations). The OPT is specifically focused on acceptability, feasibility, and safety of programming and research protocols. We will also examine pre- to post- changes on outcomes for the sole purposes of making sure scores on measures are changing in the hypothesized direction (e.g., depression scores are going from moderate to minimal as opposed to no change or depression scores increasing).

This work is deeply participatory and includes Indigenous staff as well as an advisory board (one on Pine Ridge and one in Rapid City) consisting of youth and caregivers including Elders, Indigenous 2SLGBTQ youth, and caregivers.

Endpoints. Although the ultimate goal of I-FAP is to reduce anxiety, depression, and suicidality among Indigenous/Indigenous SGMY via reductions in caregiver rejecting behaviors, the endpoints of this specific OPT include safety, appropriateness, acceptability, feasibility, and fidelity. There is growing consensus in the field of prevention and intervention science that intervention development is iterative and should include the assessment of implementation outcomes including program safety, acceptability, feasibility, and fidelity of intervention delivery [7-9]. Safety refers to any type of harm experienced by a participant that could reasonably be considered due to study participation [10]. Acceptability refers to participants' cognitive and emotional appraisals of the intervention's agreeableness, palatability, and satisfactoriness [11, 12]. Feasibility refers to the degree to which facilitators can successfully carry out the intervention and the degree to which participants can successfully apply the skills taught [13]. Fidelity refers to the quality of program delivery and the extent to which an intervention is delivered as intended [13].

Duration. We expect this study to be of ~1 year duration including study analyses and dissemination. Actual participant involvement is approximately 2 months (baseline survey, 8 weeks of programming, immediate post-test, and potentially, an exit interview).

Study Population. The study population is Indigenous peoples in Rapid City, SD or on the nearby Pine Ridge Indian Reservation. All participants will be Indigenous, with the majority expected to identify as Lakota. Participating youth will be between the ages of 13 and 18 and identify as Indigenous AND an SGMY. Caregivers are expected to be largely Lakota and consist mostly of female caregivers (e.g., mothers, aunts, grandmothers) based on our previous family-based work in the region.[14, 15] Caregivers will also be adults (18+).

Location. The study will be conducted in Rapid City, SD and the nearby Pine Ridge Reservation, home of Indigenous (predominantly Lakota) peoples. We have offices both in Rapid City and on the Pine Ridge Indian Reservation. Offices include ample space for research and program activities. We also have living quarters on the Pine Ridge Reservation and access to myriad hotels in Rapid City, SD. This is important given that Dr. Edwards is frequently in

South Dakota spending about 25 to 40% of her time there. Dr. Edwards is deeply immersed in the communities and has several Indigenous staff hired via U of M (formerly UNL).

Depending on the size of I-FAP groups, we may need to use space at an agency located in Rapid City, as our office space there is not able to accommodate very large groups. If this is the case, we will update the IRB in an amendment.

The sIRB agreement with UNL is underway.

~~Please note that there are a number of other individuals who will work on this project at U of M but they do not have U of M accounts yet given our start date is Jan 1, 2025. They are in the process of being hired by U of M. As such, these individuals cannot be added to this application; they will be added prior to any work on the study.~~

In this revised application, we have added individuals who are now University of Michigan employees to the Personnel list.

2.2 Schedule of Activities

	2025									
Activity	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct
Refine I-FAP content, manuals (2 months)	X	X								
Train facilitators (2 months)		X	X							
Recruitment (2 months)			X	X						
Screening survey (2 months)			X	X						
Pre-test survey (1 week)				X						
Programming (8 weeks)				X	X					
Post-session surveys (8 weeks)				X	X					
Immediate post-test (1 week)					X					
Exit interviews (1 month)					X					
Data analyses (1 month)						X				
Refine programming for pilot RCT (1 month)							X			
OST RRB approval to share findings (1 month)							X			
Write and submit RCT IRBs								X		
Share findings with advisory board members (1 month)								X		
Share findings with participants (1 month)								X		
Share findings with community (1 month)								X		
Scholarly publication (4 months including anticipated revise and resubmits)									X	X

3. Background & Rationale

3.1 Background & Significance

Indigenous 2SLGBTQ+ youth experience high rates of mental health problems including depression, anxiety, and suicidality and related behavioral health problems including alcohol and drug use/initiation and dating and sexual violence victimization and perpetration.[2-4, 16, 17] For example, results from the 2022 National Survey on LGBTQ Youth Mental Health documented that 55% of Indigenous 2SLGBTQ+ youth and young adults, ages 13 to 24, considered suicide in the past year, and 21% of Indigenous 2SLGBTQ+ youth attempted suicide in the past year.[1] In the same study, 83% of Indigenous 2SLGBTQ+ youth reported experiencing anxiety and 70% reported experiencing depression, which were higher percentages than any other racial/ethnic group.[1] In a study of 400 Indigenous youth in Rapid City (the location of the proposed study) conducted by PI Edwards, being a sexual minority was positively associated with depressive symptoms, suicidal ideation, dating violence, alcohol use, and negatively associated with school mattering.[18] PI Edwards and collaborators on this grant conducted a study with Lakota 2SLGBTQ+ youth ($n=36$) and adults who take care of/work with Lakota 2SLGBTQ+ youth ($n=23$) that included focus groups, talking circles, arts-based activities, and surveys.[17] Results documented that Lakota 2SLGBTQ+ youth experienced myriad challenges (e.g., rejection, victimization, depressive symptoms, alcohol use).[17] Indeed, 18%, 51%, and 64% of Lakota 2SLGBTQ+ youth reported past year alcohol use, past year teen dating violence victimization, and past year depressive symptoms.[17] Lakota 2SLGBTQ+ youth reported 13 (out of 29) ACEs on average. Importantly, our results showed that connection to culture, family acceptance, and hope for the future are important sources of resilience for Indigenous 2SLGBTQ+ youth.[17]

Terminology. *Lakota refers to the participants of the Oceti Sakowin Oyate that speak a Indigenous dialectic (other dialectics include Dakota and Nakota). Specifically, the pilot data that informs the proposed project discussed throughout this proposal was with Lakota youth and adult participants (preferred over the term participants) from the band of the Oglala Sioux Tribe (OST) and took place on the Pine Ridge Reservation that shares geography with South Dakota. The location of the proposed project is the Pine Ridge Indian Reservation and the nearby city, Rapid City, home to over 20,000 Indigenous participants, predominantly participants of the Oceti Sakowin Oyate. Also, our partners prefer that we use the term Indigenous (when referring to all Indigenous peoples in the U.S.) and Lakota (when referring specifically to the Lakota people) rather than American Indian/Alaska Native. Finally, 2SLGBTQ+ is an umbrella*

term used to describe a wide range of minoritized sexual and/or gender identities; 2S represents Two Spirit (discussed in more detail in A.3.) in the 2SLGBTQ+ acronym used throughout this proposal. We use 2SLGBTQ+ interchangeably with SGMY (sexual and gender minority youth) and use “SGMY” especially when referring to research that was not specifically focused on Indigenous 2SLGBTQ+ youth.

Theories of minority stress suggest that 2SLGBTQ+ persons experience both distal (e.g., discrimination and victimization based on 2SLGBTQ+ identities) and proximal (e.g., internalized homo/bi/transphobia, identity concealment) stressors that help explain why 2SLGBTQ+ persons, compared to cisgender heterosexual persons, report higher rates of mental and behavioral health problems.[19-22] Although not specific to Indigenous 2SLGBTQ+ youth, research with SGMY of color more broadly shows that SGMY of color experience higher rates of adversities and minority stressors than do white, non-Latinx SGMY. Research suggests that the risk of attempted suicide increased as other types of minority stressors increased, and Indigenous 2SLGBTQ+ youth reported more minority stressors than other groups of SGMY youth.[2]

Deleterious mental health and other outcomes among Indigenous 2SLGBTQ+ youth are rooted in colonization and multiple historical traumas. Prior to colonization, individuals who were Two-Spirit—an Indigenous concept that usually indicates that individuals house both a masculine and a feminine spirit—held important and honorable roles.[23-26] In some Indigenous communities and/or for some Indigenous people, Two-Spirit refers to all sexual and gender minorities.[25] Some Indigenous communities have specific terms in their languages for Two-Spirit (e.g., Lakota: *wĩŋkte*, Navajo: *nádleehé*) as well as tribally specific spiritual, social, and cultural roles for Two-Spirit participants.[24, 25] These roles included healers or medicine persons, teachers, knowledge keepers, foretellers of the future, artists, name givers, and holding of special roles at Sundance.[24, 26] However, as a result of colonization and multiple historical traumas (e.g., cultural genocide, historical traumas, forced placement in boarding schools, forced Christianity, stealing of sacred lands), many Indigenous people became disconnected from their languages, cultures, and positive Two-Spirit histories.[23-26]

Colonization and multiple historical traumas tore at the fabric of immediate and extended families, which are the foundation of most Indigenous societies. In traditional Indigenous communities, children are viewed as sacred. For example, in Lakota, *wakanyēja* (“children”) means “little sacred ones.” Homo/bi/transphobia and other forms of violence, oppression, and rejection within Indigenous communities, often referred to as lateral violence,[27, 28] are the result of colonization and cultural genocide.[29] [17]

The *tiwahe* (“family” in Lakota) plays a critical role in Indigenous culture. As Joseph Marshall III, Lakota Elder, said: *“A cornerstone of Lakota culture can be summed up in the words of family and kinship. Family is the backbone, the foundation of our culture. We are given substance, nurtured, and sustained by family. Kinship goes beyond family and is the connection we feel to the world at large and everything in it... A phrase essential to and used in all [Lakota] ceremonies is mitakuye oyasin, which means all of my relatives. Its definition reminds us of that connection.”*[30] Research with youth in general demonstrates the critical role of the family in preventing mental health problems and related deleterious issues.[31-38] Indeed, a pervasive and detrimental form of minority stress is family rejection, which is the withdrawal of warmth and love and/or engagement in hostility and aggression based on one’s SOGIE.[23, 24, 26, 39] Family rejecting behaviors that attempt to change, deny, minimize and prevent a child’s SGMY identity and gender expression and can be traumatic and even deadly (via suicide, hate-based homicide) for SGMY youth.[40, 41] Family rejection is also an ACE[40, 41] and co-occurs with other forms of child-abuse, such as emotional abuse and neglect, and physical abuse.[42, 43]

Family rejection predicts a host of deleterious mental and behavioral health problems including depression, anxiety, suicidality, alcohol and drug use/initiation, and dating and sexual violence as documented in samples of SGMY youth more broadly.[17, 35, 43-48] In the only known study ever conducted on family rejection and acceptance among Indigenous 2SLGBTQ+ youth, PI Edwards and her team documented that 61% of Indigenous 2SLGBTQ+ youth reported at least some level of family rejection which was positively associated with ACEs, depression, alcohol use, and dating violence.[17] Qualitative data from both Indigenous 2SLGBTQ+ youth and adults spoke to the devastating impacts of rejecting behaviors on Indigenous 2SLGBTQ+ youth, including being “*depressed*” and “*suicidal*” and using “*drugs and alcohol*” because “*people internalize it.*”[17] These experiences of family rejection and internalization can result in depression, anxiety, and suicidality[16, 35, 45]. Caregiver rejection may also lead to risk behaviors in SGMY youth via the lack of positive parent-child relationships, poor communication, absence of modeling of healthy attitudes and behaviors, and poor monitoring.[34, 49] The absence of these supportive parenting behaviors and parent-child relationships may lead to alcohol and drug use/initiation (via poor coping mechanisms and/or lack of parental monitoring)[50-52] as well as dating and sexual violence (via SGMYs’ reluctance to seek help for an abusive relationship if they have not disclosed their sexual orientation and fear rejection, do not have a close relationship with their caregivers due to rejection of their SOGIE, or have experienced child maltreatment which is often associated with family rejection)[53-55]. There is an urgent need to identify culturally grounded initiatives to increase family acceptance and decrease family rejection among caregivers of Indigenous 2SLGBTQ+ youth.

The Family Acceptance Project (FAP) is a rigorously developed family-based intervention for caregivers of SGMY and SGMY (within the context of their families). FAP, created by Dr. Caitlin Ryan (Consultant), seeks to prevent myriad deleterious mental and behavioral health outcomes (primarily suicide) and promote positive youth development for SGMY in the context of their families, cultures, and faith communities. FAP is designed to help families (via caregivers) decrease rejection and support and affirm their SGMY (thereby reducing SGMY behavioral, social, emotional, relational, and academic problems)[56] across systems of care, including in homes, schools and congregations, and various systems (e.g., behavioral health, foster care). FAP was initiated over 20 years ago using participatory approaches with racially/ethnically diverse SGMY and their families (including some Indigenous 2SLGBTQ+ youth/families) to be used as a standalone initiative or integrated into other intervention models (e.g., trauma-focused cognitive behavioral therapy). FAP's family support framework has been delivered to nearly 500 families with SGMY; recipients of FAP are racially, ethnically, religiously, politically, socioeconomically, linguistically and geographically diverse (and have included some Indigenous youth and their families). Of note, 80% of families and SGMY who have received FAP are families of color (including Indigenous families) and nearly all are low or middle income (with most being low income). Further, 70% of FAP recipients include families with SGMY who are receiving mental health services, are child protective system involved, are unhoused, and/or who are immigrants.

