



THE BAKER CENTER
FOR CHILDREN AND FAMILIES



HARVARD MEDICAL SCHOOL
AFFILIATE

INFORMED CONSENT FORM FOR PARENT/LEGAL GUARDIANS STUDY 1

Sponsor / Study Title: Judge Baker Children's Center / "Community-driven drug prevention implementation strategies for Native Hawaiian and Pacific Islander youth in rural Hawaii"

Protocol Number: IRD003

Principal Investigator: Kelsie Okamura, PhD

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1390 Miller St. Honolulu, HI 96813

If you are the parent or legal guardian of a child who may take part in this study, your permission and the permission of your child will be needed.

KEY INFORMATION

Your child is invited to take part in a research study. This research study is examining how a drug use prevention program, Ho'ouna Pono, may aid in preventing middle schoolers' drug use behaviors. To do this, the study will evaluate middle schoolers' drug use behaviors before and after participating in the program. The National Institutes of Health/National Institute on Drug Abuse (DP1 DA061311) is funding this program through their Racial Equity Visionary Award Program. The Baker Center for Children and Families, a Harvard affiliate, is sponsoring the study.

Why might you want your child to join? The program uses videos about relatable drug offers scenarios and activities designed specifically for middle school students. Students will learn practical skills to resist drug offers. Your child will complete surveys before and after program participation. These surveys will ask your child to answer personal questions about their drug use, drug offer contexts, and attitudes toward drug use. The program will be delivered during regular school hours at no cost to you. Your child's participation helps researchers find ways to improve drug prevention programs for all youth in the community.

Important things to know:

- This is completely voluntary, and your child can stop at any time
- Your child's grades and school standing will not be affected
- All information is kept private and secure
- Your child can skip any questions or activities that cause discomfort

BACKGROUND AND PURPOSE

Your child is being asked to participate in this research study because they are a middle school student in the Hawai'i State Department of Education Windward District. As such, they possess valuable information related to understanding students' drug use behaviors and offers within Windward District middle schools. The purpose of our research study is to assess and evaluate how the Ho'ouna Pono program may aid in preventing youths' drug use behaviors upon completion of the program. This information will be used to understand how different resistance skills may impact youths' drug use behaviors. There may be approximately 3000 participants enrolled in this research study.

WHAT WILL HAPPEN DURING THE STUDY?

Your child's participation in this study will last about three months and will include completing two surveys at the school.

Screening: All middle school students in your child's school will be eligible for this study.

Study Procedures: Your child will participate in a drug use prevention program called Ho'ouna Pono, where they will learn about resistance skills to drug offers. Your child will be participating in a 9 to 11 lesson program where they will learn resistance skills to drug offers through videos, discussions surrounding what to do in these scenarios, and interactive activities. Your child will participate in activities and discussions during each lesson, regardless of whether they participate in the research. If you and your child agree to participate in the research, before and after the program, your child will complete surveys that ask background, cultural values, drug behaviors, risk as well as protective factors to drug use, and resistance skills used when confronted with drug offers questions.

After Study Procedures: Your child will not be asked to do anything after the program. Results of the study will be shared through community presentations, conferences, and journal articles. When we report the results, we will ***not*** use your child's name or any other personal information that would identify your child. If you would like to receive a copy of any journal articles or presentations resulting from this study, please contact Dr. Kelsie Okamura by email.

EXPECTATIONS

If your child participates in this study, your child will be expected to:

- Complete two surveys before and after the program
- Learn about the different ways to say "no" to drug offers
- Participate in activities, discussions, and watch video-based drug offer scenarios

What information the research staff collects:

- Basic demographic information
- Drug use behaviors and resistance skills in the past 30 days
- Attitudes toward drug use

RISKS AND/OR DISCOMFORTS WITH STUDY PROCEDURES

There is a possibility your child may become uncomfortable when:

- Answering questions about drug use behavior

- Watching videos about drug offer scenarios
- Possible breach of confidentiality

If any discomforts occur, your child can skip the question, take a break, or stop the program at any point. Your child may also withdraw altogether from the study at any time.

UNFORESEEN RISKS

Since Ho'ouana Pono has already been conducted in Hawai'i Island, we do not anticipate any unknown risks in participating in the program or the surveys.

ALTERNATIVES TO PARTICIPATION:

This research study is for research purposes only. The only alternative is to not participate in this research study.

NEW FINDINGS

Any new and important information discovered during the study that may influence your child's willingness to continue participating will be provided to you.

BENEFITS

Your child may develop drug resistance skills through the Ho'ouana Pono program. However, there is no guarantee that your child will benefit from their participation in this study. The survey results will provide valuable insights to the research staff, teachers, school administration, and other researchers, helping them better understand youth drug use behaviors and improve programs aimed at preventing future substance use. This information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION

Your child will receive a \$5.00 gift card after each survey that they complete. Your child will receive \$10.00 total for participating in both surveys. If for any reason, your child does not complete the program, they will still be paid for the surveys completed. Your child will receive the gift card after completing the survey.

If you have any questions regarding your child's compensation for participation, please contact the study staff.

CONFIDENTIALITY

Records of your child's participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify your child by name. This means that absolute confidentiality cannot be guaranteed. Your child's survey results that are collected during the study will be kept at a secure location. If the results of this study are published, presented at conferences, or within the community, your child will not be identified.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research participants.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

COSTS

There will be no charge to you or your child for your child's participation in this study.

FUTURE RESEARCH STUDIES

Identifiers might be removed from your child's identifiable, private information collected during this study and **could then be used for future research studies or distributed to another investigator for future research studies** without additional informed consent.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if your child suffers a research-related injury or if you or your child have questions, concerns, or complaints about the study such as:

- Whom to contact in the case of a research-related injury;
- Payment or compensation for being in the study, if any;
- Your' child's responsibilities as a research participant;
- Your child's eligibility to participate in the study;

- The Investigator's or study site's decision to withdraw your child from participation;

Please contact the Investigator at the telephone number and email listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your child's rights as a research participant, contact:

- By **mail**:
Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00084099.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision for your child to participate in this study is voluntary. You may choose for your child to not participate or withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your child's academic records.

If you and your child would like to withdrawal from the study, please inform the school staff, research staff, and/or Investigator.

The Investigator can stop your child's participation at any time without your consent for the following reasons:

- If your child does not follow directions when participating in the study;
- If the study is canceled; or
- For administrative reasons.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I voluntarily agree for my child to participate in this study and to receive compensation until I decide otherwise. I do not give up any of my or my child's legal rights by signing this consent document. I will receive a copy of this signed consent document.

Child's Printed Name

Parent/Legal Guardian's Printed Name

Date

Parent/Legal Guardian's Signature

Date

Printed Name of the Person Conducting the
Consent Discussion

Signature of the Person Conducting the
Consent Discussion

Date