

Clinical Trial Consent Form Cover Sheet

Protocol ID: HUM00264029

ClinicalTrials.gov ID: NCT07326748

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

Document Date: 08/27/2026

18-Year-Old Youth Self-Consent Form



UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Development and Evaluation of an Indigenized Family Acceptance Project for Lakota 2SLGBTQ+ Youth (PHASE II: OPEN PILOT TRIAL)

Principal Investigator: Dr. Katie Edwards, University of Michigan

Study Sponsor: National Institute of Mental Health

University of Michigan IRB Number: HUM00264029

18-YEAR-OLD YOUTH PARTICIPANT SELF-CONSENT FORM

Thank you for your interest in Tiwahe Tewichaglapí – The Family Acceptance Project. This form tells you more about the project so that you can decide if you want to participate in this project. **YOU MUST BE 18 YEARS OLD TO SIGN THIS FORM.**

Before making your decision, please carefully read this form or have it read to you and ask questions about anything that is not clear. You can contact us to ask questions by phone call/text at 605-381-2568 or email us at LakotaFAP@umich.edu.

1.1 Key Information

Things you should know:

- The purpose of the study is to develop a program for Native American (e.g., Lakota) 2SLGBTQ+ (e.g., Two-Spirit, Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, or other diverse sexual and gender identities) youth and their caregivers that helps (1) caregivers support their Native American 2SLGBTQ+ youth and (2) help Native American youth feel connected to their caregivers and other Native American 2SLGBTQ+ youth.
- If you choose to participate, you will be asked to participate in the program, take surveys, and may be asked to do a 1-1 interview. This will all take approximately 19 hours.

- Risks or discomforts from this research include negative emotional reactions to program and survey content or a breach of confidentiality.
- You may find the information and skills presented in this program to be helpful or useful in your life personally, but you may also not benefit.

Taking part in this research project is voluntary. You do not have to participate and can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

Native American 2SLGBTQ+ youth have many strengths and some challenges. We want to develop a program for Native American 2SLGBTQ+ youth and their caregivers that helps (1) caregivers support their Native American 2SLGBTQ+ youth and (2) help youth feel connected to their caregivers and other Native American 2SLGBTQ+ youth. Your voice is important in helping us make this program.

3. WHO CAN PARTICIPATE IN THE STUDY

Native American 2SLGBTQ+ youth between the ages of 13-18 are eligible to take part in this study. This consent form is for youth who are 18 years old and able to consent for themselves. Also, caregivers who read and speak English are eligible to participate in this study with their teen. Caregivers must also be legal adults (18 or 19 depending on state laws) to participate. Native American 2SLGBTQ+ youth cannot participate unless a caregiver also participates with them. Caregivers can be parents, grandparents, or anyone who signs the youth's school papers.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

We are asking you to do two things in this project: (1) Take surveys, and (2) Be part of a program with your caregiver that will meet eight times in person. You may also be asked to complete an interview after the study is over if you attend most of the sessions.

If you join this project, we will ask you to take a survey at two different time points (before and after the program). Each time you take the survey; it will be about 45 minutes. You will take the survey at our office or at another location that you and/or your caregiver picks that is safe and private. The surveys will ask demographic questions about you and how you feel about yourself. Some questions will ask about strengths (e.g., connection to culture, resilience, connection to community). We will ask about your mental health (e.g., anxiety, depression, thoughts of self-harm), alcohol and drug use, sexual activity, and relationships, including unwanted sexual experiences. You will have the option to do the survey online or on paper and pencil.

The program will have eight in-person sessions, with one session per week, held at the same time every week. Each of the eight sessions will be up to two hours long (16

hours in total). The sessions will be led by two trained adults who are either Native American 2SLGBTQ+ and/or are parents/caregivers of Native American 2SLGBTQ+ people.

The program sessions are meant to be educational, interactive, and informative. You will get to meet other Native American 2SLGBTQ+ youth and their caregivers, learn more about your 2SLGBTQ+ identity, watch educational videos, and learn skills to help you have a healthy and happy future. A variety of topics will be covered, such as family accepting behaviors, positive identity development, healthy communication skills, advocacy, and guest elder storytelling about Two Spirit in Native American history. Every program session will begin with a prayer, meal, and smudging.

Also, we will be audio recording the program sessions. This will be done to make sure the people teaching the program are doing a good job. After the session is over, the tape recording will be put in a secure place so it won't be available to anyone except a small number of our research staff. One of our research staff will listen to the tape recording, to make sure that the facilitators did a good job. They will not write down your name or your caregivers' name when they take notes on the session and they will not share what you or other people say during the program with a few exceptions (see section 5.1). After the tape recording has been listened to, it will be erased.

After each of the eight sessions, you will be asked to take a short survey that will take about 5 to 10 minutes. This short survey will ask you to tell us what you liked and what you did not like about the session. You will do this survey on paper/pencil.

Sometimes youth report being sad or anxious or awkward when being asked on surveys about their feelings and experiences. You can skip any questions on the surveys that you do not want to answer. Also, in the program we will talk about things like being 2SLGBTQ+ and challenges that you might face. This could make you feel sad or anxious although most youth feel like these are important topics to discuss that help them feel better. Remember that participation is voluntary.

After each of the eight sessions, you will be asked to take a short survey that will take about 5 to 10 minutes. This short survey will ask you to tell us what you liked and what you did not like about the session. You will do this survey on paper/pencil.

In addition to the surveys and the program, we may ask you to do a 45-minute interview after the program and final survey (if you attend at least 5 of the 8 sessions). This will help us learn more from you about what you thought about the program. The interview will take place in our project office. It will be audio recorded. Audio recordings will be destroyed after the interviews are transcribed with identifying information (like names, etc.) removed. This will usually take place within 1 month or less of the interview. All these materials will be stored in a University of Michigan secure Dropbox. If you are selected for an interview, we will tell you more about the interview at that time. Like everything else in this project, the interview is voluntary. You do not have to do it.

As a participant in this research study, you will have certain responsibilities such as (1) coming to the sessions as scheduled, (2) completing the surveys as requested, and (3) letting us (the research team) know right away if anything negative happens because of being in this research project. Negative things include being upset by anything that happens in this project and/or feeling worse because you are in this research study. Although unlikely, we want to know right away if anything like this happens.

Every time we interact with you, we will make sure that you know of safe places and people you can contact if you need help for yourself or someone else. You can always reach out to us at any time if you or someone else you know needs help to be safe.

If at any point, your contact information changes or one of the ways that was OK to contact you is no longer safe, please reach out to us and we will make sure to update our information so that we only contact you in a way that is OK and safe. It is important that we are able to contact you to remind you of program sessions and surveys. We may also check in with you a few times during the study to see how you are doing, especially if you miss a session or tell us something that makes us concerned about your safety.

4.2 What will happen if you decide not to be in this research study or decide you need to stop participating once you start?

You can decide to be in this research study or not; you can stop being in this research study (“withdraw”) at any time by emailing or calling us. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator or with the University of Michigan.

4.3 How much of my time will be needed to take part in this study?

You and your caregivers will be asked to attend eight two-hour sessions (16 hours in total) over the course of eight weeks. After each of these sessions, you will be asked to take a short survey that will take about 5 to 10 minutes (up to 80 minutes in total). You will also be asked to take two longer online surveys before and after the program. Each time you take these surveys, it will take about 45 minutes. In addition to the surveys and the program, we may ask you to do a 45-minute interview after the program (if you attend at least 5 of the 8 sessions). In total, your participation will take about 19 hours of time spread out over 8 to 10 weeks.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

It is possible that you may feel upset, embarrassed, or awkward while completing the surveys or program sessions. The survey asks about sensitive topics, such as self-harm, and is reviewed in more detail above in Section 1.1. You do not have to answer any questions you do not want to answer. In general, most people do not find completing these types of survey questions to be upsetting, and those that do generally report that being upset is mild and does not last long. Also, remember that your participation is voluntary. We will provide you with a list of resources after every session and each time you take a survey that you can reach out to if you're feeling upset. You can also always reach out to us at any time if you or someone else you know needs help to be safe.