Although FAP is flexible in the way it is implemented (e.g., number of sessions), FAP includes both caregiver and SGMY components, as well as family and group sessions.[57] Work with caregivers focuses on 1) assessing caregivers' reactions to their SGMY; 2) providing psychoeducation about family accepting and rejecting behaviors in the context of their cultural and religious values; and 3) teaching skills to show support, love, and affirmation and acceptance to ones' SGMY as well as advocacy skills to stand up for their SGMY in the face of rejection. Youth components focus on 1) psychoeducation on family rejecting and accepting behaviors, 2) reducing internalized oppression and increasing positive identity development, and 3) instilling hope for the future (all of which are protective factors for deleterious mental and behavioral health outcomes)[38, 58]. FAP also offers opportunities to build connections with others (e.g., caregiver support, 2SLGBTQ+ sense of community among SGMY, family bonding/love). FAP to date has largely been delivered to an individual family by a clinician or highly trained layperson.

Despite its national recognition and reach, there is little research evaluating the efficacy of FAP and none of this research is specific to Indigenous 2SLGBTQ+ youth.

Nevertheless, results from a pilot evaluation documented that program participation decreased family rejecting behaviors and increased supportive behaviors for 30 parents and caregivers of SGMY that were investigated for abuse and neglect.[59]

Prior to this OPT protocol, as part of the larger R34 grant, we conducted theatre testing (under the UNL IRB and OST RRB). Theatre testing is a method in which the target audience (Lakota LGBTQ2S+ youth and their caregivers) were exposed to key elements of the program while stakeholders also observed. Participants then completed a survey with open- and closed-ended questions about their reactions. Next, researchers engaged in a talking circle with the goal to obtain information that can be used to subsequently adapt the content, delivery, materials, activities, and branding of the programming. Overall, the feedback on components for the Tiwahe Tewichaglapí program was very positive, particularly the emphasis on Lakota culture. There was agreement about the importance of implementing this program in a group format in which multiple families engage in the program together. To deepen the educational impact of the program, participants suggested that we include additional information about 2SLGBTQ+ identities, as well as specific ways to advocate for 2SLGBTQ+ youth. We incorporated the feedback obtained from the theatre testing results to create the first full version of I-FAP to ensure there is a balance of community priorities and feedback while maintaining fidelity to the core components and underlying theoretical framework of the FAP's family support model. The program outline is below:

Tiwahe Tewichaglapí - Family Acceptance Project® Session Outline

<u>Pre-Session Activity:</u> Caregivers and youth will check in before each session begins to connect, offer a prayer and share a meal in preparation for the program.
<u>Session 1: Program Foundation</u> Facilitators will introduce the program and participants. The session will start with an icebreaker and sharing from each participant; discussion of group guidelines and agreements; program goals and participants' goals. Content will focus on traditional Lakota parenting, nurturing and support for diverse sexual and gender identities and the impact of colonization, cultural and religious proselytization and boarding schools that disrupted and changed traditional family life and rejected diverse gender roles and how this continues to affect 2SLGBTQ children, youth, adults and families.
<u>Session 2: 2SLGBTQ Roles & Identities in Historical Context</u> Content will focus on historical and contemporary 2SLGBTQ identities, how traditional culture was replaced with colonial norms of gender and sexuality, the impact of technology on earlier ages of identifying as LGBTQ, the historical exclusion of families and lack of accurate information, education and guidance for parents and caregivers of LGBTQ children and youth and how this has contributed to disinformation about 2SLGBTQ lives and the hostile social environment that has increased health risks and victimization of 2SLGBTQ youth and adults. Caregivers will learn about trauma related to family rejection and other common experiences and how this impacts risk, self-care, connectedness and sense of the future for 2SLGBTQ children, youth and adults.
<u>Session 3: Spiritual & Religious Beliefs and Values / Virtues</u> This session will discuss Lakota spirituality and religious beliefs and values and will help caregivers to shift how they respond to 2SLGBTQ youth from religious doctrine (beliefs) to cultural and religious and spiritual values (or virtues) which are similar across denominations, despite differences in beliefs, and which align with Lakota spiritual virtues. Content will discuss how colonization has impacted traditional beliefs that shape perceptions of LGBTQ identity and how traditional beliefs connect them with a higher

power (e.g., Tunkasila, the Creator, or God that put them on this earth for a purpose and that their life has meaning and value) and understanding the impact of historical rejection of diverse gender roles that increases rejection and health risks to help them value the honorable role of Two Spirit identities, rooted in traditional Lakota society. This session will help participants begin to focus on supporting 2SLGBTQ youth as an embodiment of Lakota spiritual virtues as well as promoting well-being and reducing health risks.

Session 4: Identifying Rejecting & Accepting Behaviors

This session will focus on helping caregivers and youth to identify rejecting and accepting behaviors in their families and to understand how this affects the youth's self-perceptions, risk behaviors and family relationships; learning how to communicate about the youth's identity in ways that are more supportive and affirming and that reduce conflict and increase understanding of how family supportive behaviors embody and express Lakota spiritual values. Caregivers will learn the importance of practicing supportive and accepting behaviors that help to increase connectedness and reduce risk even when they may be struggling to deal with shame and helping them to support identities that have previously been seen as contrary to their beliefs. The value of caring and compassion (Waunsila) embodies Lakota and religious values.

Session 5: Requiring Family Members & Relatives to Treat Their Youth With Respect

This session will help caregivers learn the importance of increasing support for their LGBTQ youth with other family members and relatives. They will watch a short FAP video that shows how parents learn to support and accept their youth's LGBTQ and gender diverse identity by drawing from their cultural and religious values and how this impacts their community. Youth and caregivers will identify family rejecting and accepting behaviors and will discuss how these behaviors impact the youth's risk and well-being; they will practice ways to respond when other family members disrespect 2SLGBTQ youth and other 2SLGBTQ people. Requiring respect and having respect for oneself (Waóhholá) embodies Lakota and religious values.

Session 6: Critical Role of Advocacy

This session will teach caregivers and youth the importance of advocacy – of standing up for their 2SLGBTQ youth and other LGBTQ people when they are mistreated because of their identity and gender expression. This includes ways to respond and what to say when the youth is mistreated, disrespected or bullied in a range of settings, including schools, congregations and the community. Caregivers will learn advocacy skills and youth will learn ways to advocate for themselves. Caregivers and youth will learn the importance of education as advocacy and sharing what they have learned to teach accurate information about 2SLGBTQ lives in the broader community and oiyate. Advocacy (a key family accepting behavior that protects against risk and promotes well-being) draws on cultural and religious values of bravery, courage and generosity to prevent dehumanization and harm to others and to promote harmony in the broader community.

Session 7: Developing a Family Plan

In this session, youth and caregivers will review and process what they have learned and celebrate positive change while sharing ways their family will continue to move towards affirmation and support for their 2SLGBTQ youth and extending awareness and affirmation to other parts of the community. Each family will focus on developing an individualized family plan to identify what they want to continue to work on to increase acceptance and support and to strengthen their family. This includes what they need to receive for guidance and support to promote sustained growth and change, moving forward, and how they can help to build support in the community.

Session 8: Closing Ceremony

To close the program, youth and caregivers will meet to share their individual and family experiences with learning about their cultural and spiritual heritage as Two Spirit and other gendered tribal members with special roles in their communities and to commit to continuing to build a supportive and affirming community for 2SLGBTQ people and their families. This will include sharing their interpretations of cultural activities they engaged in during the program and participating in a closing ritual to help transcend the challenges and struggles they encountered in the past as a result of family and community rejection, internalized shame and anti-LGBTQ experiences, including victimization and harsh parenting. We will prepare a letting go ceremony such as Wiping of the Tears or Calling Your Spirit Back that will release negative emotions and memories to promote healing, renewal and peace and to allow for a new way of experiencing 2SLGBTQ identities, family harmony and pride in their family and in the broader community.

3.2 Research Question

Rationale and Justification. Indigenous 2SLGBTQ+ youth experience disproportionately high rates of mental health problems including depression, anxiety, and suicidality as well as related issues such as alcohol and drug initiation/use and dating and sexual violence. [60] There is little research on how to prevent mental health and related problems among Indigenous 2SLGBTQ+ youths. Our research demonstrates that these deleterious outcomes are rooted in family rejection as well as internalized homo/trans/bi phobia.[5] Our research also shows that Indigenous 2SLGBTQ+ youth and their adult caretakers perceived the Family Acceptance Project (FAP)—a family support approach that seeks to reduce family rejecting behaviors and increase family accepting behaviors in the context of the family’s cultural world—as highly acceptable and likely to be impactful in reducing mental health and related problems of Indigenous 2SLGBTQ+ youth.[5, 6] In line with CBPAR, Dr. Edwards and her team submitted a grant to the NIMH that provided funding for this OPT and other study activities including recently completed theatre testing (under the UNL and OST RRB) and a future pilot RCT (to be overseen by the U of M IRB and the OST RRB). In short, the justification for the selection of FAP is that it was selected by members including tribal leaders of the Oglala Sioux Tribe for implementation and evaluation in their community. The justification for the methods used in this OPT are that it aligns with best practices in prevention sciences and an NIH stage model[61, 62] to intervention development that has been deemed acceptable among the Lakota Oyate in previous research conducted by Dr. Edwards.[15, 63]

Objectives. The OPT is specifically focused on assessing acceptability, feasibility, safety of programming and research protocols. We will also examine pre- to post- changes on outcomes for the sole purposes of making sure scores on measures are changing in the hypothesized direction (e.g., depression scores are going from moderate to minimal as opposed to no change or depression scores increasing). We will use this data to further refine I-FAP prior to the start of the pilot RCT.

3.3 Outcomes/Endpoints

Study outcomes/endpoints should be prioritized and should correspond to the study’s objectives or hypotheses. Define the specific criteria used to assess the study’s objectives. Include the study visits or time points at which data will be recorded or samples will be obtained.

Endpoints for acceptability include that 90% or more of participants rate the program as acceptable as determined via post-session surveys (i.e., strongly agree or agree on items in Part I of the post-session survey [uploaded in Section 29]) and items on the immediate post-test assessing implementation outcomes[13, 64] (see Qualtrics T2 survey uploaded in Section 29). Qualitative data on the post-session surveys (post-session survey [uploaded in Section 29]) will be used to further assess acceptability.

Endpoints for feasibility include observer ratings of the extent to which facilitators can successfully carry out the intervention (see example fidelity forms uploaded in Section 44) and participants agreeing on average with items on the post-session survey inquiring about

facilitator likeability (see post-session survey [uploaded in Section 29) on the post session surveys (see uploads in Section X) and immediate posttests (see implementation outcomes in Measures Table and Qualtrics T2 survey uploaded in Section 29) assessing facilitators skills and the extent to which participants can successfully apply the skills taught.

Safety refers to any type of harm experienced by a participant that could reasonably be considered due to study participation. Safety is tracked by (1) documenting the number and type of serious adverse events (which we do not anticipate) and (2) asking questions at all points of contact about being upset and safety concerns related to the study (see uploaded post-session surveys, and baseline and immediate post-test surveys in Section 29).

Finally, the exit interview data will provide additional qualitative information on acceptability and feasibility. We expect major themes to emerge that suggest the program is acceptable, relevant, and impactful. The exit interview script is uploaded in Section 29.

Regarding the endpoint for fidelity, we strive for adherence to the program manual at 90% or greater and that when there is non-adherence the rationale is well-justified (e.g., ran out of time to finish the final part of the session given rich participant discussion). See uploaded fidelity forms in Section 44. Please note that these are examples from another FAP study with LGBTQ+ youth of color and their caregivers (IRBHUM00264028). The fidelity forms for this study are currently being developed in tandem with the program. We will come back to the IRB with an amendment that includes the final programming materials and fidelity forms prior to their use.

We will not be powered to test changes from pre- to post- in outcomes. However, we will also examine pre- to post- changes on outcomes for the sole purpose of making sure scores on measures are changing in the hypothesized direction, which is the endpoint on the survey instruments. Below is a table with specific measures and relevant details.

