

ADULT INFORMED CONSENT

Principal Investigator:

Study Title:

IRB No.:

Sponsor/Supporter/Funded By:

PI Version Date:

Key Information about the Study

We are asking you to volunteer for a research study about challenges [Tribe] adults have faced in their childhood. We want to understand how these experiences affect people, how they deal with them and how community members care for themselves and others.

- You do not have to join the study. It is your choice and there is no penalty for not joining. Ask as many questions as you need to help you make your decision. Please review the details outlined in the rest of this document before deciding.
- We received your contact information from a member of our community advisory board. They thought you might have knowledge about this subject that would be valuable to share.
- If you join, we will ask you to participate in 1 or 2 interviews with research staff lasting no more than 2 hours each. These discussions will take place in a safe, private convenient location.
- Being in this study takes time. You will receive up to \$35 in gift cards for your participation.
- There are no direct benefits to participating in this study. We are hoping that information from this study will be able to help others in your community in the future.

Details about the Study

Why is this research being done?

This study is about challenges [Tribe] adults have faced in their childhood. We want to better understand these experiences so that we can design a program to help people who are struggling with the lasting effects of these experiences.

Who can join this study?

Adults (18-65yrs) who have had challenging experiences in their childhood and who are knowledgeable about the impacts of these types of experiences.

What will happen if you join this study?

If you agree to be in this study, we will ask you to do one or both of the following things:

- Participate in an interview to list challenging experiences that adults in the community commonly faced as children.
- If you are still interested, and we feel there is more we can learn from you about this topic, we may ask you to participate in a second interview about the impacts of these experiences, coping strategies and ways the community cares for individuals.

Audio Recordings:

As part of this research, we would like your permission to audio record our discussions to help us with our research. Recording our discussions with you will ensure that we do not miss or forget any of the valuable information that you share with us. During the interview we will be careful not to use any information that could identify you. We will not use recordings for advertising or non-study related purposes.

You should know that:

- We will only use these recordings for the purposes of this research.
- You may ask us to stop recording at any time.
- If you agree to allow the recording and then change your mind, just ask us to destroy that recording.
- Audio recordings need to be transcribed for analysis. We will use an outside company that has agreed to keep all data confidential.
- Audio recordings will be erased after all interviews and transcripts have been completed and verified for completeness.
- We will do our best not to identify you during the recording. If there is personal information recorded, the transcriptions of the audio recordings will be de-identified. This means that any information included in the transcript—your name, specific places, names of other people mentioned etc. will be removed from the transcript. Once this happens, no one will be able to tell that it was you talking.
- We may use quotations from the transcript when presenting or writing about this research. Your name or other information that could identify you will not be presented in or with the quote.
- Only members of this research team will have access to the recordings.

How long will you be in the study?

We anticipate your participation would last up to 4 hours. We will ask you to participate in up to two interviews, each lasting a maximum of 2 hours.

What happens to data that are collected in the study?

The data we collect from you will help us understand how to help adults who had difficult experiences in childhood. As a participant, you will not own your research data, and you will not benefit financially from any new product or idea that might arise from our work. Sharing of research data is often done to increase what researchers, service providers and policy makers can learn. Data will only be shared anonymously (that is, the data would not be linked to your name address or date of birth).

What are the risks or discomforts of the study?

Participation in any research study comes with risks. We anticipate only minimal risks associated with this study. Potential risks include:

- *Emotional Discomfort*—You may experience discomfort discussing problems faced by others in your community. However, questions will be asked about problems experienced by the community in general, and not about problems faced by you or your family. If you experience discomfort, you may take a break or end the interview. You do not have to answer any questions you do not want to answer. Research staff can refer you to counseling services available in the community if needed.

Personal Privacy

All discussions will take place in a private location where others cannot overhear what we are discussing. If you are uncomfortable with the location or worried others can hear what is being said, please let us know.

Identifiable private information

To keep your information private, we will assign you a study code number when you start the study. Any information we collect from you will only have this code number on it. If personal information is recorded during the interview, we will remove it from the transcript. Once this happens, no one will be able to tell that it was you talking.

How will the confidentiality of your data be protected?

We will keep a separate list that links your study code number to your name. This list will be private and all information about you will be stored in a locked file cabinet in the Johns Hopkins office. All electronic data will be stored on computers that are password protected. If in the future your tribe allows the study data to be accessed by the general public, there will be no way to link the data to your personal information.

You cannot be in the study unless you agree that we can use the information you provide to evaluate the study findings. No identifying information will be included with the data that is analyzed. There will be no way to identify you in any publications or study results.

What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. Disclosures that you make yourself are also not protected.

This study is protected by a Certificate of Confidentiality that helps keep your information private when stored in the U.S.

What are the potential benefits to being in the study?

There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

Will it cost you anything to be in this study?

No, it will not cost you anything to be in the study.

Will you be paid if you join this study?

Yes, you will be paid if you join this study. We appreciate you giving us your time to be part of this study. To show our appreciation, we will give you a \$10 gift card for participating in an interview where we ask you to list challenging experiences that adults in the community commonly faced as children.

We will give you a \$25 gift card if you participate in discussion about the impacts of these experiences, coping strategies and ways the community cares for individuals.

Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care, your employment/education.

What other things should you know about this research study?

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people including scientists and community people, that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at:

- **[IRB Contact Information]**

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

- Call the principal investigator, [Name] at [Contact Number]
- If you wish, you may contact the principal investigator by letter:
[Mailing Address]
- If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at [Contact Number].

Documenting Participant Choices

Audio Recordings

You may agree to or decline our request to make and use the recording described above. Please indicate your decision below by checking the appropriate box.

Yes ☐ No ☐

What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
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Signature of Person Obtaining Consent	(Print Name)	Date/Time
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NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO [Fax #]; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).