During the program, we cannot guarantee complete confidentiality because program sessions will be completed as a group. As a group, we will have an agreement to honor one another by keeping what is said in the group discussions private. But we cannot promise that other people in the group will not share what you and other people say. At each session, we will emphasize that only program participants can attend. We will remind everyone at the beginning of every session that what other caregivers and teen participants share is confidential and is not to be shared with others outside of the group.

There are certain instances in which we may need to share information that you tell us, If you tell us that (1) a child is being hurt or abused, (2) that you plan to hurt yourselves or someone else, and/or (3) someone else, like an elder, is being hurt or abused, we will have to share this information with someone to make sure that you and other people are safe. We may also need to have a mental health care provider on our team follow up with you if we have concerns about your safety.

Additionally, you should also know that if a parent or another individual in your life (who is NOT participating in this program) contacts us about the project, we will provide them with general information about the project (that it is focused on teaching youth life skills and about healthy choices) and why it is important. We will not provide them with any information about you, including whether you are participating in the study.

This study involves the collection of private information (name, dates, etc.) so that we can link survey data across time, send you reminders about upcoming program sessions and surveys, and give you cash. Information collected as part of research will only be used by the research team and will not be used or distributed to other people outside of this research team for new research studies. Because this study collects information about you, one of the risks of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 How could I benefit if I take part in this study?

You may find the information and skills presented in this program to be helpful and/or useful in your life personally (for example, it might make you have a better relationship

with your caregiver, you may feel more hopeful about the future, etc.), but you may also not benefit.

How could others benefit?

We will ask you questions about what you liked about the program and surveys and how to make these things better for other Native American 2SLGBTQ+ youth. We will take into consideration all the feedback you give us to make the program better before we offer it to 2SLGBTQ+ youth and their caregivers all over the United States. Your voice is so important to us and will make a difference in helping to increase family support for 2SLGBTQ+ youth!

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty. If you decide to leave the study before it is finished, we will ask you to please tell one of the people listed in Section 9. "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless asked to delete it from our records. If the researchers have already used the information in a research analysis it will not be possible to remove your information.

You should also know that participants who do not adhere to the group agreements (for example, being respectful, keeping what people say confidential) outlined at the beginning of each session, or those who tell us or show signs that the study is causing them distress, may be removed from the project.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

We will give you \$20 cash for the first survey, and \$30 cash for the survey you will complete in about two months from today. You will also get \$20 cash for each short survey you take at the end of each program session. You will not be eligible to complete surveys about any sessions you do not attend or sessions that you leave early. Finally, you will receive \$25 cash for doing a 1-1 interview after the program sessions end if you attend at least five of the eight sessions.

In total, you can earn up to \$235 in cash for being in this study. Even if you skip survey or interview questions, you will still get the cash. However, you must get to the end of the survey and interview to get the cash. You will also still get the cash if you do not want to talk in the sessions, but you need to stay for the entire session and do the brief

survey (you can skip questions) after the session to get the cash. You do not have to receive cash if you do not want to do so. You will also get a certificate for completing the program.

If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than \$400 for this study or 2) if you receive payments of greater than \$400 for being in more than one study, the University of Michigan finance department will also require their Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

Your research data will be kept in a secure Drop Box folder that only the members of the research team will have access to. This information will be stored electronically on the cloud; the term “cloud” refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards.

8.1.1 Special Protections

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify you in any action or lawsuit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document.
- We may share information with appropriate authorities if we think you may harm yourself or others.
- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.

- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop guardians or teens from personally releasing information about their involvement in this research if they wish.

More information about Certificates of Confidentiality and the protections they provide is available at <https://grants.nih.gov/policy/humansubjects/coc.htm>

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The Oglala Sioux Tribe Research Review board (OST RRB) may require the study team to submit information as part of its duty to monitor the research project. The OST RRB is an independent body that reviews research conducted within the exterior boundaries of the Pine Ridge Indian Reservation and/or involving tribal members or resources to minimize potential harms for the participants, families, and the community and to maximize potential benefits for the participants, families, and the community.
- University, government officials, study sponsors or funders, auditors, and/or the University of Michigan Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others.

8.3 What will happen to the information collected in this study?

We will keep the information we collect about you during the research in order to present this information in academic papers or presentations. Any form that you sign will be kept for study recordkeeping. During the duration of the project, your name and other information that can directly identify you will be stored securely and separately from the research information we collected from your caregiver. After the final surveys are completed for all participants, we will deidentify your data and delete individual identifiers from our records.

The results of this study could be published in an article or presentation but will not include any information that would let others know who you are. The OST RRB must approve anything we share publicly.

8.4 Will my information be used for future research or shared with others?

No. The OST RRB owns the data meaning that the researchers at the University of Michigan are not allowed to share your data with anyone other than the OST RRB once

the study ends. When the OST RRB gets the data, it will not have any names or other identifying information on it.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Katie Edwards

Email: LakotaFAP@umich.edu

Phone: 605-381-2568

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

**University of Michigan – Health Sciences and Behavioral Sciences
Institutional Review Board (IRB-HSBS)**

2800 Plymouth Road

Building 520, Room 2144

Ann Arbor, MI 48109-2800

Telephone: 734-936-0933 or toll free (866) 936-0933

Fax: 734-936-1852

E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

Great Plains Area: IRB00000635

Dewey Ertz, EdD, Chair, Great Plains Area IRB

Marsha Stevens, Great Plains Area IRB Coordinator

Indian Health Service

Federal Building, Room 309

115 – 4th Ave. SE

Aberdeen, SD, 57401

Phone: (605) 226-7493

Fax: (605) 226-7214

Toll Free: (866) 331-5794

Oglala Sioux Tribe Research Review Board IRB308

Phone: 605-867-1704

Email: ost.rrb16@gmail.com

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about, and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Please print the first and last name(s) of the caregiver(s) who will participate with you in the study:

Please provide their relationship(s) to you.

What is the best way to reach them? Please provide as much information as you can so we can get in touch with them. You can also give them our contact information too (on p. 9).

Caregiver_Self_Consent



UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Development and Evaluation of an Indigenized Family Acceptance Project for Lakota 2SLGBTQ+ Teens (PHASE II: OPEN PILOT TRIAL)

Principal Investigator: Dr. Katie Edwards, University of Michigan

Study Sponsor: National Institute of Mental Health

University of Michigan IRB Number: HUM00264029

CAREGIVER CONSENT FORM

Thank you for your interest in Tiwahe Tewichaglapí – The Family Acceptance Project. This form contains information that will help you decide whether to join the study. Before making your decision, please carefully read this form or have it read to you and ask questions about anything that is not clear. You can contact us to ask questions by phone call/text at 605-381-2568 or email us at LakotaFAP@umich.edu. Please allow one business day for a response. If you are in a crisis, please call 911.

1.1 Key Information

Things you should know:

- The purpose of the study is to develop a program for Native American (e.g., Lakota) 2SLGBTQ+ teens and their caregivers that helps (1) caregivers support their Native American 2SLGBTQ+ teens and (2) help teens feel connected to their caregivers and other Native American 2SLGBTQ+ teens.
- If you choose to participate, you will be asked to participate in the program with your Native American 2SLGBTQ+ teen, take surveys, and possibly be asked to do a 1-1 interview. This will all take approximately 19 hours.
- Risks or discomforts from this research include negative emotional reactions to program and survey content or a breach of confidentiality.
- You may find the information and skills presented in this program to be helpful or useful in your life personally, but you may also not benefit.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

Native American 2SLGBTQ+ teens have many strengths and some challenges. We want to develop a program for Native American 2SLGBTQ+ teens and their caregivers that helps (1) caregivers support their Native American 2SLGBTQ+ teens and (2) help teens feel connected to their caregivers and other Native American 2SLGBTQ+ teens. Your voice is important in helping us make this program.