Table . Summary of Intervention Outcomes and Corresponding Assessments

Aim		Measure	Points of Administration			
			Youth		Caregivers	
			Pre	Post	Pre	Post
Youth Primary Outcomes						
Decreased suicidality	Suicidal Ideation Attributes Scale (SIDAS) [65]	X	X	X	X	
Decreased anxiety symptomology	Generalized Anxiety Disorder ScreenerGAD-7 Anxiety [66]	X	X	X	X	
Reduce depressive symptomology	Patient Health Questionnaire (PHQ-9) [67]	X	X	X	X	
Youth Secondary Outcomes						
Decreased dating and sexual violence victimization/perpetration	Measure of Adolescent Relationship Harassment and Abuse [68, 69] AND Items from the Youth Risk Behavior Survey [70]	X	X			
Decreased alcohol use/initiation	Items from Youth Risk Behavior Survey [71]	X	X			
Decreased drug use/initiation	Items from Youth Risk Behavior Survey [71]	X	X			
Increased school engagement	Items from Husley et al. [72]	X	X			
Decreased sexual risk taking	Items from Youth Risk Behavior Survey [71]	X	X			

Targets/Mechanisms					
Decreased caregiver rejecting behaviors and Increased caregiver accepting behaviors	FAP-Reactions, Advocacy, Feelings/Experiences[73] AND LGBTQ Microaggressions and Microaffirmations in Families Scale [74]	X	X	X	X
Decreased caregiver harsh parenting	Brief Family Relationship Scale [75]	X	X	X	X
Increase connection to Indigenous culture/cultural identity	Indigenous Cultural Identity Scale [76, 77]	X	X	X	X
Increased connection to community	Adapted items from The Sense of Community Index II [78]	X	X	X	X
Increased connection to Lakota Virtues	Research created with community input	X	X	X	X
Increased positive ethnic/racial identity among SGMY	Multi-group Ethnic Identity Scale [79, 80]	X	X		
Decreased youth internalized homo/bi/trans phobia	Items from the 2017 LGBTQ+ Teen Survey [81]	X	X		
Increased hope for the future	Items from the 2017 LGBTQ+ Teen Survey [81]	X	X		
Increased family bonding	Brief Family Relationship Scale [75]	X	X	X	X
Increased Family Resilience	The Family Resilience Inventory [82]	X	X	X	X
Control/Other Variables					
Demographics	Social identities (e.g., race, ethnicity, sexual orientation, gender identity, SES) including religiosity [70, 83]	X	X	X	X
Contamination	Researcher-created items assessing if participants at baseline have heard about or participated in FAP (which is highly unlikely) and then at follow-ups the extent to which treatment families talked to other families about I-FAP and control families heard about I-FAP [84]		X		X

A copy of the questions to be included in this survey can be found in the Measures Table and Qualtrics Surveys uploaded in Section 29.

4. Study Population

4.1 Inclusion Criteria

Individuals must meet all of the inclusion criteria to be eligible to participate in the study. Inclusion criteria for youth and caretakers are outlined separately below. Inclusion criteria for youth across all study activities requires that they: 1) identify as 2SLGBTQ+ (and their identity must be known to their participating caregiver); 2) identify as Indigenous (multiracial youth who are also Indigenous are eligible); 3) be between the ages of 13 and 18 years; 4) read and speak English (we have never encountered an Indigenous participant who does not speak English); 5) report moderate to high levels of caregiver/family rejection (as evidenced by agreement on items that assess the presence and frequency of specific family rejecting behaviors [includes ambivalent and moderately and highly rejecting caregivers]; and 6) report an ability and commitment to attending eight sessions at two hours a week over eight weeks with their caregiver. Of note, we seek to engage Indigenous 2SLGBTQ+ youth who are at elevated risk for caregiver rejection given that these SGMY are at increased risk for myriad

psychosocial and behavioral health problems, and Indigenous 2SLGBTQ+ youth who are not experiencing any caregiver/family rejection will likely find much of the intervention content irrelevant and less at risk for mental and behavioral health problems.[17, 85, 86]

Participating caregiver(s) of Indigenous 2SLGBTQ+ youth must 1) be over the age of 18; 2) read and speak English, 3) be aware of the SGM identity of their Indigenous 2SLGBTQ+ youth and 4) report an ability and commitment to attending eight sessions at two hours a week over eight weeks with their teen. Caregivers are broadly defined and may include a biological parent, stepparent, grandparent, aunt/uncle, or other adult who provides care to the Indigenous 2SLGBTQ+ youth. We recognize that 13 to 18 years old spans early to late adolescence. We elected to group younger and older adolescents together given that SGM youth in both early and late adolescence face family rejection and in our other programmatic research in the region, Indigenous youth who ranged in age from 13 to 18 reported liking opportunities to get to know youth of different ages[17, 87]. Having variability in age in I-FAP may also help to support its sustainability given that dividing groups by age may prove to be an implementation challenge and not feasible. Nevertheless, we will examine in a future fully powered R01 if the I-FAP works better for younger versus older Indigenous 2SLGBTQ+ youth. Of note, multiple caregivers (who meet criteria) as well as multiple Indigenous 2SLGBTQ+ youth (who meet criteria) from the same family will be allowed to participate although only one caregiver and only one Indigenous 2SLGBTQ+ youth will complete the outcome surveys given our study design utilizing patched pairs dyadic data and feasibility of including multiple family members beyond the two, and the OPT should closely model the method of the pilot RCT.

As discussed at the IRB meeting (on February 20, 2025), we will permit non-research caregivers to attend programming sessions. This is consistent with Lakota culture, which prioritizes family and close familial relationships. These individuals will not complete the pre- and post-test surveys but will be permitted to attend sessions and participate in programming content. In planning for this study with the Oglala Sioux Tribe, inclusion of non-research caregivers was essential in obtaining their support. We will ask these individuals to complete the anonymous post-session surveys, as this is an essential component of obtaining information about program safety. Because these surveys are administered anonymously in a group, it will be impossible to exclude these individuals from survey administration. The consent form for non-research caregiver participants has been revised to indicate this.

Step 1 of the screening process will involve the Qualtrics questions, as marked on the attached file “Qualtrics Screener Questions”. An individual will be asked to respond to all of these questions to determine their eligibility. Once it has been determined that they are ineligible, they will not proceed onto the next set of screening questions (Step 2) and their data will be erased.

4.2 Exclusion Criteria

We will exclude Indigenous 2SLGBTQ+ youth and caregivers at imminent risk for suicide and/or who are experiencing current psychosis symptoms. Potential participants who are deemed eligible after the first set of screening questions (items 1 to 28 in Measures Table in “Screener Questions” Section- --uploaded in Section 29- that align with the inclusion criteria above) will be asked to complete safety items as a second step in the screening process. These questions include items 29 to 31 in Measures Table in “Screener Questions Section” --uploaded in Section 29) and are pasted below as well. If participants answer affirmatively to the questions bolded below they will be contacted by a licensed clinical psychologist (Dr. Gayle Beck) or one of the Indigenous mental health clinicians for further assessment for the purposes of (1) connecting them to resources and (2) determining eligibility. Contacts from mental health clinicians will only occur via phone or Zoom, in order to provide rapid screening and referrals as needed. Scheduling face-to-face contacts would unnecessarily delay assessment of safety for potential participants who report significant suicidal ideation or intent. Likewise, if a participant is experiencing psychotic symptoms, we do not want to delay referrals until a face-to-face interview can be scheduled.

Abbreviated Youth Psychosis at Risk Questionnaire (YPARQ-B)[88]

- **Do you ever hear the voice of someone talking that other people can't hear?**
- **Do you see things that others can't or don't see?**

The Suicidal Behaviors Questionnaire-Revised(SBQ-R1)[89]

1. In the past month, have you thought about or attempted to kill yourself?
 - a. Never
 - b. It was just a brief passing thought
 - c. I have had a plan to kill myself at least once but did not try to do it
 - d. **I have had a plan to kill myself and really wanted to die**
 - e. **I have attempted to kill myself, but did not want to die**
 - f. **I have attempted to kill myself, and really wanted to die**
2. In the past month, have you told someone that you were going to commit suicide, or that you might do it?
 - a. No
 - b. Yes, at one time, but did not really want to die
 - c. **Yes, at one time, and really wanted to die**
 - d. Yes, more than once, but did not want to do it
 - e. **Yes, more than once, and really wanted to do it**

These questions will be assessed in Step 2 of the screening process (see attached file “Qualtrics Screening Questions”). If an individual responds with one of the bolded answers above, they will be asked to speak with a mental health professional, as detailed in the next paragraph. Potential participants will not be routinely excluded based only on the answers to Step 2 screening questions; they will be routed to our mental health professional who will make the determination of whether they should be excluded and referred for different services.

Dr. Gayle Beck (licensed clinical psychologist) or one of the Indigenous mental health providers will reach out to participants who endorse any of the bolded response options above, to complete a brief clinical interview by phone or Zoom and assist participants in finding appropriate referrals, using a standardized protocol. A copy of this protocol can be found in the file named Assessment of Suicide Risk and Psychotic Symptoms (uploaded in Section 44). Any individual deemed at imminent risk of suicide based on this interview will be assisted in finding appropriate local treatment resources and informed that they are not currently eligible to participate. Similarly, if an individual is experiencing active psychosis, they will be assisted in finding appropriate local treatment resources and informed that they are not currently eligible to participate. Qualtrics screening data from individuals who are excluded will be securely discarded. We will retain the clinical interview notes from individuals who are excluded, consistent with ethical guidelines from the American Psychological Association and best practice guidelines within Psychology. These records will be stored in a restricted access section of Drop Box, which will only be available to Dr. Edwards, Dr. Beck, and the Indigenous clinicians who are assisting with the screenings.

If individuals are deemed to be at low risk (not imminently suicidal, not psychotic), they will be permitted to participate in the study if they consent/assent to do so.

Please note that Indigenous 2SLGBTQ+ youth and their caretakers in acute crisis need a higher level of care than the family support intervention provided by I-FAP. We recognize that reductions in suicidality are a major outcome of the I-FAP. Please keep in mind that Indigenous 2SLGBTQ+ youth with suicidal ideation, plans, and so forth are permitted to participate in I-FAP; we are only excluding individuals at current imminent risk for suicide who require a higher level of care. We anticipate that we will exclude approximately 10% of Indigenous 2SLGBTQ+ youth based on research that 1 in 5 Indigenous 2SLGBTQ+ youth attempted suicide in the past year.[1, 4]

Regarding additional details about Dr. Beck, she is currently licensed in Tennessee (2854 HSP, certificate uploaded) and is now licensed in South Dakota (license # 676, certificate uploaded). She is credentialed by PSYPACT (certificate uploaded in Section 44) an interjurisdictional certification that allows cross-state practice for participating states. Both Tennessee and South Dakota participate in PSYPACT. Dr. Beck has significant clinical and research experience with survivors of interpersonal trauma. She has worked closely with Dr. Edwards for the past 18 months and has made multiple trips to the Pine Ridge Reservation. She is very familiar with the norms and practices of the Lakota peoples on Pine Ridge and works well with our Indigenous staff.

Additional details on recruitment and scripts for informing participants of the need to speak with a mental health provider are on p. 34 of this protocol.

5. Study Design

5.1 Design

Type/Design. This study is an open pilot trial (OPT).

Number of Groups/Arms. There is only one arm in this OPT and that is the intervention group.

Duration. Once enrolled in the study, participants complete a baseline survey. Then they will participate in I-FAP is an 8-session group intervention; sessions will be scheduled once a week for eight weeks (at 2 hours per session), with recognition that weather-related issues may require flexibility with scheduling. Participants will complete survey instruments before and immediately after the program sessions, in addition to post-program surveys and an exit interview. There will be no follow-up interval.

Randomization. Participants will not be randomized, given that there is only 1 arm of the study.

Sites. Two sites will be involved: 1. Rapid City, SD and 2. Pine Ridge Reservation. There will be one I-FAP cohort in Rapid City, SD and one I-FAP cohort on the Pine Ridge Reservation. The two sites are approximately 90 minutes apart. There will be research, programming, and administrative staff (with considerable staff overlap) at both sites. Most of these individuals are Indigenous. We will meet weekly as a team and more often as needed especially during busy periods of the project to ensure strict adherence to protocols and make modifications as needed (with U of M IRB and OST RRB approvals). All of this work is taking place at U of M facilities in Rapid City SD and Pine Ridge SD. Work is being done by U of M hired staff overseeing by PI Edwards and Dr. Ryan (Family Acceptance Project; FAP). We will do a Collaborative Institutional Agreement with the FAP. Co-I Dr. Wheeler at UNL will have access to data as her role is to analyze data but she will not be involved in programming or other human subjects activities (e.g., consenting, enrolling). Co-I Dr. Coburn at UNL will be engaged in some human subjects activities when they make visits to SD and support enrollment/recruitment efforts as well as fidelities and analysis of qualitative data.

Design Details.

