APPENDIX A.1:

Initial GenIC Request

Proof of Concept Parental Consent and Youth Assent Forms

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Voluntary Parent/Guardian Consent for Youth to Participate in the [STUDY NAME]

Study description and purpose

As part of your child’s participation in the Summer Youth Employment Program, they have the opportunity to participate in a study to understand if the Native Students Together Against Negative Decisions (NativeSTAND) curriculum, which is designed to help youth make positive decisions that will impact their health and wellness in a positive way, is effective in improving youth outcomes. NativeSTAND provides a safe learning environment for youth to explore their goals, values, attitudes and beliefs around sexual health, as well as communication skills and adult learning skills. The study will enroll youth in the summer of 2025 and be implemented at Chapter Houses on Navajo Nation.

**This is a permission form with information to help you decide if you want your child to participate in the study.** Whether your answer is “yes” or “no,” your **child will receive a $10 gift card if you complete and return this form.**

Mathematica, an independent research firm, is conducting this study for the Administration for Children and Families (ACF). ACF is an agency in the federal government within the U.S. Department of Health and Human Services that supports the health and well-being of youth. ACF administers the Sexual Risk Avoidance Education grant program, which supports organizations in providing youth with programs such as NativeSTAND.

What will my child be asked to do as part of the study?

* ***Your child will have a 50/50 chance of receiving either the NativeSTAND program or Catch My Breath program.*** If you choose to allow your child to participate in the study, they will be randomly placed into a group that will receive either the NativeSTAND program, orthe Catch My Breath program. Both programs focus on healthy decision making for youth. Catch my Breath is an evidence based cigarette and vaping prevention program. ***Your child’s*** assignment to one of the programs will be done by the study team and is completely random –like flipping a coin. Your child will have an equal chance of being placed in either program. They will attend their assigned program, NativeSTAND or Catch My Breath, as part of their participation in the Summer Youth Employment Program. Your child’s participation in the study will not affect their participation in the Summer Youth Employment Program. Even if you do not allow your child to participate in the study, they can still participate in the summer youth employment program.
* ***Your child will be asked to complete three surveys over the next 6 months.*** One survey will be completed before they receive NativeSTAND or Catch My Breath begins and another will be completed immediately after it ends at the Summer Youth Employment Program. The final survey will be completed approximately 6 months after the Summer Youth Employment Program ends.The survey questions will be about friends, well-being, and relationships. The surveys also include questions about attitudes, intentions, knowledge about pregnancy and STDs/STIs, activities, including sexual activity, and drug and alcohol use. Each survey takes about 30 minutes to complete. Your child will receive $40 gift card for completing the final survey.

What are the risks and benefits to participating?

* **There are no known risks associated with this study.** Your child might feel uncomfortable answering some of the questions in the survey. However, your child does not need to answer any questions that make them uncomfortable.
* **Your child’s participation is entirely voluntary.** Even if you give permission for your child to participate, they can choose for themselves whether they want to participate or not. There are no consequences if your child decides not to participate in this research study or if they decide to discontinue participation at any point in the study. They can still participate in the Summer Youth Employment Program even if they are not participating in the study.

How will my child’s privacy be protected?

* For all data collection activities, the responses your child provides will be combined with the responses from other youth participating in the study.
* Your child’s name and responses will not be disclosed or used, in identifiable form.
* All information collected will be securely stored and will not be shared with anyone outside of the study team.
* We are required by law to report your child’s name to authorities if:
* We suspect child abuse or neglect.
* Your child says something that suggests they are likely to harm themselves, harm another person, or that someone is likely to harm them.

How will the information collected from the survey be used?

The study team will write a report for ACF that summarizes the findings from the data collection activities. The study team will publish the results of the study in a peer-reviewed publication and present them at scientific conferences. Your child’s name and responses to the survey will not be disclosed or used in identifiable form.

Who can I contact for more information?

**For additional answers to questions about the research and research participant’s rights, the contact person for the Navajo IRB Office and for Capacity Builders Inc. is below:**

Dr. Sonja Shin, MD, Board Chairperson Eudora Redhouse, Senior Project Director

Navajo Research Office Capacity Builders, Inc.

Navajo Department of Health 2200 Bloomfield Hwy

P.O. Box 1390 Window Rock, AZ 86515 Farmington, NM 87401

Phone: (928)871-6929 Phone: (505) 278-7789

 Email: e.redhouse@capacitybuilders.info

Agreement to participate

* If you agree, then your child will decide on their own whether to participate. They will be asked to sign their own agreement form.
* You must indicate you give permission for your child to participate by checking the box below and submitting this form.