3. WHO CAN PARTICIPATE IN THE STUDY

Caregivers who speak English and who are a caregiver to a Native American 2SLGBTQ+ teen between the ages of 13-18 are eligible to participate in this study. You must also be a legal adult (18+) to participate.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

We are asking you to do two things in this project: (1) Take surveys (2) Be part of a program with your teen that will meet eight times in person. You may also be asked to complete an interview after the study is over if you attend most of the sessions.

If you agree to be in this project, we will ask you to take a survey at two different time points (before and after the program). Each time you take the survey, it will be about 45 minutes. You will take the survey at our office or at another location that you pick that is safe and private. The surveys will ask you demographic questions about yourself and your teen, including how you feel about their 2SLGBTQ+ identity and your behaviors toward them. Questions will also ask about strengths (e.g., Lakota virtues, family resilience, connection to community). Other questions ask things about harder topics such as mental health issues and family challenges. You will have the option to do the survey online or on paper and pencil.

The program will have eight in-person sessions, with one session per week, held at the same time every week. Each of the eight sessions will be up to two hours (16 hours total). You and your teens will attend group sessions with other 2SLGBTQ+ teens and their caregivers. The sessions will be led by two trained adults who are either 2SLGBTQ+ and/or are parents/caregivers of 2SLGBTQ+ people.

The program sessions are meant to be educational, interactive, and informative. You will get to meet other caregivers of 2SLGBTQ+ teens and complete activities like watching videos, having discussions with other caregivers and teens, giving and receiving support, and learning skills to help the teens who is in the project with you have a healthy and happy future. A variety of topics will be covered, such as family

accepting behaviors, positive identity development, healthy communication skills, standing up for your teen, and guest elder storytelling about Two Spirit peoples in Native American history. Every program session will begin with a prayer, meal, and smudging.

Also, during the program, there will be other adults there watching the program. These adults are not there to watch you or your teen. They are there to make sure the people teaching the program are doing a good job teaching the program. They will not write down your name when they take notes. The people watching the program will not share what you or other people say during the program with a few exceptions (see section 5.1).

After each of the eight sessions, you will be asked to take a short survey that will take about 5 to 10 minutes. This short survey will ask you to tell us what you liked and what you did not like about the session. You will do this survey on paper/pencil.

In addition to the surveys and the program, we may ask you to do a 45-minute interview after the program and final survey (if you attend at least 5 of the 8 sessions). This will help us learn more from you about what you thought about the program. The interview will take place in our project office. It will be audio recorded. Audio recordings will be destroyed after the interviews are transcribed with de-identifying information removed (e.g., approximately 10-30 days after the interview). All these materials will be stored in a University of Michigan secure Dropbox. If you are selected for an interview, we will tell you more about the interview at that time. Like everything else in this project, the interview is voluntary. You do not have to do it.

As a participant in this research study, you have certain responsibilities such as (1) coming to the sessions as scheduled, (2) completing the surveys as requested, and (3) letting us (the research team) know right away if anything negative happens because of being in this research project. Negative things include being upset by anything that happens in this project and/or feeling worse because you are in this research study, someone finding out you are in this research study and hurting you or your teen, etc. We want to know right away if anything like this happens.

After every survey, session, and interview, we will make sure that you know of safe places and people you can contact if you need help for yourself or someone else. You can always reach out to us at any time if you or someone else you know needs help to be safe.

If at any point your contact information changes or one of the ways you said was OK to contact you is no longer safe, please reach out to us and we will make sure to update our information so that we only contact you in a way that is OK for you and safe. It is important that we are able to contact you to remind you of program sessions and surveys. We may also check in with you and/or your teen a few times during the study

to see how you are doing, especially if you miss a session or tell us something that makes us concerned about your safety or your teen's safety.

4.2 What will happen if you decide not to be in this research study or decide to stop participating once you start?

Participation is voluntary. You have the right to quit the study at any time or to not answer any question(s) that you do not want to answer. You are still eligible to receive a cash even if you refuse/skip questions on any of the surveys. Deciding to participate, not to participate, or deciding to withdraw from this research project will not affect you or your relationship with the investigator or with the University of Michigan.

4.3 How much of my time will be needed to take part in this study?

Participants will be asked to attend eight two-hour sessions (16 hours in total) over the course of seven weeks. After each of these sessions, you will be asked to take a short survey that will take about 5 to 10 minutes (up to 80 minutes in total). You will also be asked to take two longer online surveys before and after the program. Each time you take these surveys, it will take about 45 minutes. In addition to the surveys and the program, we may ask you to do a 45-minute interview after the program (if you attend at least 5 of the 8 sessions). In total, your participation will take about 19 hours of your time spread out over about 8 to 10 weeks.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

It is possible that you may feel upset, embarrassed, or awkward while completing the surveys or programming sessions. The survey asks about sensitive topics and are reviewed in more detail above in Section 4.1. You do not have to answer any questions you do not want to answer. In general, most people do not find completing these types of survey questions to be upsetting, and those that do generally report that being upset is mild and does not last long. Also, remember that your participation is voluntary. We will provide you with a list of resources after every session and each time you take a survey that you can reach out to if you're feeling upset. You can also always reach out to us at any time if you or someone else you know needs help to be safe.

During the program, we cannot guarantee complete confidentiality because program sessions will be completed as a group. As a group, we will have an agreement to honor one another by keeping what is said in the group discussions private. But we cannot promise that other people in the group will not share what you and other people say. At each session, we will emphasize that only program participants can attend. We will remind everyone at the beginning of every session that what other caregivers and teens share is confidential and is not to be shared with others outside of the group.

There are certain instances in which we may need to share information that you tell us, If you tell us face to face that (1) a teen is being hurt or abused, (2) that you plan to hurt yourself or someone else, and/or (3) someone else, like an elder, is being hurt or abused, we will have to share this information with someone to make sure that you and other people are safe. Further, if you tell us or we learn something that makes us believe that you, your teen, or others have been or may be abused, neglected, or exploited, we may, and in some cases must, report that information to the appropriate agencies. We may also need to have a mental health care provider on our team follow up with your teen and/or you if we have concerns about your teen's safety.

Additionally, you should also know that if another individual in your life (who is NOT participating in this program) contacts us about the project, we will provide them with general information about the project (that it is focused on teaching teens life skills and about healthy choices) and why it is important. We will not provide them with any information about you or your teen, including whether you or your teen are participating in the study.

Further, this study involves the collection of private information (name, dates, etc.) so that we can link survey data across time, send you reminders about upcoming program sessions and surveys, and compensate you with cash. Information collected as part of research will only be used by the research team and will not be used or distributed to other people outside of this research team for new research studies. Because this study collects information about you, one of the risks of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 How could I benefit if I take part in this study?

You may find the information and skills presented in this program to be helpful or useful in your life personally (for example, it might make you have a better relationship with the teen who is in this program with you, you may feel more hopeful about the future, etc.), but you may also not benefit.

How could others benefit?

We will ask you questions about what you like about the program and surveys and how to make these things better for other caregivers of Native American 2SLGBTQ+ teens. We will take into consideration all the feedback you give us to make the program better before we offer it to Native American 2SLGBTQ+ teens and their caregivers all over the United States. Your voice is so important to us and will make a difference in helping to increase family support for Native American 2SLGBTQ+ teens!

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the people listed in Section 9. "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis, it will not be possible to remove your information.