5.2 Interaction/Intervention Details

The specific study activities of enrolled participants include:

1. Baseline and immediate post-test surveys
2. Programming and post-session feedback forms in between the baseline and immediate post-test
3. Exit interviews for participants who attended five or more sessions

To meet the Rule of Threes under the UM Minors in Research policy, we will ensure that pairs of staff members will always work together during recruiting efforts (including at community events and door knocking), during screening and survey administration, and when providing programming. We cannot follow the Rule of Threes when conducting mental health assessment for youth who endorse high levels of suicidal ideation or intent and/or psychotic symptoms. Having a second staff person participate in the phone calls or Zoom meetings (which will be used for these screenings) is not accepted practice in mental health assessment and easily may influence youths' willingness to disclose information about their current suicidal ideation, past suicide attempts, and related risk factors. We will not record these screening assessments for the same reason, specifically that this will likely reduce youths' willingness to discuss highly sensitive, personal information. All mental health clinicians will keep detailed notes (see attachment: Assessment of suicide risk and psychotic symptoms) - these notes will be stored in a restricted access folder in the project's DropBox.

Each of these specific study activities are described in detail below

1. Baseline and immediate post-test surveys

Participants who are enrolled (meet criteria AND have done all applicable consent/assent forms) will be given the option of doing the baseline survey surveys at a time and location of their choosing so long as the location is safe and private. Research staff including Indigenous (mostly Lakota) research staff will collect data and Dr. Edwards and other Investigators will support in these endeavors. We will strongly encourage participants to take the surveys in our offices in Rapid City or on the Pine Ridge Reservation. Participants will have the choice of doing the surveys on a tablet or on paper and pencil. The surveys will have participants unique ID on it but will not have their name or other identifying information. This ID is needed to link surveys over time and conduct follow-ups to participants endorsing safety items on the surveys (see next paragraph more details). Participants will be reminded of the voluntary nature of the survey and that they can skip questions and still receive monetary compensation. Participants will be provided with a resource sheet at the end of each survey and study staff will ask participants if they would like help accessing any of these resources after reviewing the resource list with them. Staff will then provide participants with the gift card compensation and remind them of when the first session will begin. All study staff are trained in trauma-informed data collection protocols as well as managing disclosures and participant distress (see Disclosure and/or Upset Participant Protocol IFAP OPT uploaded in Section 44).

Dr. Gayle Beck or one of the Indigenous mental health providers will follow-up with participants within 24 hours who answer affirmatively to the following items:

- Thoughts that you would be better off dead, or of hurting yourself? (from the PHQ)[67]
- Score 21 or higher on the SIDAS[65]

Regarding the immediate post-test, participants will be asked if they would like to do this after the final program session. If they do not wish to do it then or miss the final program session, they will be scheduled to do it at a time and location of their choosing using the protocols described above for the baseline survey. See Reminder and Check-In Scripts uploaded in Section 8.1.

2. Programming and post-session feedback forms in between the baseline and immediate post-test.

I-FAP involves 8 sessions, as outlined on pp. 11-12. Sessions will be held face-to-face, in a quiet and private space that protects confidentiality. On the Pine Ridge Reservation, this will be at our office space that has large and small meeting rooms and private offices. Our Rapid City office is not as large and thus we will use a Native American Community Center for programming. Individual interviews and surveys can be conducted in a private room at our Rapid City office. Caregivers meet separately from 2SLGBTQ+ youth for some of these sessions, while they meet together for other sessions (see Table p. 11-12). Weather permitting, the groups will be held once per week for 8 weeks. Each session will last for 2 hours. Two groups will be conducted, one in Rapid City, SD and the other at the Pine Ridge Reservation. Each group session will begin with a smudging (burning sacred herbs such as sage to cleanse the soul and space of negative energy), a Lakota prayer, and a meal followed by a check-in and warm-up activity to allow members the opportunity to express their feelings and provide time to fully transition into the group space. Group members will be guided in the process of creating a set of group participation guidelines in the first session, and they will be shared at the start of each group session. Group facilitators will review content from the previous session and invite feedback and reflections from participants. At the end of each group, facilitators will provide time and space to close the group by completing the following: (1) summarize the topics covered during the group session; (2) ask participants to reflect on what was learned during the session and how they will use it in their lives and what key points or information they would like to share with the other group members; (3) ask participants to share a self-care activity they will do after the group. Detailed resources (e.g., mental health, food insecurity) will be provided verbally and via a handout at all sessions to both Indigenous 2SLGBTQ+ youth and their caregivers. In between sessions, program participants will have short homework assignments that include individual and family-based activities and assignments.

Of note, if a caregiver/youth dyad miss a program session or leaves early, they will be provided with handouts summarizing the missed session when they return to the next session. Because the content of each session is equally important (the content of no one session is more critical than the others), this practice will ensure that absences will be accommodated in a way that is fair to all participants. Stated differently, program facilitators will not spend part of the session reviewing missed material, as this would result in reduced time to present new material as well as introducing redundancy to participants who have not missed sessions.

If only one member of the dyad arrives to a given program session alone, they will be asked to return when both members of the dyad can attend together. If one member of the dyad drops out of the program, we will ask the remaining member to stop attending sessions. Both of these procedures align with the program content, which is to teach skills to foster greater family acceptance of 2SLGBTQ+ youth, as well as provide dyad-focused activities that increase positive affect and connection.

The programming will be facilitated by Indigenous (mostly Lakota) adults with lived experience as a caregiver to an Indigenous (mostly Lakota) 2SLGBTQ+ youth. We will also have 2SLGBTQ+ young people (alongside a more seasoned/experienced adult facilitator) facilitating sessions that include youth. These individuals will be hired by UM and supervised by Dr. Katie Edwards (U of M) and Dr. Caitlin Ryan (FAP; covered under an IIA). To ensure adherence to

the program curriculum and provide support to facilitators, Dr. Ryan will meet with the facilitators weekly, and Dr. Edwards will attend many of these sessions too. All I-FAP sessions will be audiotaped so that they can be scored for program fidelity.

Following the program, participants will be given a copy of the Resource Sheet (uploaded in Section 44). In addition to giving this resource sheet to participants at all points of contact (including after each program session), staff will review the resource sheet verbally with participants and encourage them to let a staff member know if they need help accessing resources. In the past, many families/participants have taken us up on the offer to help facilitate connections to resources for food, shelter, mental health care, and so forth.

Following each session, participants will be asked to complete a short (10 minute) post-session survey (see Post Session Feedback Forms uploaded in Section 29) to document acceptability, safety, and so forth. This will be done on paper and pencil and participants will be told not to write their name on this sheet. Stated differently, these surveys will be anonymous. They will hand it in to the research staff on site, receive their compensation, and a resource sheet with a reminder of the next meeting.

We will track attendance at each session (for youth, research caregivers, and non-research caregivers) in order to have a complete picture of program involvement. This information will be stored in the restricted access area of our Dropbox. The only individuals who will have access to this information will be Dr. Edwards, the project coordinator, and the two senior program facilitators (who will require access to upload this information).

3. Exit interviews for participants who attended five or more sessions.

Participants who attended five or more of the eight sessions will be invited to an exit interview. Of the 28 participants (14 dyads across two sites), we anticipate that this will be about 20 individuals. We will not include people who attended only a few sessions as it may be hard for them to answer some of the questions. Nevertheless, the post session surveys and immediate post-test (see Section 29 for uploaded materials) will ask people reasons for missing sessions and their feedback on the sessions they attended so we will have this data from low attenders as well.

We will email (1x), call (1x), and text (1x) eligible participants and invite them to an interview using a script (Exit Interview Invitation Scripts).

Guardian consent is required for teens under 18 and teens must assent too. Adults will provide their own consent. The interviews will take place in our office or another safe/private location of the participants choosing. The exit interview, which will last about 30 to 45 minutes, will ask in depth questions about perceptions of the program (e.g., what was liked, what was not liked), how the program impacted them, etc. (see uploaded script). Interviews will be conducted in private locations with trained research staff and for the purposes of interview integrity, they will be audio-recorded. The audio recordings will be uploaded to secure Dropbox restricted folders and then transcribed and deidentified. Research staff will transcribe audio recordings or we will use a transcription service (e.g. Rev.com). Then after transcription, the audio-recording will be

destroyed. Participants will receive \$25 and a resource sheet (and encouraged to ask for help accessing resources if needed).

6. Risks & Benefits

6.1 Known Risks

There are 4 known risks of this study:

1. One risk is that the research and/or programming may be upsetting to participants. Because the survey questions focus on family dynamics (e.g., caregiver rejection) and their negative impacts (e.g., internalized homophobia), it is possible that completion of questions may heighten participants' awareness of these negative processes, increasing distress. With respect to distress during programming, it is possible that participants may feel upset by the content of the I-FAP programming, given that it addresses caretaker rejection, negative attitudes/beliefs about 2SLGBTQ+ identities, and unhealthy communication patterns. In our experiences this type of risk occurs infrequently (10%-15% of participants) and it is often a sign they need resources/supports, which we connect them to.

2., It is possible that participating in the intervention could lead to increases in family conflict or risk for harm/rejection by non-participating family members as well as participating caregivers if Indigenous 2SLGBTQ+ youth become more confident and out in their identity over the course of the intervention and caregivers are not showing progress in their acceptance of their Indigenous 2SLGBTQ+ youth. In our experiences, this is rare (less than 1%).

3. A third risk breach in confidentiality. This can happen in two ways. First, someone could access the data that should not access the data, although this is extremely rare (<1%). Second, if a participant were to disclose instances of child abuse, suicidality, homicidality, and/or Elder abuse we would need to make the appropriate reports to relevant authorities. These disclosures (which happen infrequently in our work, 10-15%) could happen during a program session, outside of a program session via email or by phone/text, or based on an answer to survey questions that would require follow up. Addressing these disclosures requires conveying the participant's name, which is a permissible breach of confidentiality. Dr. Edwards will support staff in making mandated reports (or calling 911 if its an imminent threat). Dr. Beck will assist with these efforts although her primary role will be during screening for eligibility of participants who ping on suicide and/or psychosis items. We have discussed our reporting of potential child abuse with the Risk Management Office and individuals who assist with the Minors in Research policy. Risk management has approved of our method of handling and reporting cases of suspected child abuse in South Dakota and on the Pine Ridge Reservation. Minors in Research policy does apply to research on sovereign lands; several of the steps required by this policy will occur after IRB approval of the study (e.g., background checks). We will adhere to all relevant University of Michigan policies concerning involvement of minors in research.

4. A fourth risk is a youth being outed by a program participant to individuals outside of the program.

6.2 Known Potential Benefits

Benefits to Society. Although research documents the concerning rates of mental health and related problems among Indigenous 2SLGBTQ+ youth, there is very little known about how to prevent these deleterious issues that devastate Indigenous communities. This project aims to adapt and evaluate the first ever culturally grounded, family-based program to prevent mental health and related problems among Indigenous 2SLGBTQ+ youth. The project aligns with Healthy People 2030 Goals to eliminate health disparities, which includes reductions in violence and injury among 2SLGBTQ+ youth and youth of color. As such, the proposed project has the potential for paramount public health impact and thus benefits society.

Benefits to Participants. Research suggests that many youth and adults report personal benefits (e.g., insight, validation) from participating in research focusing on sensitive topics and that the benefits to this type of research outweigh the costs. In our previous research with youth, including Indigenous 2SLGBTQ+ youth, we have had no adverse events, and many participants have reported that participating was a very positive experience. In addition to participating in surveys, interviews, etc., the I-FAP programming may also directly benefit participants although this is not guaranteed. For example, caregivers may become more accepting of their children which may enhance the mental health of Indigenous 2SLGBTQ+ youth. The program may also give hope and validation to Indigenous 2SLGBTQ+ youth. Again, these are not guarantees but are potential benefits that we will be working hard to study in a rigorous way.

6.3 Risk/Benefit Ratio Assessment

Rationale. The study cannot be conducted without potential exposure to risks. Risks are detailed in the consent and assent form and verbally reviewed with participants. Participants are also reminded at all points of contact that participation in the research (surveys, exit interviews, programming) is completely voluntary. Risks are also minimal and far outweighed by potential benefits to participants and society.

Minimization of Risk.

Our strategies to mitigate the four risks are as follows:

Regarding participants being upset, our collective experience suggests that, although the subject matter of the study is sensitive, adverse reactions to completing surveys are very rare. Dr. Edwards has published a number of studies that have all shown that participating in violence-related research is not upsetting to the vast majority of participants.[90, 91] Furthermore, even for the few participants who report being upset by survey questions, it is minimal, transient, and often outweighed by personal benefits of participating. All respondents will be provided with multiple relevant local, regional, and national resources so that they can

reach out for help if they so choose. In general, steps that will be taken to minimize discomfort include reminding participants that they can refuse or stop participating at any time and that they do not have to answer questions that they do not wish to answer (each survey item will have an "I do not want to answer" response option). Also, all data collection procedures are described at the outset as ones that will ask about strengths such as connection to culture, pride in one's identities as well as experiences with conflict in relationships, mental health (e.g., anxiety, depression, thoughts about self harm), alcohol and drug use, sexual activity, including unwanted sexual experiences, etc., so that participants can give informed consent. In our previous research, 10-15% of Indigenous participants reported feeling awkward, sad, and/or anxious after taking surveys, but there was no indication of psychological harm or persistent distress. We have used most of these measures in our previous research with Indigenous populations and they were also selected with input from our advisory boards.