**Please complete and sign the enclosed permission form and return it to [LOCATION/CONTACT PERSON]. Thank you!**

Parent or Guardian Permission Form

|  |
| --- |
| **We need your answer, whether it is yes or no.**Please fill out the form and have your child return it [FILL RETURN LOCATION]. |

|  |
| --- |
| In giving permission for my child to participate, I understand my child will be asked to complete three surveys over the next 6 months. By giving permission for my child to be in the study, I agree that this information can be collected, and that my child may receive an email or text message to the numbers provided to arrange for them to participate in the follow-up survey. I understand participation is voluntary, and my child can stop at any time with no consequences. I also understand that all information about my child will be kept private and used only for the purposes of the study. **I have read the information sheet describing the study. By signing this form, I am saying** (CHOOSE ONE):  **Yes, I permit my child**, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, to participate in the study **Child’s Date of Birth:** \_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_]  **No, I do not permit my child**, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, to participate in the study.  (Print child’s name) **Parent/Guardian Signature:** **Date:**  |

Youth Participation Agreement Form for [STUDY NAME]

Study description and purpose

We invite you to participate in a study as part of the Summer Youth Employment Program. Your parent or guardian has already provided permission for you to participate, but you can now decide for yourself. This study will help understand if the Native Students Together Against Negative Decisions (NativeSTAND) curriculum is effective in improving youth outcomes. NativeSTAND provides a safe learning environment for youth to explore their own goals, values, attitudes and beliefs around their sexual health, as well as communication and adult learning skills The study will enroll youth in summer of 2025 and 2026 and be implemented at Chapters Houses on Navajo Nation.

**This is a permission form with information to help you decide if you want to participate in the study.**

Mathematica, an independent research firm, is conducting this study for the Administration for Children and Families (ACF). ACF is an agency in the federal government within the U.S. Department of Health and Human Services that supports the health and well-being of youth and administers the SRAE grant program. The SRAE grant program supports organizations in providing youth with programs such as Native STAND or programs that promote healthy decision making.

What will I be asked to do as part of the study?

* ***You will have a 50/50 chance of receiving either the NativeSTAND program or Catch My Breath program.*** If you choose to participate in the study, you will be randomly placed into a group that will receive either the NativeSTAND program, or the Catch My Breath program. Both programs focus on healthy decision making for youth. Catch my Breath is an evidence-based cigarette and vaping prevention program. Your assignment to one of the programs will be done by the study team and is completely random –like flipping a coin. You will have an equal chance of being placed in either program. You will attend the assigned program, NativeSTAND or Catch My Breath, as part of your participation in the Summer Youth Employment Program. Your participation in the study will not affect your participation in the Summer Youth Employment Program. Even if you do not want to participate in the study, you can still participate in the summer youth employment program.
* ***You will be asked to complete three surveys over the next 6 months.*** One survey will be completed before the NativeSTAND or Catch My Breath program begins and another will be completed immediately after that program ends. The final survey will be completed approximately 6 months after the summer youth employment program ends. The survey questions will be about friends, well-being, and relationships. The surveys also include questions about attitudes, intentions, knowledge about pregnancy and STDs/STIs, activities, including sexual activity, and drug and alcohol use. Each survey takes about 30 minutes to complete.

What are the risks and benefits to participating?

* **There are no known risks associated with this study**. You might feel uncomfortable answering some of the questions on the survey. If that happens, you do not need to answer any questions that make you uncomfortable.
* If you choose to participate, you will receive a $40 gift card for completing the 6 month follow up survey.

Do I have to participate?

* No. You can choose to participate or not participate without any consequences. You can still participate in the Summer Youth Employment Program even if you do not agree to join the study. You can also stop participating in the study at any point.

How will my privacy be protected?

* **Nothing will be shared with your parents, teachers, or anyone outside of the study team.** **However, we are required by law to report your name to authorities if**:
* We suspect child abuse or neglect.
* You say something that suggests you are likely to harm yourself, harm another person, or that someone is likely to harm you.
* All information collected will be kept in a secure location for the study team to use, and we will destroy the information at the end of the project.

How will the information from the surveys be used?

The study team will write a report for ACF that summarizes the findings from the data collection activities. The study team will publish the results of the study in a peer-reviewed publication and present them at scientific conferences. Your child’s name and responses to the survey will not be disclosed or used, in identifiable form.

Who can provide more information about this study?

**For additional answers to questions about the research and research participant’s rights, the contact person for the Navajo IRB Office and for Capacity Builders Inc. is below:**

Dr. Sonja Shin, MD, Board Chairperson Eudora Redhouse, Senior Project Director

Navajo Research Office Capacity Builders, Inc.

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P.O. Box 1390 Window Rock, AZ 86515 Farmington, NM 87401

Phone: (928)871-6929 Phone: (505) 278-7789

Fax: (928)-871-6255 Email: e.redhouse@capacitybuilders.info

Agreement to participate

* By signing below, you agree to participate in the study.
* Your signature means that you have read and understood the information provided above.

I accept the terms described above and will voluntarily participate in the study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Print your name**

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**Your Signature Date**