You should also know that participants who do not adhere to the group agreements (for example, being respectful, keeping what others say confidential) outlined at the beginning of each session, or those who tell us or show signs that the study is causing them distress, may be removed from the program.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

We will give you \$20 cash for the first survey, and \$30 cash for the survey you will complete in about two months from today. You will also get \$20 cash for each short survey you take at the end of each session. You will not be eligible to complete surveys about any sessions you do not attend or sessions that you leave early. Finally, if selected, you will receive \$25 cash for doing a 1-1 interview after the program sessions end.

In total, you can earn up to \$235 in cash for being in this study. Even if you skip survey or interview questions, you will still get the cash. However, you have to get to the end of the survey and interview to get the cash. You will also still get the cash if you do not want to talk in the sessions, but you need to stay for the entire session and do the brief survey (you can skip questions) after the session to get the cash. You do not have to receive cash if you do not want to do so. You will also get a certificate for completing the program.

If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than \$400 for this study or 2) if you receive payments of greater than \$400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

Your research data will be kept in a secure Drop Box folder that only the members of the research team will have access to. This information will be stored electronically on the cloud; the term “cloud” refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards.

8.1.1 Special Protections

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify you in any action or lawsuit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document.
- We may share information with appropriate authorities if we think you may harm yourself or others.
- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at <https://grants.nih.gov/policy/humansubjects/coc.htm>

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The Oglala Sioux Tribe Research Review board (OST RRB) may require the study team to submit information as part of its duty to monitor the research project. The OST RRB is an independent body that reviews research conducted within the exterior boundaries of the Pine Ridge Indian Reservation and/or involving tribal members or resources to minimize potential harms for the

participants, families, and the community and to maximize potential benefits for the participants, families, and the community.

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others.

8.3 What will happen to the information collected in this study?

We will keep the information we collect about you until the data are analyzed and presented shared with other people who want to learn from this project. We will keep any documents you sign for study recordkeeping. During the duration of the project, your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. After the final surveys are completed for all participants, we will deidentify your data and delete individual identifiers from our records.

The results of this study could be published in an article or presentation but will not include any information that would let others know who you are. The OST RRB must approve anything we share publicly.

8.4 Will my information be used for future research or shared with others?

No. The OST RRB owns the data, meaning that the researchers at the University of Michigan are not allowed to share your data with anyone other than the OST RRB once the study ends. When the OST RRB gets the data it will not have any names or other identifying information on it.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Katie Edwards
Email: LakotaFAP@umich.edu
Phone: 605-381-2568

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

**University of Michigan – Health Sciences and Behavioral Sciences
Institutional Review Board (IRB-HSBS)**

2800 Plymouth Road
Building 520, Room 2144
Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

Great Plains Area: IRB00000635

Dewey Ertz, EdD, Chair, Great Plains Area IRB
Marsha Stevens, Great Plains Area IRB Coordinator
Indian Health Service
Federal Building, Room 309
115 – 4th Ave. SE
Aberdeen, SD, 57401
Phone: (605) 226-7493
Fax: (605) 226-7214
Toll Free: (866) 331-5794

Oglala Sioux Tribe Research Review Board: IRB308

Phone: 605-867-1704
Email: ost.rrb16@gmail.com

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Name (first and last) of teen I'd like to participate with: _____

Contact information for the teen: _____

Teen Assent for Self



UNIVERSITY OF MICHIGAN ASSENT/CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Development and Evaluation of an Indigenized Family Acceptance Project for Lakota 2SLGBTQ+ Teens (PHASE II: OPEN PILOT TRIAL)

Principal Investigator: Dr. Katie Edwards, University of Michigan

Study Sponsor: National Institute of Mental Health

University of Michigan IRB Number: HUM00264029

TEEN ASSENT / CONSENT FORM

Thank you for your interest in Tiwahe Tewichaglapí – The Family Acceptance Project. This form has information that will help you decide whether to join the study. Your guardian/caregiver has said you can be in this project, but you get to decide for yourself if you want to be in this project. Please carefully read this form or ask to have it read to you. Please ask questions about anything that is not clear. You can contact us to ask questions by phone, call/text at 605-381-2568 email us at LakotaFAP@umich.edu.

1.1 Key Information

Things you should know:

- The purpose of the study is to develop a program for Native American (e.g., Lakota) 2SLGBTQ+ teens and their caregivers that helps (1) caregivers support their 2SLGBTQ+ teens and (2) teens feel connected to their caregivers and other Native American 2SLGBTQ+ teens.
- If you choose to participate, you will be asked to attend the program, take surveys, and may be asked to do a 1-1 interview. This will all take approximately 19 hours.
- You might feel sad or anxious or awkward when taking the surveys and/or during program sessions especially when discussing hard topics like depression. We talk about these things to help teens feel better.

- You may find the information and skills presented in this program to be helpful or useful in your life personally, but you may also not benefit.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this whole form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THE STUDY

Native American 2SLGBTQ+ teens have many strengths and some challenges. We want to develop a program for Native American 2SLGBTQ+ teens and their caregivers that helps (1) caregivers support their Native American 2SLGBTQ+ teens and (2) help teens feel connected to their caregivers and other Native American 2SLGBTQ+ teens. Your voice is important in helping us with this program.

3. WHO CAN PARTICIPATE IN THE STUDY

Native American teens who are between the ages of 13 and 18, identify as 2SLGBTQ+, and who speak English can take part in this study. Your caregiver must participate with you.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

We are asking you to do two things in this project: (1) Take surveys (2) Be part of a program that will meet in person for 8 meetings (2 hours each meeting). You may also be asked to complete an interview after the study is over if you attend most of the sessions.

If you agree to be in this project, we will ask you to take a survey twice – once before the program and once after the program. Each time you take the survey, it will take about 45 minutes. You can take the survey at our office or at another location that you and/or your caregiver pick that is safe and private. The surveys will ask demographic questions about you and how you feel about yourself. Some questions will ask about strengths (e.g., your connection to Lakota culture, ability to cope with stress, connection to community and family). We will ask about your mental health (e.g., anxiety, depression, thoughts of self-harm), alcohol and drug use, sexual activity, and relationships, including unwanted sexual experiences. You will have the option to do the survey online or using paper and pencil.

The program will have eight in-person sessions, with one session per week, held at the same time every week. Each of the eight sessions will be up to two hours long (16 hours in total). The sessions will be led by two trained adults who are either Native American 2SLGBTQ+ and/or are parents/caregivers of Native American 2SLGBTQ+ people.

The program sessions are meant to be educational, interactive, and informative. You will get to meet other Native American 2SLGBTQ+ teens and their caregivers, learn more about your 2SLGBTQ+ identity, watch educational videos, and learn skills to help you have a healthy and happy future. A variety of topics will be covered, such as family accepting behaviors, positive identity development, healthy communication skills, advocacy, and guest elder storytelling about Two Spirit peoples in Native American history. Every program session will begin with a prayer, meal, and smudging.

Also, during the program, there will be other adults there watching the program. These adults are not there to watch you or your caregiver. They are there to make sure the people teaching the program are doing a good job teaching the program. They will not write down your name or your caregivers' name when they take notes. The people watching the program will not share what you or other people say during the program with a few exceptions (see section 5.1).

After each of the eight sessions, you will be asked to take a short survey that will take about 5 to 10 minutes. This short survey will ask you to tell us what you liked and what you did not like about the session. You will do this survey on paper/pencil.

In addition to the surveys and the program, you may be asked to do a 45-minute interview after the program and final survey (if you attend at least 5 of the 8 sessions). This will help us learn more about what you thought about the program. The interview will take place in our project office and will be audio recorded. Audio recordings will be destroyed after the interviews are transcribed with information that identifies you removed. This will take place within 1 month or less of the interview. All these materials will be stored in a University of Michigan secure Dropbox. If you are selected for an interview, we will tell you more about the interview at that time. Like everything else in this project, the interview is voluntary. You do not have to do it.