It is also possible that participants could be upset by the intervention content. The group agreements, which are reviewed each session, discuss the importance of voluntary participation and the need to take care of oneself, which might include disengaging from the intervention content (e.g., taking a break for a few minutes, stopping participation in the intervention). The intervention does not focus on deficits but instead focuses on family and cultural strengths and skill development. We will closely monitor for iatrogenic effects. We will ask participants if they were upset by any of the intervention content and/or survey questions on all surveys, including post-session surveys. For those answering affirmatively, we will ask them to provide more detail about what specifically made them upset, how upset they were, and what suggestions they have for us that could have minimized such feelings. The fact that Indigenous staff and community members are helping to write this program should also minimize risk of participant discomfort.

Research and programming staff are all trained in how to manage participant distress and trauma-informed research/programming practices, using a detailed protocol (see Disclosure and/or upset participant protocol). All staff who have contact with human participants will undergo a 3-hour training session, followed by multiple role-plays, opportunities for questions/answers, and feedback. They will be asked to pass a certification role play prior to having any contact with our participants. We have discussed our reporting of potential child abuse with the Minors in Research office. Because the study will take place in South Dakota (in Rapid City) and on sovereign land (at the Pine Ridge Reservation), this office approved of our method of handling and reporting cases of suspected child abuse.

To mitigate the risk of increases in family conflict or risk for harm/rejection by non-participating family members as well as participating caregivers during programming, we will begin each class with a check-in concerning how communication and relationships are going within the family, focused primarily on 2SLGBTQ+ participants. If a youth reports increases in family conflict, two facilitators will talk with the youth privately (following the rule of 3s) to help them to develop a safety plan of somewhere they could stay if they are in danger or are expelled from their home. Dr. Edwards will support staff with these efforts and applicable reports of potential child abuse will be made to the appropriate authorities. Second, participants will be provided with local and national resources for Lakota LGBTQ2S+ youth in case any issues arise between sessions. If a youth discloses having experienced a significant issue during a session (e.g., having been expelled from their house), Dr. Edwards or Dr. Beck will help them access

necessary resources and develop a plan and ensure their safety. Facilitators will also be carefully trained regarding how to respond to such disclosures during an intervention session (see uploaded protocol in section 44). The management of such disclosures will be discussed during facilitator supervision meetings as well. Participants will be told during the consent/assent and enrollment process, data collection sessions, and at all program sessions to reach out immediately to the study office with any concerns about programming and/or research procedures. We will also ask about safety concerns on each post-session survey (uploaded in section 29) and take immediate corrective action as needed

To mitigate risk for someone accessing data who are not authorized to do so, several steps are in place to ensure data protection. For participants doing surveys online, Qualtrics has robust confidentiality protections in place. The University of Michigan has also licensed the Qualtrics Insight Platform, a Web-based survey and data analysis service. This license provides the U of M community with a set of powerful online survey and research tools and allows an unlimited number of surveys and survey responses annually. Qualtrics protects participant data using industry best standards and best practices and methods for protecting information. Qualtrics carries out testing of their services to make sure they meet the highest levels of data security. As a company, Qualtrics has surpassed expectations and received high praise from large international organizations. High-end firewall systems protect Qualtrics servers, and scans are performed regularly to ensure that any vulnerabilities are quickly found and resolved. Complete penetration tests are performed yearly. All services have quick failover points and redundant hardware, with complete backups performed nightly. Most important is Qualtrics confidential system component design. It uses multiple checks to certify that packets from one subsystem can only be received by a designated subsystem. Access to systems is severely restricted to specific individuals whose access is monitored and audited for compliance. Customer data are stored in a specific location; they do not float around in the cloud. In addition, all data are processed in that location and are not moved to another jurisdictional area. In other words, if data are collected in the U.S., all data are processed in the U.S.

Exit interviews will be done in person and recorded via a hand-held recorder. Recordings will be transferred immediately after the interview to the restricted Dropbox and deleted from the hand held recorder. Recordings will be destroyed from Dropbox immediately after the interviews are transcribed by a member of the research team or Rev.com with de-identifying information removed. Transcriptions will happen within a month of the interviews. All these materials will be stored in a U of M secure Dropbox.

To assess program fidelity, all I-FAP sessions will be audiotaped using a hand-held recorder. Recordings will be transferred immediately after the class to the restricted Dropbox and deleted from the hand-held recorder. Recordings will be destroyed from Dropbox immediately after fidelity is rated by a member of the research team.

There is also the small potential for a data breach (recordings and/or survey responses) of data being accessed by someone who should not access them. This risk will be mitigated by transporting paper data in a lockbox from community sites to our office and storing paper data in a locked cabinet until it is scanned into a secure Dropbox Folder.

To manage child disclosures of abuse, we will give all youth reporters a safe space to discuss what they have experienced or witnessed. All facilitators and research staff will be trained in how to manage disclosures in a sensitive, validating way. A copy of the protocol to be used to

handle disclosure of child abuse can be found in the file named Disclosure and/or Upset Participant Protocol (Section 44), which staff will be extensively trained on (as previously described). In the event of a disclosure of child or elder abuse, two research staff will meet privately with the participant to take the participant's report. This procedure follows the University of Michigan's Rule of 3. In listening to the individual who is reporting potential child or elder abuse, all staff will be validating and supportive, in keeping with Dr. Edward's approach to all of her work. We will keep an internal record of child abuse disclosures, which will include reporting steps that were taken on a form named Disclosure Documentation Form (page 3 of Disclosure and/or Upset Participant Protocol). Youth who themselves have experienced abuse will be provided with local resources (either in Rapid City or on Pine Ridge). The consent and assent forms carefully outline the fact that confidentiality will be compromised if a participant discloses child or elder abuse. During recruitment and enrollment, staff will carefully verbally review this section of the consent and assent forms, to ensure that participants understand our processes. Participants will also be encouraged to ask questions about study procedures, prior to providing consent and assent.

Regarding an Indigenous 2SLGBTQ+ youth being outed by another program participant, we will emphasize the importance of caregivers not sharing with anyone outside the program the SOGIE status of their Lakota LGBTQ2S+ youth. Lakota LGBTQ2S+ youth will be provided with resources and support from facilitators in the event this happens, and facilitators would reiterate to caregivers the importance of allowing Lakota LGBTQ2S+ youth to make all decisions about who and when and how to share their SOGIE (sexual orientation, gender identity, and expression). A group member who does not follow group agreements such as outing someone may be dismissed from the program as outlined in the consent forms.

Justification for Benefits Outweighing Risks. Risks are minimal and disclosed to potential participants at the outset. Participants can stop participating at any time without penalty. Evidence suggests the potential benefits to Indigenous 2SLGBTQ+ youth and their caregivers outweigh the risks of emotional distress. The study is also deeply participatory and most of the staff are Indigenous—this ensures that the work we are doing is driven by the community. The potential benefits to society are reductions in depression, anxiety, and suicidality among a highly structurally minoritized population (i.e., Indigenous 2SLGBTQ+ youth). Dr. Edwards has a history of working with SGMY, including Indigenous 2SLGBTQ+ youth, within the context of research studies as well as clinical interventions/prevention initiatives and has developed carefully constructed procedures for managing risks. The study will also be closely monitored by a DSMB and the U of M IRB.

7. Recruitment

7.1 Planned Recruitment Strategies

Strategies of recruitment adapted to Indigenous cultural context: Participants will have multiple ways to enroll in the study. They will have the option of attending informational sessions/feeds in person where they can engage with staff and ask questions and enroll in-person or take

information to review or share with others. In addition, they can enroll by calling/texting the project phone, emailing the project email, reaching out through the online portal on a project website, or in person at various locations across Rapid City and Pine Ridge. We will also offer to go to the home of interested participants to enroll them in the study, if requested. These recruitment strategies were developed in close collaboration with our Lakota staff and Advisory Boards and used with previous experience on prior studies. Their experiences in both Rapid City and on the Pine Ridge Reservation suggest that community events, radio announcements, word-of-mouth, and locale-specific social media outlets are the strongest way to spread the word about this study within the Indigenous community. In these recruitment efforts, the Rule of Threes will be followed (two or more staff will be present when interacting with potential youth participants).

Participants will be recruited via fliers placed throughout the community, posted social media ads (including those boosted on Facebook and Instagram), radio announcements, attending community events (e.g., powwows, health fairs, informational sessions/feeds), and word-of-mouth (e.g., a staff member telling a neighbor about the research project). These materials can be found Section 8 (uploaded). We will be thoughtful in the intensity with which we saturate the communities with materials given we do not want to have to turn many families away. We will rely on guidance from our two advisory boards and our Lakota staff to ensure that recruitment is proceeding in a culturally appropriate way.

We also will recruit from multiple youth- and family-serving agencies in Rapid City and on the Pine Ridge Reservation. These partnering agencies will do some of the following as detailed in their letters of support: (1) post about the project on their social media sites; (2) allow the project team to table at events hosted by the agency; (3) send out recruitment letters to families involved with/who attend the agency (letter is found in a file named Recruitment Letter for Collaborators); (4) share information about the project with staff who are part of the agency so that they can pass along information to the youth and families that they serve; and/or (5) encourage families to invite other families to the project and extend personal invitations.

If needed (although unlikely given the other methods of recruitment), like previous studies in the region, we will engage in “door knocking” on the north side of Rapid City where the vast majority of residents are low income and Indigenous. Door knocking includes identifying an area or areas within a community that has a large proportion of the target population. Once identified, pairs of staff members of our research team will be trained to go door-to-door and explain the nature of the study to potential participants, assess eligibility criteria, and enroll families that are interested and meet inclusion criteria. We will also door knock on the Pine Ridge Indian reservation across districts, if needed. We have attached our door knocking protocol which outlines clear strategies for best practices of “do’s and don’ts” when going door to door to ensure staff safety and project integrity and includes scripts. Pairs of trained team members will be assigned neighborhoods to canvas in each area and carry project materials (e.g. consents, fliers) and speak with residents who could be eligible to participate. This is in keeping with UM’s Rule of Three policy. The protocol outlines clear strategies for different scenarios and possible questions with scripts to follow. If staff have eligible participants, they can screen them, consent them, and enroll them in the study and provide resource sheets. All paper consents and survey

instruments will be stored in secure lockboxes and returned to the office in Rapid City or Pine Ridge, scanned into a secure UM restricted Dropbox folder and paper consents and survey instruments will be locked in office filing cabinets. We have had great success using this method in previous studies in SD.

We will also advertise the study in other ways as recommended by the Youth Advisory Board and Caregiver Advisory Board.

Ensuring an equitable study population: We will keep a list of participants for the RCT in the event we have more families express interest than we can include in the OPT. The diverse approaches in recruitment should allow for equitable inclusion of the study population and again if we have more families expressing interest than we can include in the OPT, we will take their name and contact information to share recruitment materials with them for the RCT.

A copy of the scripts to be used to recruit and enroll potential participants (as well as to remind individuals who obtained information about the study but may not have reached out further) can be found in the files named < Eligibility Determination and Enrollment Protocol IFAP, Reminder and Check-In Scripts>.

Recruitment in public places: Some of our recruitment will occur in public settings (e.g., at powwows and health fairs). To ensure confidentiality of our participants, partitions will be used to visually separate participants from one another (and from study staff). If a participant wishes to listen to the consent, screening questions, and survey, we will provide headphones to ensure privacy. We can also read the consent and questions to the participant, with the individual providing their answers on a tablet or paper/pencil survey. All staff attending these events will follow written protocols to manage disclosure of child abuse (discussed previously). Staff safety in these public places will be assured by the attendance of multiple staff (no staff will recruit alone in a public space). This is in keeping with UM's Rule of Three policy.

Recruitment of Program Only participants: Research participants eligible and enrolled to participate in the program will have the option to identify additional relatives/caregivers age 18 and older who they would like to attend the program with them. These individuals will not take pre/post test surveys. They can attend the eight two-hour sessions and participate in the session activities. We will ask them to complete anonymous post-session surveys and will receive the \$20 Visa card incentive for completion of each of these surveys. Program Only participants will be identified during the screening process after determining eligibility of caregiver/youth dyads. Scripts and the Qualtrics survey will include questions to identify Program Only participants. Program only participants will be required to sign a consent form (see Program Only Adult Consent IFAP OPT). In a previous study (Rapid City Family Project Tiwahe Wicagwicayapi) with indigenous families, we included program-only participants successfully finding that it also helps increase participation and attendance.

Additional details concerning the recruitment protocol, including recruitment scripts, are included in the on-line e-Research system.

7.2 Identification of and Approach to Potential Participants

Potential participants will be recruited as described in Section 7.1 and screened using a short questionnaire, via Qualtrics.

We anticipate that we will screen 20+ youth-caregiver pairs to obtain the 14 youth-caregiver pairs for this project. This number is based on Dr. Edward's experience conducting research with 2SLGBTQ+ youth in the locale. More specifically, ~12 caregivers will be screened and ~12 youth will be screened (who are under the care of these individuals). Regarding demographics, we expect caregivers to be largely Indigenous and female identified caregivers and ranging in age from younger adults to elders. All youth will be 2SLGBTQ+ and Indigenous ages 13 to 18.

There is a possibility that a caregiver may have more than one youth who meets eligibility criteria. In this instance, we will allow each eligible youth to enroll in the study based on feedback from our Lakota staff and our experience with previous family-based studies where it is inequitable to allow only one youth to participate. We don't anticipate this occurring often within this population and within the small sample size we are targeting. However, the caregiver will be asked to answer questions only about the youth with the most recent birthday.

If more than one caregiver signs up to participate with the same eligible youth, the caregiver who spends the most time with the youth will complete surveys. The other caregiver can participate in programming only.

8. Informed Consent/Assent

8.1 Informed Consent/Assent Process

There will be a total of four consent/assent forms in this study, specifically:

1. Guardian consent for teen if under 18 (and which caregivers can participate with their teen if it is not them). This consent form will be signed by the legal guardian of the eligible teen participating in the project.
2. Teen assent for self (for programming and surveys). This assent form will be signed by the eligible youth who is participating in the program.
3. Caregiver consent for self (for programming and surveys). This consent form will be signed by the caregiver who is participating in the program (that the guardian of the teen has said can participate if different than the guardian).
4. Additional caregivers (programming only). This consent form will be signed by non-research participant family members of the youth-caregiver pair. These family members will attend programming sessions with their family but will not participate in the research component of the project (e.g., no survey data will be collected).

Note: It is possible that the legal guardian of the child may not be the caregiver participating in the intervention. As such, the guardian consent form will provide information on who is allowed to participate in I-FAP with the child.

Consent forms are uploaded in Section 10 and contain all required elements. Of note, per the Flesch Kincaid Calculator, reading levels are as follows: 8.2 for guardian consent for teen if under 18, 7.9 for teen assent for self, 9.2 for caregiver consent for self, 8.8 for additional caregivers (programming only).

Once it is determined that a teen and caregiver within a dyad both meet criteria and wish to participate, a study staff member will meet with them at a time and place of their choosing to complete the consent/assent forms. The researcher will read the forms out loud to the participants, stopping periodically asking if they have questions. After reviewing the consent forms, the participants will indicate if they wish to participate and complete the forms. In the event that a participant wishes to do the consent form not in the presence of a researcher, we will offer to meet on Zoom or on the phone and read them the form and they can do the form including electronically signing the form on Qualtrics. Participants will be offered a copy of the consent forms for their records as well as a resource sheet and contact information for the project team too.

8.2 Informed Consent/Assent Documentation Process

Forms are closely reviewed to ensure there are no errors (e.g., forgot to sign). If there are errors on the form, we respectfully ask participants to fix the errors/fill in missing parts. When a form with no errors is finalized, a member of the research team processes the form by scanning it into a secure Dropbox folder and adding details from the form (e.g., contact information) to the master list. Signed consent and assent forms will be stored in a secure Dropbox folder in addition to hard copies being stored in locked filing cabinets in our offices on Pine Ridge Reservation and in Rapid City. Forms obtained via Qualtrics will be downloaded and stored in a secure Dropbox folder. We will delete forms from Qualtrics after recruitment and enrollment are completed.

9. Confidentiality and Privacy

9.1 Plans to Ensure Participant Privacy

To further protect the privacy of study participants, this study will be/has been issued a Certificate of Confidentiality (CoC) to all researchers engaged in the research. The CoC protects researchers and institutions from the forced disclosure of participants' individually identifiable information, sensitive research information, records, or data to anyone not associated with the research, except in certain instances when federal, state, or local law or regulation requires disclosure. The study team will inform research participants of the protections afforded to them by the CoC through the informed consent process.

9.2 Plans to Ensure Participant Data Confidentiality

Access. Only staff listed on this protocol will have access to study records. Staff will only access study records that are needed for their specific roles/tasks on the project.

Data Security. Data will be stored on a restricted Dropbox at U of M. We will share the quantitative data (pre- and immediate post-test surveys) with our statistician (Dr. Wheeler) at UNL all of which will be outlined in an sIRB agreement. Dr. Wheeler will access that data through a Dropbox folder at U of M. She will copy and paste it into a restricted OneDrive folder (the platform used by UNL).

Record Retention Requirements. De-identified data will be given to the OST RRB via flash drive (their requirements) once the study is completed and findings are published/disseminated (with OST RRB approval). Once data are given to the OST RRB, the data will be destroyed from both U of M and UNL per OST RRB policies. See uploaded OST RRB policies in section 44 of the application.

Identifiers. It is important for several reasons (e.g., matching surveys across time, to do follow-up calls with participants indicating safety issues on surveys) to have a master list that ultimately links participants names to their data. The master list will have each participants name along with their contact information and a participant ID. Dyads will share a number but one will be labeled Y (for youth) and C (for caregiver). For example, 101Y and 101C. Only these numbers/letters will be on surveys, exit interviews, etc. The master list will only be accessible to the study coordinator, mental health clinician, and Dr. Edwards.

Regarding exit interviews, they will be conducted in-person in a private room at our office. We will audio record using a hand-held recorder for in-person interviews. Recordings will be destroyed following transcribing the interviews with de-identifying information removed. Interviews will be transcribed and recordings destroyed within one month of the interviews. Materials will be stored in a U of M secure Dropbox.

Access. Personally identifiable information will not be released to any third party. We will use our NIH Certificate of Confidentiality to resist any situation (e.g., court order) to share identifiable information. If a participant asks for a copy of their data, we will consult with the study team and U of M IRB and ultimately follow the guidance of the U of M IRB. If the DSMB or IRB need to access our data, we will provide only de-identified data unless required to do otherwise.

10. Data Analysis Plan

Type and sources of data: Data to be collected include pre and post test surveys, post session surveys, and exit interview data. Data are being collected for the purposes of assessing acceptability, feasibility, and safety and to ensure that changes from pre to post are in the hypothesized directions.

Acceptability data will be analyzed using descriptive statistics, specifically by calculating the means, standard deviations, and ranges. We will also look at the percentage of people who said agree/strongly agree versus disagree/strongly disagree at the item level to be able to provide an

overall indicator of acceptance. One-sample one-sided t-tests were utilized to determine if mean scores were significantly different than scores expected by chance responding (i.e., whether scores were significantly higher than the scale midpoint). SPSS 29 was used for quantitative analyses. In addition to the quantitative data, acceptability and feasibility will be assessed using content analysis to code responses (which are anticipated to be short) on the post-session surveys. We will use thematic analysis to code responses (which are anticipated to be more in-depth) to the exit interviews. Content and thematic analyses are described below.

Regarding fidelity, a research staff will be present at all sessions (sitting in the back of the room) to answer YES or NO to a list of main buckets of content for each session. We will calculate fidelity by session and an average fidelity score across all sessions by dividing the number of responses that indicated adherence to the program manual by the total number of possible adherence questions.

Content analysis is an appropriate method for the open-ended survey data because the responses on post-session surveys are anticipated to be brief. This strategy will allow us to identify both overarching categories of responses and quantify the frequency of responses. Under the supervision of PI Edwards, research staff will first read all responses and discuss the diversity of responses that are present in the short-answer questions. This discussion will result in a provisional codebook, which will be used by the coders to code the data individually.

Whereas the open-ended post-session survey responses are expected to be succinct/brief, interviews will be longer and semi-structured, allowing for conversation between the interviewer and interviewee. Thus, instead of quantifying this data using content analysis, we will use a thematic analysis approach[94]. Thematic analysis is a flexible “method for identifying, analyzing and reporting patterns” within data, suitable for analyzing “rich, detailed, and complex” accounts of the study topic[96] (pp. 79). Under the close supervision of PI Edwards, research staff will analyze the exit interview data. Initial codes will be developed using questions drawn from the semi-structured interview guide. The team members then add further codes, independently reading and open coding each interview for emergent themes. Then, coders will meet to discuss each interview. These meetings will result in a list of major themes that arose during the interviews. Consistent with a thematic inductive saturation model[97], the coding will occur while the interview data are still being collected, so that we can determine when the data is saturated and thus, when interview data collection should be completed[94].

We will look at changes in outcomes from pre- to post- test using dependent sample t-tests. We are doing this merely to ensure that outcomes are changing on average in the correct direction (e.g., depression is decreasing) and to get a sense of effect sizes.

Sample size: Because this is an open pilot trial, the sample is not intended to be adequately powered to perform a rigorous test of efficacy. The sample is sufficiently large to gather information on acceptability of I-FAP to 2SLGBTQ+ youth and their caretakers, as well as feasibility and safety of the programming.

11. Data Management and Sharing

11.1 Data Management Plan

Description of Data to be Collected

All data will be collected at the individual level from both caretakers and 2SLGBTQ+ youth. Survey data will include both numerical and short-answer data. Interview data will be collected for a subset of the sample (at the individual level) and transcribed.

Data Identifiability

Self-report survey data collected via Qualtrics (or paper surveys if needed) will not contain names. These data will be coded only with subject identification numbers. The master list will be stored in a folder separate from data files. We will share the quantitative data (pre- and immediate post-test surveys) with our statistician (Dr. Wheeler) at UNL all of which will be outlined in a sIRB agreement. Interview data is inherently identifiable. Interviews will be audio recorded. After transcription, the audio recordings will be deleted and transcripts will be de-identified. Consent and assent forms as well as any notes from disclosures/mandated will not be destroyed since these are important records to keep. We will maintain these records for at least 7 years.

Data Storage Methods

Survey data at U of M will be confidential and stored in secure Dropbox folders, separate from the master list which will link identifying information with participant numbers. The only individuals who will have access to the master list (or any information about participant identities) will be the project coordinator, the mental health provider, and the PI. Data will be stored on a restricted Dropbox at U of M. The audiotaped interviews and program sessions will be uploaded to a restricted Dropbox at U of M. The recorded interviews will be transcribed within 1 month of the interview by a research staff on this protocol or by Rev. The recorded program sessions will be rated by research staff for the fidelity to the program protocol. All audio recordings will be deleted after data are transcribed and/or scored. Transcripts will be de-identified by a study team member by replacing anything with identifying information with the category mentioned. For example, if someone said: "My friend Katie who lives in Ann Arbor", the transcript would read "My friend NAME who lives in CITY". Transcripts will also be randomly assigned numbers (1, 2, 3, etc.) so during coding we can easily refer back to them. Transcripts will be kept in a secure password protected Dropbox folder, only accessible to research personnel. We will conduct thematic analyses of the interview transcriptions. Although the interview data will be aggregated in presentations or publications, and participants' responses may be used in the form of quotations, no names or other identifying information will be included. All of this will be disclosed to participants in the informed consent/youth assent documents, including information about recordings and confidentiality practices.

Associated Metadata

Syntax, codebooks, and documentation of decisions made during data cleaning and analysis will be stored in a restricted Dropbox folder (at U of M and UNL) and on a restricted SharePoint folder at UNL. These materials will not contain any identifying information. More specifically, documentation will provide a detailed description of variables and their key attributes as well as what was done as data were collected and why choices were made. We will ensure that our data is supported by standard documentation of the method of data collection (e.g., survey, individual interview), what the data represent, and potential limitations for its use.

Documentation will include questionnaires used for surveys and exit interviews; guidance materials used for training the research team; instructions for interview facilitation; consent and assent forms; approved IRB application, descriptions of methods used to analyze the data; description of how derived materials were created and coding schemas. We will create codebooks that include documentation of all the raw (i.e., questions, response values, and related variable names) and constructed (i.e., variable names and scoring procedures) data. The documentation will also include all published citations relevant to the measures and constructs. Notes will be kept on all file names and formats associated with the project, how the data are organized, how the data was generated (including any equipment or software used), and information about how the data has been altered or processed. We will include an explanation of codes, abbreviations, or variables used in the data or in the file naming structure. Documentation will include name of the dataset/research project, key dates associated with the data, including project start and end date, and time period covered by the data; keywords or phrases describing the content of the data; NIH as funding agency (and required disclaimers); how the data were generated as well as the corresponding codebooks.

We will also note that we adhered to best practices for robust research data systems ensuring high data quality. In particular, we will utilize the secure online data collection tool, Qualtrics. Qualtrics has embedded features to address data quality (e.g., restriction of range of response values, reduction of data entry errors). Extensive testing of the Qualtrics surveys will be done before data collection to ensure data quality. Once data collection has been completed, data quality checks will be completed by the rigorously trained data management team led by Co-I Wheeler at UNL, including checking for mischievous responses (e.g., straight lining answers, short survey times), examining item frequency distributions, and checking for outliers. Syntax will be used for both data cleaning and analysis as a form of documentation and to support replication.

Data Availability

De-identified data will be given to the OST after papers are published and the study is completed.