As a participant in this research study, you have certain responsibilities such as (1) coming to the sessions as scheduled, (2) completing the surveys as requested, and (3) letting us (the research team) know right away if anything negative happens because of being in this research project. Negative things include being upset by anything that happens in this project and/or feeling worse because you are in this research study, someone finding out you are in this research study and hurting you, etc. We want to know right away if anything like this happens.

If your contact information changes or one of the ways you said was OK to contact you is no longer safe, please reach out to us and we will make sure to update our information so that we only contact you in a way that is OK for you and safe. It is important that we are able to contact you to remind you of program sessions and surveys. We will never contact you about the study at an email or phone number that you request that we do not use. We may also check in with you a few times during the study to see how you are doing, especially if you miss a session or tell us something concerning your safety.

4.2 What will happen if you decide not to be in this research study or decide to stop participating once you start?

Participation is voluntary. You have the right to quit the study at any time or to not answer any question(s) that you do not want to answer. You are still eligible to receive a cash even if you refuse/skip questions on any of the surveys. Deciding to participate, not to participate, or deciding to withdraw from this research project will not affect you or your relationship with the investigator or with the University of Michigan. If you are under age 18, even though your caregiver/guardian said you can participate, you can still choose not to participate.

4.3 How much of my time will be needed to take part in this study?

You will be asked to attend eight two-hour sessions (16 hours in total) over the course of eight weeks. After each of the eight sessions, you will be asked to take a short survey that will take about 5 to 10 minutes (up to 80 minutes in total). You will also be asked to take two longer online surveys before and after the program. Each time you take these surveys, it will take about 45 minutes. In addition to the surveys and the program, we may ask you to do a 45-minute interview after the program and final survey (if you attend at least 5 of the 8 sessions). In total, your participation will take about 19 hours of your time spread out over about 8 to 10 weeks.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

It is possible that you may feel upset, embarrassed, or awkward while completing the surveys or during program sessions. The survey asks about sensitive topics, such as thoughts of self-harm, and are reviewed in more detail in Section 4.1. You do not have to answer any questions you do not want to answer. Most people are not upset by completing these types of survey questions and people who do get upset tell us that the feelings are mild and go away quickly. Remember: your participation is voluntary. We will give you a list of resources every time you participate in this study, and you can reach out if you need help with anything. You can also always reach out to us at any time if you or someone else you know needs help to be safe.

During the program, we cannot guarantee complete confidentiality because program sessions will be completed as a group. As a group, we will have an agreement to honor one another by keeping what is said in the group discussions private. But we cannot promise that other people in the group will not share what you and other people say. At each session, we will emphasize that only program participants can attend. We will remind everyone at the beginning of every session that what other teens and caregivers share is confidential and is not to be shared with others outside of the group.

There are certain instances in which we may need to share information that you tell us, If you tell us face to face that (1) a child is being hurt or abused, (2) that you plan to hurt yourself or someone else, and/or (3) someone else, like an elder, is being hurt or abused, we will have to share this information with someone to make sure that you and other people are safe. We may also need to have a mental health care provider on our team follow up with you if we have concerns about your safety.

Additionally, you should also know that if a parent or another individual in your life (who is NOT participating in this program) contacts us about the project, we will provide them with general information about the project (that it is focused on teaching teens life skills and about healthy choices) and why it is important. We will not provide them with any information about you, including whether you or your caregiver are participating in the study.

Further, this study involves the collection of private information (name, dates, etc.) so that we can link survey data across time, send you reminders about upcoming program sessions and surveys, and give you cash. Information collected as part of research will only be used by the research team and will not be given to other people outside of this research team. Because this study collects information about you, there is a little chance other people may need to see your data. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 How could I benefit if I take part in this study?

You may find the information and skills presented in this program to be helpful or useful in your life personally (for example, it might make you have a better relationship with your caregiver, you may feel more hopeful about the future, etc.), but you may also not benefit.

How could others benefit?

We will ask you questions about what you like about the program and surveys and how to make these things better for other 2SLGBTQ+ teens. We will review all the feedback you give us to make the program better before we offer it to 2SLGBTQ+ teens and their caregivers all over the United States. Your voice is important to us and will make a difference in helping to increase family support for 2SLGBTQ+ teens!

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study any time. You may be asked to leave the study if you become disruptive, are unable to complete the requested tasks, or have a strong emotional response to the material. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the people listed in Section 9. "Contact Information". If you choose to tell the us why you are leaving the study, your reasons may be kept as part of the study record. The

researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

You should also know that participants who do not adhere to the group agreements (for example, being respectful, keeping what others say private) outlined at the beginning of each session, or those who tell us or show signs that the study is causing them distress, may be asked to leave the program.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

We will give you \$20 cash for the first survey, and \$30 cash for the survey you will complete in about two months from today. You will also get \$20 cash for each short survey you take at the end of each session. You will not be eligible to complete surveys about any sessions you do not attend or sessions that you leave early. Finally, you will receive \$25 cash for doing a 1-1 interview after the program sessions end, if you are asked to do an interview.

In total, you can earn up to \$235 in cash for being in this study. Even if you skip survey or interview questions you will still get the cash. However, you have to get to the end of the survey and interview to get the cash. You will also still get the cash if you do not want to talk in the sessions, but you need to stay for the entire session and do the brief survey (you can skip questions) after the session to get the cash. You do not have to receive cash if you do not want to do so. You will also get a certificate for completing the program.

If you receive any payments for taking part in this study, the University of Michigan will need your name and address for tax reporting. The University of Michigan finance department will also require your Social Security Number for tax reporting purposes if during 1 calendar year: 1) your payments total greater than \$400 for this study or 2) if you receive payments of greater than \$400 for being in more than one study. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

Your research data will be kept in a secure Drop Box folder that only the members of the research team will have access to. This is a folder that is very secure and private.

8.1.1 Special Protections

This research holds a Certificate of Confidentiality. This means no one can make us give your information to anyone else, even in a court or with police, unless we have your permission. But, if we learn anything that means you or someone else might get hurt, we will tell someone who can help.

Otherwise, if we share any of your information, it would only be with other researchers or in reports, but no one could figure out who you are.

8.2 Who will have access to my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The Oglala Sioux Tribe Research Review board (OST RRB) may require the study team to submit information as part of its duty to monitor the research project. The OST RRB is an independent group that reviews research conducted on the Pine Ridge Indian Reservation and/or involving tribal members. Their job is to make sure that potential harms for the participants, families, and the community are reduced and potential benefits for the participants, families, and the community are increased.
- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others.

8.3 What will happen to the information collected in this study?

We will keep the research information that you give us to analyze and publish, so others know about this important program. We will keep this assent form for study record keeping. During the duration of the project, your name and other information that can directly identify you will be stored securely and separately from the other research information. After the final surveys are completed for all participants, we will destroy the list that connects your Participant Number from your name and delete any other information that could identify you from our records.

The results of this study could be published in an article or presentation but will not include any information that would let others know who you are. The OST RRB must approve anything we share publicly.