Access to Data Data will not be archived. The level of public access will be restricted. The Oglala Sioux Tribe owns this data. When the study is complete and results are published, data will be turned over to the Oglala Sioux Tribe Research Review Board. Data will not be archived. The NIMH has approved our Data Management and Sharing Plan (uploaded in Section 44).

Standards to be Used for the Collected Data

Dr. Edwards will take the lead on implementing data safety procedures. Regular team meetings led by PI Edwards with research staff will dedicate time to recruitment/retention/informed consent and assent procedures, data safety and monitoring to ensure that all data quality and IRB policies and procedures are being followed. We will ensure that all study staff are highly trained and closely supervised in following all protocols for data acquisition storage. The research materials consist of survey responses, fidelity data, and interview transcripts. No identifying participant information will be included in any of the surveys, fidelity data, or transcribed interview data. Data will be stored on a password protected Dropbox folder that only the PI and key research staff have access to. Only survey data will be shared with Dr. Lorey Wheeler at UNL and her research team at UNL. Finally, we will ensure that all study staff complete PEERs / CITI training prior to engaging in any project activities, are aware of appropriate procedures, closely supervised, and are aware that we limit access to data (including consent/assent documents, survey data, interview data) to only study staff as necessary. We will also frequently consult experts, NIH /HHS policies, and our IRB to ensure that best practices for ethical and safe practice of research are being followed.

11.2 Data Sharing Plan

Please see our NIH approved Data Management and Sharing Plan (see uploaded document titled “Edwards NIH R34 submitted DMS plan 2-14-23”). Data are owned by the Oglala Sioux Tribe (OST). They will decide if and how it is shared. There is a long history of exploitation of Indigenous peoples in research and as such, it is important to recognize the sovereignty of the OST, which includes data sovereignty.[98-101] Thus, data will not be shared via a public repository. Any requests for access to deidentified data will go through the OST Research Review Board (RRB) and/or OST Health and Human Services (the OST is currently working establishing protocols and procedures for data sharing).

Deidentified study data will be made available only to individuals permitted to access it by the OST. Best practices will be followed in deidentifying participants, including ensuring that the dataset does not contain any safe harbor identifiers and removing any text entry responses (e.g., individuals who write in their sexual orientation or gender identity) as well as any open-ended responses from the dataset that could be potentially identifying.

As mentioned previously, all identifying or potentially identifying information will be removed from the dataset prior to sharing. If the OST decides they would like to share the data prior to the launch of the study (to be decided during the official review of the study protocol during the OST RRB process), study participants will be asked to consent to data sharing with the wider research community. Participants will be informed of their right to decline to have their data shared and provided with contact information of both the PI and the OST RRB office if they wish to withdraw their consent from having their data shared. Participants will be able to decline to have their data shared up to after completion of the OPT and will be informed of this.

12. Data Safety and Monitoring Plan

Safety oversight will be under the direction of a Data and Safety Monitoring Board (DSMB)/Safety Monitoring Committee (SMC) composed of individuals with the appropriate expertise. Four individuals serve on the DSMB. Dr. Amy Elliot at the Avera Research institute has expertise in health disparities, population health, quantitative analysis, and early childhood development. Dr. Teresa LaFromboise at Stanford University has expertise in American Indian/Alaska Native (AI/AN) education and health; efforts of non-dominant racial/ethnic groups to thrive in the face of adversity, development and testing of school and community-based psychological interventions with AI/AN adolescents, and the American Indian Life Skills Curriculum. Dr. Dorothy Espelage at the University of North Carolina has expertise in youth violence prevention, intervention programming, social-emotional learning, LGBT resilience, prevention science, school-based interventions, social-emotional learning interventions, bullying prevention, teen dating violence, sexual harassment/violence, and school-based suicide prevention. Dr. Mary Cwik has expertise in youth suicide, Indigenous mental health disparities, mixed methods designs, randomized control trials, psychology mental health, suicide, suicide

screening, self-injury, American Indian health, trauma, substance misuse, opioids. and health disparities.

Each prospective member of the DSMB will be assessed by the PI and Co-PI, with particular attention given to ensuring no perceived, potential, or actual conflicts of interest. All members of the DSMB will have completed IRB training and will sign a Board charter that includes verbiage prescribed by both the funder/sponsor and the home institution of the PI. A quorum of members of the DSMB will meet virtually a minimum of once every two months during data collection and program implementation, with larger intervals between meetings during study preparation and dissemination. Meetings will be scheduled more regularly as needed, especially in the wake of adverse events or other serious issues requiring DSMB input. Before each meeting, when the agenda is distributed, the PI will ask all DSMB members to state whether they have developed any new conflicts of interest since the last formal annual report to NIMH. If a new conflict is reported, the PI and DSMB members will determine if the conflict limits the ability of the DSMB member to participate in the discussion, and whether further evaluation of the conflict by the awardee institution is warranted. The DSMB will review all IRB and study protocols. Additionally, the DSMB will have access to all study recruitment and retention logs, deidentified participant data, and other research materials/logs as requested. The DSMB will have authorization to make any modifications to study procedures deemed necessary to ensure participant safety and well-being. The DSMB also will review adverse event data, other safety data, enrollment data, and quality and completeness of study data at each meeting to ensure proper conduct of the clinical trial. The DSMB will also have authorization to terminate the study in response to concerns about participant safety (physical, psychological, or otherwise) or privacy violations. The DSMB will operate under the rules of an approved charter that will be written and reviewed at the organizational meeting of the DSMB. Please see document titled Section 32 the DSMB charters. During the organizational meeting, each data element that the DSMB needs to assess was clearly defined. Dr. Katelyn Coburn (Co-I) and Dr. Laura Wolter (Postdoctoral Associate) will coordinate the DSMB activities, including scheduling meetings, keeping detailed minutes of board members' concerns and how each concern is addressed, preparing reports, and making timely summary reports of any adverse events (as necessary) for distribution to the U of M IRB and OST RRB. All protocols are consistent with the NIH DSMB guidelines and will be revisited annually (and more often as needed) for updates or corrections originating with either the funder/sponsor or the PI's institution.

The DSMB will provide its input to the study team and following each DSMB meeting, the board must submit a written report to the PI. The options available for the outcome of the review are:

1. Recommend continuation with no modification,
2. Recommend continuation with modification(s) to protocol,
3. Recommend suspension of enrollment pending additional information,
4. Recommend suspension of all trial activities pending additional information,
5. Recommend termination of trial.

13. Study Completion/Off Study Criteria

Participants are free to withdraw from participation in the study at any time upon request. An investigator may discontinue or withdraw a participant from the study for the following reasons: if they report being distressed or iatrogenic effects associated with their participation and/or they are highly disruptive during the delivery of the intervention that could negatively impact other participants.

The reason for participant discontinuation or withdrawal from the study will be recorded on a list maintained by the U of M researchers.

Subjects who sign the informed consent form and receive the study intervention, and subsequently withdraw voluntarily, or are withdrawn or discontinued from the study by the study team, will not be replaced

Early termination/suspension of study.

In the event of a serious, unexpected, and related AE, the PI will consult with the DSMB immediately concerning whether to continue the study, to temporarily suspend the study until the cause of the AE is addressed, or to continue with the study. The outcome of this decision will be communicated to the IRB immediately. If the study is discontinued or suspended, all participants will be informed by phone or email. NIMH will also be informed of such a decision.

14. Adverse Events and Unanticipated Problems

This study will use a Standard U-M IRB AE reporting timetable.

We will follow the U-M IRB AE reporting timetable except for making reports within 48 hours instead of 1 week. We will also report AE to our DSMB.

PI Edwards will be responsible for determining if the incidents is an Adverse Event (AE), Other Reportable Information and Occurrences (ORIO), and/or Unanticipated Problems (UAP), as defined below:

Adverse Event (AE)

AEs are events that involve physical, social, economic, or psychological harm to subjects; or indicate the possibility of harm to others. For research reviewed by the IRB-HSBS, an example of an AE would be a study involving questions or procedures that caused subjects to become upset to a degree unanticipated by the study team. The study team files an AE with the IRB to report the possible psychological

harm to the subjects. Due to the unexpectedness of the subjects' reaction, the IRB may determine this to be an "[unanticipated problem](#)."

Other Reportable Information and Occurrences (ORIO)

The University of Michigan uses the term "ORIO" to cover multiple types of events associated with a human subjects study, including:

- Accidents/incidents involving subjects, data/specimens, or U-M facilities
- Protocol deviations or violations, whether deliberate or accidental
- Complaints
- Lapses in IRB approval
- Audits, reports, or letters from federal oversight agencies

Most of the incidents reportable to the IRB-HSBS are ORIOs. An example of an ORIO would be a data breach as the result of a lost or stolen laptop, or system hacking. The study team files an ORIO with the IRB to report this event as "Accident/incidents involving subjects, data/specimens, or U-M facilities." In an event where the study team deliberately or accidentally breached confidentiality (e.g., mailed identifiable psychological or blood test results to the wrong participant), this would be reported as a protocol deviation.

Unanticipated Problems (UaP)

An "unanticipated problem" is an event, occurrence, incident, experience, information or outcome that is:

1. Unexpected (by the participants or investigators in terms of nature, severity, or frequency) given:

- the research procedures that are described in the IRB-approved research protocol, informed consent document, and data and safety monitoring plans; and
- the characteristics of the subject population being studied (i.e., the traits, behaviors, symptoms, diseases, life experiences, etc. being studied); and

2. Related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by, or is linked in some significant way to the procedures involved in the research); and

3. Suggests that the research places subjects or others at a greater risk of, or actual, harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

The event must meet all three of the above criteria. Depending on the nature of the incident, the study team reports the UaP as an Adverse Event or ORIO for IRB determination. Per federal and institutional policies, the IRB reports unanticipated problems to the Office of the Vice President for Research, [OHRP\(link is external\)](#), and the sponsor (if necessary).

Assessment of adverse event severity will be assessed by the PI Dr. Edwards. All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by PI Edwards based on temporal relationship and her expertise. She will also consult with Co-Is, U of M IRB staff, and the DSMB as needed. The degree of certainty about causality will be graded using the categories below.

Adverse Event/ORIO Submission

Study teams can submit Adverse Event and ORIO reports online in U-M's **eResearch Regulatory Management (eRRM)** system. The system steps to initiate the report are the same, but once you select the type of report (Adverse Event or ORIO), the system displays applicable information and options for that type of report. [See Resources below for step-by-step system instructions](#). In general, researchers should wait until after learning the IRB review outcome before making changes to the protocol in response to an AE or ORIO event. However, changes may be made at the time of the incident in order to protect human subject safety or to mitigate risk that could result from the AE or ORIO event. In such cases, the researcher should include this information in the AE or ORIO submission.

Roles & Responsibilities

Investigators and study teams are responsible for:

1. Identifying unanticipated problems
2. Analyzing the causes of these problems
3. Filing an AE/ORIO report in eResearch to alert the applicable U-M IRB
4. Responding appropriately to events and other problems involving risk to human subjects.

The **IRB-HSBS** reviews the report and may:

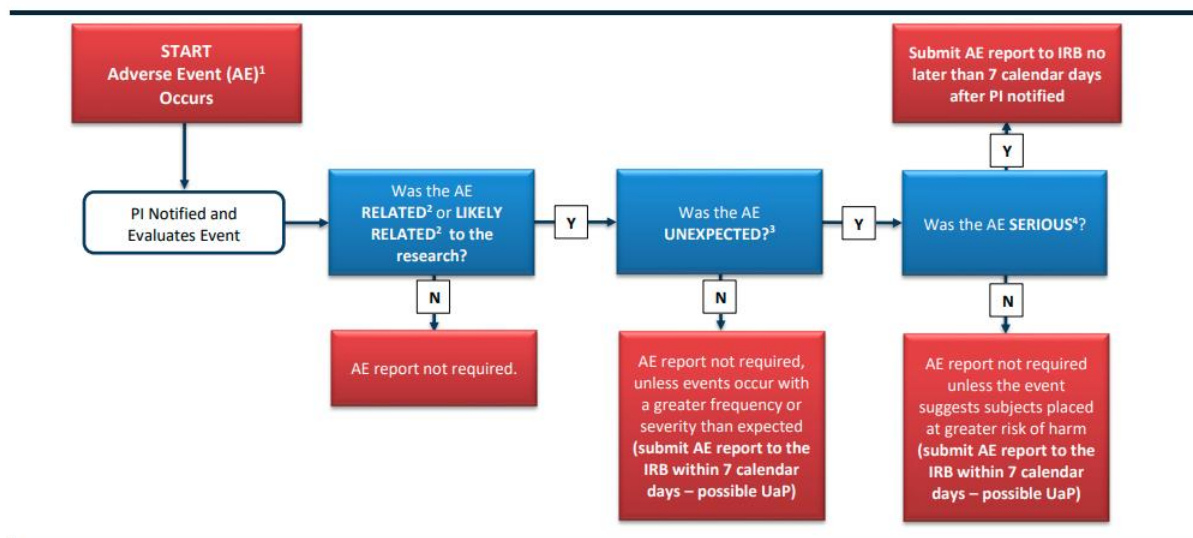
- Acknowledge the report, requiring no further action on the part of the study team

- Require [changes](#) to the protocol, procedures, or informed consent process in order to protect human subjects
- Request more frequent [continuing review](#) or status reporting for the project
- Suspend or terminate the research in cases (rare) of unacceptable risk to subjects

The IRB reports events that demonstrate serious or continuing non-compliance to the Office of the Vice President for Research, [OHRP\(link is external\)](#), and the sponsor (if necessary).