8.4 Will my information be used for future research or shared with others?

No. The OST RRB owns the data meaning that the researchers at the University of Michigan are not allowed to share your data with anyone other than the OST RRB once the study ends. When the OST RRB gets the data, it will not have any names or other identifying information on it.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctor(s))
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Katie Edwards

Email: LakotaFAP@umich.edu

Phone: 605-381-2568

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

**University of Michigan – Health Sciences and Behavioral Sciences
Institutional Review Board (IRB-HSBS)**

2800 Plymouth Road

Building 520, Room 2144

Ann Arbor, MI 48109-2800

Telephone: 734-936-0933 or toll free (866) 936-0933

Fax: 734-936-1852

E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

Great Plains Area: IRB00000635

Dewey Ertz, EdD, Chair, Great Plains Area IRB

Marsha Stevens, Great Plains Area IRB Coordinator

Indian Health Service

Federal Building, Room 309

115 – 4th Ave. SE

Aberdeen, SD, 57401

Phone: (605) 226-7493

Fax: (605) 226-7214

Toll Free: (866) 331-5794

Oglala Sioux Tribe Research Review Board: IRB308

Phone: 605-867-1704

Email: ost.rrb16@gmail.com

10. YOUR ASSENT/CONSENT

Assent/Consent to Participate in the Research Study

By signing this document, you agree to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Your Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Adult_Program Only Self_Consent Form



UNIVERSITY OF MICHIGAN CONSENT TO ATTEND PROGRAMING AS PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Development and Evaluation of an Indigenized Family Acceptance Project for Lakota 2SLGBTQ+ Teens (PHASE II: OPEN PILOT TRIAL)

Principal Investigator: Dr. Katie Edwards, University of Michigan

Study Sponsor: National Institute of Mental Health

University of Michigan IRB Number: HUM00264029

PARENT/GUARDIAN PROGRAM ONLY SELF-CONSENT FORM

Thank you for your interest in attending the group sessions of Tiwahe Tewichaglapí – The Family Acceptance Project. This form contains information that will help you decide whether to attend the programming sessions. You will not be involved in the research component of this project (e.g., completing surveys, interviews). You are invited to attend as an additional caregiver to the teen participating in this project. You will be able to fully participate in the program - we just will not ask you to do any other research activities and you will not be paid for attending the program.

Before making your decision, please carefully read this form or have it read to you and ask questions about anything that is not clear. You can contact us to ask questions by phone call/text at 605-381-2568 or email us at LakotaFAP@umich.edu.

1.1 Key Information

Things you should know:

- The purpose of the study is to develop a program for Native American 2SLGBTQ+ (e.g., Two-Spirit, Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, or other diverse sexual and gender identities) teens and their caregivers that helps (1) caregivers support their Native American 2SLGBTQ+ teens and (2) help teens feel connected to their caregivers and other Native American 2SLGBTQ+ teens.
- If you choose to participate, you will be asked to attend group sessions.

- Risks or discomforts from this research include negative emotional reactions to program or a breach of confidentiality.
- You may find the information and skills presented in this program to be helpful or useful in your life personally, but you may also not benefit.

Attending the group sessions of this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

Native American (e.g., Lakota) 2SLGBTQ+teens have many strengths and some challenges. We want to develop a program for Native American2SLGBTQ+ teens and their caregivers that helps (1) caregivers support their Native American2SLGBTQ+ teens and (2) help teens feel connected to their caregivers and other Native American2SLGBTQ+ teens. Your voice is important in helping us make this program.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

Caregivers and relatives of +2SLGBTQ Native American teens between the ages of 13-18 are eligible to attend the group sessions of this project. You must also be a legal adult (18 or 19 depending on state laws) to attend.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

We are asking you to attend an in-person program will have eight sessions, with one session per week, held at the same time every week. Each of the eight sessions will be up to two hours long (16 hours in total). The sessions will be led by trained adults who are either 2SLGBTQ+ and/or are parents/caregivers of 2SLGBTQ+ people.

The program sessions are meant to be educational, interactive, and informative! You will get to meet caregivers of 2SLGBTQ+ teens and complete activities like watching videos, having discussions with other caregivers and teens, giving and receiving support, and learning skills to help the teen who is in the project with you have a healthy and happy future. A variety of topics will be covered, such as family accepting behaviors, positive identity development, healthy communication skills, advocacy, and guest elder storytelling about Two Spirit in Native American history. Every program session will begin with a prayer, meal, and smudging.

Also, we will be audio recording the program sessions. This will be done to make sure the people teaching the program are doing a good job. After the session is over, the tape recording will be put in a secure place so it won't be available to anyone except a small number of our research staff. One of our research staff will listen to the tape

recording, to make sure that the facilitators did a good job. They will not write down your name or your caregivers' name when they take notes on the session and they will not share what you or other people say during the program with a few exceptions (see section 5.1). After the tape recording has been listened to, it will be erased.

After each of the eight sessions, you will be asked to take a short survey that will take about 5 to 10 minutes. This short survey will ask you to tell us what you liked and what you did not like about the session. You will do this survey on paper/pencil.

Remember that your attendance is voluntary. After each of the program sessions, we will make sure that you know of safe places and people you can contact if you need help for yourself or someone else. You can always reach out to us at any time if you or someone else you know needs help to be safe.

As a participant in this research study, you have certain responsibilities such as (1) coming to the sessions as scheduled, and (2) letting us (the research team) know right away if anything negative happens because of being in this research project. Negative things include being upset by anything that happens in this project and/or feeling worse because you are in this research study, someone finding out you are in this research study and hurting you, etc. We want to know right away if anything like this happens.

4.2 What will happen if you decide not to be in this research study or decide to stop participating once you start?

Participation is voluntary. You have the right to quit the study at any time. Deciding to participate, not to participate, or deciding to withdraw from this research project will not affect you or your relationship with the investigator or with the University of Michigan.

4.3 How much of my time will be needed to take part in this study?

You will be asked to attend eight two-hour sessions over the course of eight weeks. In total, your participation will take about 16 hours of your time.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

It is possible that you may feel upset, embarrassed, or awkward while attending programming sessions. Also, remember that your attendance is voluntary. We will provide you with a list of resources after every session that you can reach out to if you're feeling upset. You can also always reach out to us at any time if you or someone else you know needs help to be safe.

During the program, we cannot guarantee complete confidentiality because program sessions will be completed as a group. As a group, we will have an agreement to honor

one another by keeping what is said in the group discussions private. But we cannot promise that other people in the group will not share what you and other people say. At each session, we will emphasize that only program participants can attend. We will remind everyone at the beginning of every session that what other caregivers and teens share is confidential and is not to be shared with others outside of the group.

There are certain instances in which we may need to share information that you tell us, If you tell us that (1) a child is being hurt or abused, (2) that you plan to hurt yourself or someone else, and/or (3) someone else, like an elder, is being hurt or abused, we will have to share this information with someone to make sure that you and other people are safe. We may also need to have a mental health care provider on our team follow up with your teen and you if we have concerns about your teen's safety.

5.2 How could I benefit if I take part in this study?

You may find the information and skills presented in this program to be helpful or useful in your life personally (for example, it might make you have a better relationship with the teen who is in this program with you, you may feel more hopeful about the future, etc.), but you may also not benefit.

How could others benefit?

What we learn from this project will help us to make the program even better and then we can give it to more Native American 2SLGBTQ+ teens and their caregivers all over the United States. This may help Native American 2SLGBTQ+ teens have happy and healthy lives.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the people listed in Section 9. "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis, it will not be possible to remove your information.

You should also know that participants who do not adhere to the group agreements (for example, being respectful, allowing others to speak) outlined at the beginning of each session, or those who tell us or show signs that the study is causing them distress, may be removed from the program.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

Yes, you will get \$20 cash for each short survey you take at the end of each program session. By signing this form, you are volunteering to attend the family group sessions with your family.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

As a family member who is important in the life of the teen participating, you are invited to participate in the program, but we will not collect research data from you except for the short survey you take at the end of each program session.

8.1.1 Special Protections

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document.
- We may share information with appropriate authorities if we think you may harm yourself or others.
- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at <https://grants.nih.gov/policy/humansubjects/coc.htm>

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Katie Edwards

Email: LakotaFAP@umich.edu

Phone: 605-381-2568

Oglala Sioux Tribe Research Review Board: IRB308

Email: ost.rrb16@gmail.com

Phone: 605-867-1704

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-
HSBS)
2800 Plymouth Road
Building 520, Room 2144
Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

Great Plains Area: IRB00000635

Dewey Ertz, EdD, Chair, Great Plains Area IRB
Marsha Stevens, Great Plains Area IRB Coordinator
Indian Health Service
Federal Building, Room 309
115 – 4th Ave. SE
Aberdeen, SD, 57401
Phone: (605) 226-7493
Fax: (605) 226-7214
Toll Free: (866) 331-5794

Oglala Sioux Tribe Research Review Board

Phone: 605-867-1704

Email: ost.rrb16@gmail.com

10. YOUR CONSENT

Consent to Participate in the Research Study

By signing this document, you agree to attend group sessions with your family who are research participants in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about, and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Guardian_Consent for Teen



UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Development and Evaluation of an Indigenized Family Acceptance Project for Lakota 2SLGBTQ+ Youth (PHASE II: OPEN PILOT TRIAL)

Principal Investigator: Dr. Katie Edwards, University of Michigan

Study Sponsor: National Institute of Mental Health

University of Michigan IRB Number: HUM00264029

GUARDIAN CONSENT FOR TEEN FORM

Thank you for your interest in Tiwahe Tewichaglapí – The Family Acceptance Project. This form tells you more about the project so that you can decide if you want your teen to participate in this project. **YOU MUST BE THE LEGAL GUARDIAN TO SIGN THIS FORM.**

Before making your decision, please carefully read this form or have it read to you and ask questions about anything that is not clear. You can contact us to ask questions by phone call/text at 605-381-2568 or email us at LakotaFAP@umich.edu.

1.1 Key Information

Things you should know:

- The purpose of the study is to develop a program for Native American (e.g., Lakota) 2SLGBTQ+ teens and their caregivers that helps (1) caregivers support their Native American 2SLGBTQ+ youth and (2) help Native American youth feel connected to their caregivers and other Native American 2SLGBTQ+ youth.
- If your teen chooses to participate, they will be asked to participate in the program, take surveys, and may be asked to do a 1-1 interview. This will all take approximately 19 hours.
- Risks or discomforts from this research include negative emotional reactions to program and survey content or a breach of confidentiality.

- You may find the information and skills presented in this program to be helpful or useful in your life personally, but you may also not benefit.

Taking part in this research project is voluntary. Your teen does not have to participate and can stop at any time. Please take time to read this entire form and ask questions before deciding whether to allow your teen to take part in this research project.

2. PURPOSE OF THIS STUDY

Native American 2SLGBTQ+ youth have many strengths and some challenges. We want to develop a program for Native American 2SLGBTQ+ youth and their caregivers that helps (1) caregivers support their Native American 2SLGBTQ+ youth and (2) help youth feel connected to their caregivers and other Native American 2SLGBTQ+ youth. Your teen's voice is important in helping us make this program.

3. WHO CAN PARTICIPATE IN THE STUDY

Native American 2SLGBTQ+ teens between the ages of 13-18 are eligible to take part in this study. Also, caregivers who read and speak English are eligible to participate in this study with their teen. Caregivers must also be legal adults (18 or 19 depending on state laws) to participate. Native American 2SLGBTQ+ teens cannot participate unless a caregiver also participates with them. Caregivers can be parents, grandparents, or anyone who signs the teens school papers.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to my teen in this study?

We are asking your teen to do two things in this project: (1) Take surveys (2) Be part of a program with their caregiver that will meet eight times in person. Your teen may also be asked to complete an interview after the study is over if they attend most of the sessions.

If your teen joins this project, we will ask them to take a survey at two different time points (before and after the program). Each time they take the survey, it will be about 45 minutes. They will take the survey at our office or at another location that you and/or the teen picks that is safe and private. The surveys will ask demographic questions about your teen and how your teen feels about themselves. Some questions will ask about strengths (e.g., connection to culture, resilience, connection to community). We will ask about their mental health (e.g., anxiety, depression, thoughts of self-harm), alcohol and drug use, sexual activity, and relationships, including unwanted sexual experiences. Teens will have the option to do the survey online or on paper and pencil.

The program will have eight in-person sessions, with one session per week, held at the same time every week. Each of the eight sessions will be up to two hours long (16 hours in total). The sessions will be led by two trained adults who are either Native

American 2SLGBTQ+ and/or are parents/caregivers of Native American 2SLGBTQ+ people.

The program sessions are meant to be educational, interactive, and informative. Your teen will get to meet other Native American 2SLGBTQ+ youth and their caregivers, learn more about your 2SLGBTQ+ identity, watch educational videos, and learn skills to help your teen have a healthy and happy future. A variety of topics will be covered, such as family accepting behaviors, positive identity development, healthy communication skills, advocacy, and guest elder storytelling about Two Spirit in Native American history. Every program session will begin with a prayer, meal, and smudging.

Also, during the program, there will be other adults there watching the program. These adults are not there to watch your teen or the caregiver participating with them. They are there to make sure the people teaching the program are doing a good job teaching the program. They will not write down your teen's name when they take notes. The people watching the program will not share what you or other people say during the program with a few exceptions (see section 5.1).

Sometimes youth report being sad or anxious or awkward when being asked on surveys about their feelings and experiences. Your teen can skip any questions on the surveys that they do not want to answer. Also, in the program we will talk about things like being 2SLGBTQ+ and challenges that your teen might face. This could make your teen feel sad or anxious although most youth feel like these are important topics to discuss that help them feel better. Remember that participation is voluntary.

After each of the eight sessions, your teen will be asked to take a short survey that will take about 5 to 10 minutes. This short survey will ask your teen to tell us what they liked and what they did not like about the session. Your teen will do this survey on paper/pencil.

In addition to the surveys and the program, we may ask your teen to do a 45-minute interview after the program and final survey (if they attend at least 5 of the 8 sessions). This will help us learn more from your teen about what they thought about the program. The interview will take place in our project office. It will be audio recorded. Audio recordings will be destroyed after the interviews are transcribed with identifying information (like names, etc.) removed. This will usually take place within 1 month or less of the interview. All these materials will be stored in a University of Michigan secure Dropbox. If your teen is selected for an interview, we will tell you and your teen more about the interview at that time. Like everything else in this project, the interview is voluntary. Your teen does not have to do it.

As a participant in this research study, your teen will have certain responsibilities such as (1) coming to the sessions as scheduled, (2) completing the surveys as requested, and (3) letting us (the research team) know right away if anything negative happens because of being in this research project. Negative things include being upset by anything that happens in this project and/or feeling worse because they are in this

research study. Although unlikely, we want to know right away if anything like this happens.

Every time we interact with your teen, we will make sure that your teen knows of safe places and people they can contact if they need help for themselves or someone else. You and your teen can always reach out to us at any time if you or someone else you know needs help to be safe.

If at any point, your teen's contact information changes or one of the ways that was OK to contact your teen is no longer safe, please reach out to us and we will make sure to update our information so that we only contact your teen in a way that is OK and safe. It is important that we are able to contact your teen to remind them of program sessions and surveys. We may also check in with your teen a few times during the study to see how they are doing especially if they miss a session or tell us something that makes us concerned about their safety.

4.2 What will happen if you decide not to allow your teen to be in this research study or decide they need to stop participating once they start?

You can allow your teen to be in this research study or not; you can have your teen stop being in this research study ("withdraw") at any time by emailing or calling us. Deciding not to allow your teen to be in this research study or deciding to withdraw will not affect you or your teen's relationship with the investigator or with the University of Michigan.

4.3 How much of my teen's time will be needed to take part in this study?

Teens and their caregivers will be asked to attend eight two-hour sessions (16 hours in total) over the course of eight weeks. After each of these sessions, your teen will be asked to take a short survey that will take about 5 to 10 minutes (up to 80 minutes in total). Your teen will also be asked to take two longer online surveys before and after the program. Each time they take these surveys, it will take about 45 minutes. In addition to the surveys and the program, we may ask your teen to do a 45-minute interview after the program (if they attend at least 5 of the 8 sessions). In total, your teen's participation will take about 19 hours of time spread out over 8 to 10 weeks.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will my teen face by taking part in the study? What will the researchers do to protect my teen against these risks?