Adverse Event Reporting: Flowchart and Guidance
Revised: February 7, 2020



DEFINITIONS (terms found on page 1 and 2)

- ADVERSE EVENT (AE):** an event in that results in harm to research subject during the time of their participation in research. AEs typically represent actual physical harm to subjects, but may also represent psychological, emotional or social harm.
- RELATED/LIKELY RELATED:** the event was caused/likely caused by the subject's participation in the research itself.
- UNEXPECTED:** the event has not been addressed in one or more of the following – Protocol, IRB application, or Informed Consent Document
- SERIOUS:** the event resulted in death, or involved severe social/psychological/emotional trauma, or a life altering/threatening or other serious outcome (see reverse for examples within each category).
- NON-SERIOUS:** the event does not meet the definition of a serious adverse event, but resulted in the subject experiencing psychological/emotional distress or social harms such as stigmatization.
- UNANTICIPATED PROBLEM (UaP):** An incident, experience, or outcome that warrants consideration of substantive changes in the research protocol or informed consent process/documents or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.
- REPORTING DATE:** 7 days after the event occurs or after the study team becomes aware of the event.

-1-

Characterization of Adverse Events (AEs) and Reporting Requirements	
SERIOUS ⁴ and Related	Report ASAP, but no later than 7 calendar days of the event, or study team becomes aware of the event
	Severe Social, Psychological, or Emotional Trauma: Loss of job, insurance, benefits; criminal prosecution, stigmatization of community/group, destruction of familial/social relations.
	Life Altering or Other Serious Event: An event that jeopardizes the subject's physical, mental, emotional, social well-being, or livelihood. This could include, subject or family mental health crisis resulting in hospitalization or prolonged treatment; severe asthma attack; assault, battery, or other threats of physical violence; any incident requiring security measures; in-patient hospitalization or prolonged hospitalization; a persistent or significant disability, incapacity; or other serious adverse events requiring further monitoring.
	Death: For projects involving a health-related intervention, an adverse event report should be submitted if related to the research.
SERIOUS OR NON-SERIOUS UNANTICIPATED PROBLEM (UaP) ⁶	Unanticipated Problem (UaP) Involving Risks to Subjects or Others: An event that suggests the research places subjects or others at a greater risk of harm than was previously known or recognized and/or is significant to the rights and welfare of human subjects in the study. An event, occurrence, or information that is not expected by the research participants or investigators in terms of its nature, severity, or frequency given the: • Procedures as described in the study documents • Characteristics or qualities typically found in the eligible study participants • Possibility that the event or information has been caused by, or is linked in a significant way to, the research • Potential for greater risk of, or actual harm to, the subjects or others than was previously known or recognized. Depending on the nature of the incident, <u>the study team reports the event as an Adverse Event or ORIO following the time lines for serious or non-serious events.</u> Generally: If the event involved risk of physical/mental harm and harm occurred, submit an Adverse Event report. If the event involved risk of harm but no actual harm occurred, or the event involved a data breach, submit an ORIO. The IRB determines whether the event is a UaP. Per federal and institutional policies, the IRB reports UaPs to the U-M Vice President for Research and to the research sponsor, and for federally sponsored research, to the Office of Human Research Protections (OHRP).
	Report to IRB at any time ten or more such incidents have occurred
	Social or Psychological Trauma or Upset: Mild to moderate or temporary emotional distress or upset, significant embarrassment, stigmatization of individual or community/ group, disruption of familial/social relationships
	Emergency and/or Urgent Treatment: Emergency Room, physician or other provider visit required to treat non-life threatening physical injury and/or emotional trauma or distress.
NON-SERIOUS ⁵ and Related	



- ORIOs are used to report a number of different types of events associated with the conduct of a human research projects that are not reported as Adverse Events.
- Some ORIOs describe events that represent **noncompliance** with human subjects regulations, laws, institutional policies or IRB requirements or may describe unanticipated problems (UaP). Events that represent potential **serious or continuing noncompliance or a UaP** require **prompt reporting (within 7 calendar days)** to the IRB.
 - **Serious noncompliance** materially increases risks or causes substantive harm to research participants or materially compromises the rights or welfare of participants.
 - **Continuing noncompliance** recurs after an investigator has been notified of a similar or related noncompliance concern pertaining to one or more protocols.
 - **Unanticipated problems** are any incident, experience, or outcome that meets **all** of the following criteria:
 - It is "unexpected" in terms of its nature, severity, or frequency given 1) the research procedures described in the protocol-related documents, such as IRB-approved research protocol and informed consent documentation; and 2) the characteristics of the subject population being studied;
 - It is "related" or "possibly related" to the participation in the research; meaning there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and
 - It suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
- Examples of events requiring prompt reporting include (**within 7 calendar days**):
 - Human research conducted **without IRB approval** or determination of exemption
 - Research conducted **without informed consent**, unless the IRB approved a waiver
 - **Major protocol deviations** that impact subjects safety or the integrity of the data
 - **Multiple protocol deviations** of the same type that suggest a problem with the design or conduct of the study (10+ deviations of a similar type, such as use of an incorrect consent document)
 - **Incidents involving subject data** or biospecimens that may impact subject confidentiality or the integrity of the research
 - **Complaints** about the study that cannot be resolved by the study team
- Investigators are encouraged to report other ORIOs as they are occur.

Nature of Event	eResearch Report Description
Accident/Incident	Use to report accidents/incidents involving: • Data • Specimens • Facilities For example, events involving server intrusions, stolen laptops, loss of specimens, etc. To report accidents or incidents involving harm to subjects, submit an Adverse Event report.

**HEALTH SCIENCES &
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**Other Reportable Information or Occurrences
(ORIO) Reports**

Complaint	Use to report complaints from: - Subjects - Others - Potential subjects who were recruited but did not enroll - Family members or others complaining on behalf of a subject - Researchers, students, or staff - Reports from the U-M Compliance Hotline
Protocol Deviation/Violation	Use to report: - Deliberate Procedural Deviations (including "protocol exceptions") - Accidental Procedural Deviations - Appointment/Visit Deviations - Intervention Errors or Deviations - Consent Process Deviations or Problems
Report of Study Lapse	Use to report: Status of research during a lapse in IRB approval when Continuing Review is required. This includes any: - Recruitment - Subject enrollment - Interaction/interventions with subjects - Analysis of identifiable data
Subject Incarceration	For studies not previously approved to enroll prisoners, use to report when: - A prisoner is enrolled unintentionally - Intent to continue participation of a previously enrolled subject who becomes incarcerated (prisoner, involuntarily committed psychiatric patient, etc.) Note: For most research reviewed by IRB-HSBS, an amendment is required prior to enrolling a prisoner in research or continuing to interact with someone who has become incarcerated.
Notification of Audit/Inspection/Inquiry	Use to: Advise the IRB, prior to an audit/inspection/inquiry, of any documentation that may be needed by the auditor/inspector (e.g. copies of IRB outcomes regarding protocol issues)
Pertinent Publication/Public announcement	Use to report: - Information affecting the risk/benefit ratio of the study - Information affecting subjects willingness to participate in the research
Report to/from Oversight Entity	Use to report: - Review reports from the U-M Office of Research Compliance Review (ORCR) - Progress report to the IRB - Annual report to or from DSMB - Other reports to the IRB that do not fit into one of the other categories
Subject Withdrawal	Use this: - When withdrawal(s) prompt an amendment to change the research (complete the ORIO and obtain IRB acknowledgement prior to beginning the amendment submission) - To track withdrawals as they occur (optional)

1/27/2020

All the above information is all in alignment with federal policies and university policy, as reflected here:

[https://research-compliance.umich.edu/incident-reporting-aeorio#:~:text=Adverse%20Event%20\(AE\)&text=For%20research%20reviewed%20by%20the,psychological%20harm%20to%20the%20subjects](https://research-compliance.umich.edu/incident-reporting-aeorio#:~:text=Adverse%20Event%20(AE)&text=For%20research%20reviewed%20by%20the,psychological%20harm%20to%20the%20subjects)

AND

<https://documentation.its.umich.edu/node/1327>

AND

https://research-compliance.umich.edu/sites/default/files/resource-download/ae_standard_timetable_2.7.2020_final_0.pdf

AND

https://research-compliance.umich.edu/sites/default/files/resource-download/orio_events_and_reporting_1.27.2020_final_0.pdf

15. Protocol Deviations Reporting Plan

It will be the responsibility of the study investigators to use continuous vigilance to identify and report deviations to appropriate individuals. All deviations will be addressed in study source documents. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements. Further details about the handling of protocol deviations is above in Section 14.

16. References

16.1 Citations and References

Please see below on p. 53.

16.2 Abbreviations and Special Terms

NIH	National Institute of Health
CDC	Centers for Disease Control and Prevention
NSF	National Science Foundation
CIHR	Canadian Institutes of Health Research
DOJ	Department of Justice
NIMH	National Institute of Mental Health
PI	Principal Investigator
Co-I	Co-Investigator
OPT	Open Pilot Trial
RCT	Randomized Control Trial
2SLGBTQ+	Lesbian Gay Bisexual Transgender Queer/Questioning Two Spirit
LGBTQ+	Lesbian Gay Bisexual Transgender Queer/Questioning
SGMY	Sexual and Gender Minority Youth
SGM	Sexual and Gender Minority
SOGIE	Sexual orientation, gender identity, and expression
ACEs	Adverse childhood experiences
CBPAR	Community-based participatory action research
FAP	Family Acceptance Project
I-FAP	Indigenized Family Acceptance Project
UNL	University of Nebraska-Lincoln
UNL IRB	University of Nebraska-Lincoln Institutional Review Board
U of M	University of Michigan
U of M IRB	University of Michigan Institutional Review Board
OST	Oglala Sioux Tribe
OST RRB	Oglala Sioux Research Review Board
sIRB	Single Institutional Review Board
IIA	Individual Investigator Agreements
AE	Adverse Event

CIA	Collaborating Institution Agreement
ORIO	Other Reportable Information and Occurrences
UAP	Unanticipated Problems
eRRM	U-M's eResearch Regulatory Management
IRB-HSBS	U-M's Health Sciences and Behavioral Sciences IRB
GAD	Generalized anxiety disorder
PHQ	Patient Health Questionnaire
SIDAS	Suicidal Ideation Attributes Scale
YPARQ-B	Abbreviated Youth Psychosis at Risk Questionnaire
SBQ-R1	Suicidal Behaviors Questionnaire-Revised
YRBS	Youth Risk Behavior Survey
SMC	Safety Monitoring Committee
DSMB	Data Safety Monitoring Board

16.3 Protocol Change Log

The table below is intended to capture changes to the IRB-approved versions of the protocol, including a description of the change and rationale. Add rows to the table as needed.

Version control is important to track protocol development, revisions, and amendments. Always ensure that the most recently IRB approved version of a protocol is used by all staff conducting the study. With each revision, update the version number and date located in the page header.

Protocol Version	Date of Change	Description of Change	Brief Rationale
V2	Jan 30 2025	Response to IRB pre-review	We received pre-review feedback which we have incorporated into the revised application.

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14. Edwards, K.M., et al., *Using intergenerational photovoice to understand family strengths among Native American children and their caregivers*. *Journal of Community Psychology*, 2022. **50**(8): p. 3625-3639.
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16. Abreu, R.L., et al., *Parental support, depressive symptoms, and LGBTQ adolescents: Main and moderation effects in a diverse sample*. *J Clin Child Adolesc Psychol*, 2022: p. 1-16.
17. Edwards, K.M., Diamond-Welch, B., Hayes, L., Catlett, J., Herrington, R., Farquhar-Leicester, A., Coburn, K., Green-Maxomi, C., Matson, A., Schrader, L., Hespe, P., Hunt, K., & Spitz, C., "We've Always Been Here": A multi-method, multi-informant study

- documenting strengths challenges of Lakota LGBTQ2S+ youth*. Manuscript under review, 2022.
18. Edwards, K.M., et al., *Experiences and Correlates of Violence among American Indian and Alaska Native Youth: A Brief Report*. Journal of Interpersonal Violence, 2020. **36**(23-24): p. 11808-11821.
 19. Tan, K.K., et al., *Gender minority stress: A critical review*. J Homosex, 2020. **67**(10): p. 1471-1489.
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