It is possible that your teen may feel upset, embarrassed, or awkward while completing the surveys or program sessions. The survey asks about sensitive topics, such as self-harm, and is reviewed in more detail above in Section 1.1. Your teen does not have to answer any questions they do not want to answer. In general, most people do not find completing these types of survey questions to be upsetting, and those that do generally report that being upset is mild and does not last long. Also, remember that your teen's

participation is voluntary. We will provide your teen with a list of resources after every session and each time they take a survey that they can reach out to if they're feeling upset. You can also always reach out to us at any time if you or someone else you know needs help to be safe.

During the program, we cannot guarantee complete confidentiality because program sessions will be completed as a group. As a group, we will have an agreement to honor one another by keeping what is said in the group discussions private. But we cannot promise that other people in the group will not share what your teen and other people say. At each session, we will emphasize that only program participants can attend. We will remind everyone at the beginning of every session that what other caregivers and teens share is confidential and is not to be shared with others outside of the group.

There are certain instances in which we may need to share information that your teen tells us. If your teen tell us face to face that (1) a child is being hurt or abused, (2) that they plan to hurt themselves or someone else, and/or (3) someone else, like an elder, is being hurt or abused, we will have to share this information with someone to make sure that your teen and other people are safe. We may also need to have a mental health care provider on our team follow up with your teen and you if we have concerns about your teen's safety.

Additionally, you should also know that if a parent or another individual in your teen's life (who is NOT participating in this program) contacts us about the project, we will provide them with general information about the project (that it is focused on teaching youth life skills and about healthy choices) and why it is important. We will not provide them with any information about your teen, including whether your teen is participating in the study.

This study involves the collection of private information (name, dates, etc.) so that we can link survey data across time, send your teen reminders about upcoming program sessions and surveys, and give them cash. Information collected as part of research will only be used by the research team and will not be used or distributed to other people outside of this research team for new research studies. Because this study collects information about your teen, one of the risks of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 How could my teen benefit if they take part in this study?

Your teen may find the information and skills presented in this program to be helpful and/or useful in their life personally (for example, it might make them have a better relationship with their caregiver, they may feel more hopeful about the future, etc.), but they may also not benefit.

How could others benefit?

We will ask your teen questions about what they liked about the program and surveys and how to make these things better for other Native American 2SLGBTQ+ youth. We will take into consideration all the feedback they give us to make the program better before we offer it to 2SLGBTQ+ teens youth and their caregivers all over the United States. Your teen's voice is so important to us and will make a difference in helping to increase family support for 2SLGBTQ+ youth!

6. ENDING THE STUDY

6.1 If my teen wants to stop participating in the study, what should they do?

Your teen is free to leave the study at any time. If they leave the study before it is finished, there will be no penalty. If your teen decides to leave the study before it is finished, we will ask them to please tell one of the people listed in Section 9. "Contact Information". If they choose to tell the researchers why they are leaving the study, their reasons may be kept as part of the study record. The researchers will keep the information collected about your teen for the research unless asked to delete it from our records. If the researchers have already used the information in a research analysis it will not be possible to remove your teen's information.

You should also know that participants who do not adhere to the group agreements (for example, being respectful, keeping what people say confidential) outlined at the beginning of each session, or those who tell us or show signs that the study is causing them distress, may be removed from the project.

7. FINANCIAL INFORMATION

7.1 Will my teen be paid or given anything for taking part in this study?

We will give your teen \$20 cash for the first survey, and \$30 cash for the survey they will complete in about two months from today. Your teen will also get \$20 cash for each short survey they take at the end of each program session. Your teen will not be eligible to complete surveys about any sessions they do not attend or sessions that they leave early. Finally, they will receive \$25 cash for doing a 1-1 interview after the program sessions end if they attend five of the eight sessions.

In total, your teen can earn up to \$235 in cash for being in this study. Even if your teen skips survey or interview questions, they will still get the cash. However, they must get to the end of the survey and interview to get the cash. They will also still get the cash if they do not want to talk in the sessions, but they need to stay for the entire session and do the brief survey (they can skip questions) after the session to get the cash. They do not have to receive cash if they do not want to do so. They will also get a certificate for completing the program.

If your teen receives any payments for taking part in this study, the University of Michigan finance department will need their name and address for tax reporting purposes. In a calendar year if: 1) their payments total greater than \$400 for this study or 2) if they receive payments of greater than \$400 for being in more than one study, the University of Michigan finance department will also require their Social Security Number for tax reporting purposes. If they do not wish to provide their Social Security Number, they may continue to participate in research studies, but they will not be able to receive payment for the remainder of the calendar year.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my teen's information?

Your teen's research data will be kept in a secure Drop Box folder that only the members of the research team will have access to. This information will be stored electronically on the cloud; the term "cloud" refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards.

8.1.1 Special Protections

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify your teen in any action or lawsuit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document.
- We may share information with appropriate authorities if we think your teen may harm themselves or others.
- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about your teen to others when you and your teen say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.

- The Certificate of Confidentiality does not stop guardians or teens from personally releasing information about their involvement in this research if they wish.

More information about Certificates of Confidentiality and the protections they provide is available at <https://grants.nih.gov/policy/humansubjects/coc.htm>

8.2 Who will have access to my teen's research records?

There are reasons why information about your teen may be used or seen by the researchers or others during or after this study. Examples include:

- The Oglala Sioux Tribe Research Review board (OST RRB) may require the study team to submit information as part of its duty to monitor the research project. The OST RRB is an independent body that reviews research conducted within the exterior boundaries of the Pine Ridge Indian Reservation and/or involving tribal members or resources to minimize potential harms for the participants, families, and the community and to maximize potential benefits for the participants, families, and the community.
- University, government officials, study sponsors or funders, auditors, and/or the University of Michigan Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to your teen or others.

8.3 What will happen to the information collected in this study?

We will keep the information we collect about your teen during the research in order to present this information in academic papers or presentations. Any form that you sign will be kept for study recordkeeping. During the duration of the project, your teen's name and other information that can directly identify them will be stored securely and separately from the research information we collected from you. After the final surveys are completed for all participants, we will deidentify your teen's data and delete individual identifiers from our records.

The results of this study could be published in an article or presentation but will not include any information that would let others know who your teen is. The OST RRB must approve anything we share publicly.

8.4 Will my teen's information be used for future research or shared with others?

No. The OST RRB owns the data meaning that the researchers at the University of Michigan are not allowed to share your data with anyone other than the OST RRB once the study ends. When the OST RRB gets the data it will not have any names or other identifying information on it.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Katie Edwards

Email: LakotaFAP@umich.edu

Phone: 605-381-2568

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

**University of Michigan – Health Sciences and Behavioral Sciences
Institutional Review Board (IRB-HSBS)**

2800 Plymouth Road

Building 520, Room 2144

Ann Arbor, MI 48109-2800

Telephone: 734-936-0933 or toll free (866) 936-0933

Fax: 734-936-1852

E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

Great Plains Area: IRB00000635

Dewey Ertz, EdD, Chair, Great Plains Area IRB

Marsha Stevens, Great Plains Area IRB Coordinator

Indian Health Service

Federal Building, Room 309

115 – 4th Ave. SE

Aberdeen, SD, 57401

Phone: (605) 226-7493

Fax: (605) 226-7214

Toll Free: (866) 331-5794

Oglala Sioux Tribe Research Review Board: IRB308

Phone: 605-867-1704

Email: ost.rrb16@gmail.com

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

By signing this document, you are agreeing for your teen to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about, and my questions so far have been answered. I agree for my teen to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Please print the name(s) of the teen/teens you are giving permission to participate:

Will you be participating with your teen? (circle one)

YES NO

If NO, what caregiver do you give permission to participate with your teen? Please provide their first and last name and relationship to your teen.

What is the best way to reach them? Please provide as much information as you can so we can get in touch with them. You can also give them our contact information too (on p. 9).
