# Instructions for Investigators

**Reminder:** The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. The documentation of informed consent must comply with 45 CFR 46.117. These requirements are changed in the Final Revisions to the Common Rule, which are in effect as of January 19, 2018. These regulations are available at: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html>.

Use this type of CONSENT FORM for research projects that involve:

* Research participants who are MINORS (age 17 and under). Since minors typically may not provide informed consent for themselves, a parent/guardian needs to provide consent for the minor to participate. The researcher must get both the minor's assent (which is a separate document, not listed in this file), and the consent/permission of the minor's parent/guardian for the minor to participate.
* Interview, Survey or Observation in a setting where there is a reasonable expectation of privacy.
* Always have two copies of the consent form for each potential participant. One signed copy is kept by the PI or research team, and the other is to be given to the enrolled participant after written consent is given.

Highlighted sentences are mandatory for all consent forms.

Be sure to enter the version number of the consent form in the footer.

**Please remove the yellow highlights and *red notes* before finalizing and submitting your consent form.**

Aloha! My name is Kainoa Researcher. I am requesting your permission for your child to participate in my research project. I am a *(state whether student, faculty, etc)* at the University of Hawai’i at Mānoa (UHM), from the (*insert department affiliation*). *(If student, indicate that results will contribute to senior project, thesis or dissertation)*.

***What is my child being asked to agree to?***

If you agree for your child to be in the study, I will interview/survey/observe your child *(state how many interview/survey sessions are proposed)*. The interview/survey questions will ask *(briefly describe the type of questions)*.

***Your child taking part in this study is your choice.***

You can choose to allow your child to take part, or you can choose for your child to not take part in this study. *(If the minor subject is age 7 or older, an assent may also be required. If using an assent, state:* I also will ask your child to agree to participate in this project*)*. You, (or your child – *if using assent*) also can change your mind about participating at any time. If your child stops being in the study, there will be no penalty or loss to them or you.

***Why is this study being done?***

The purpose of my research project is to (*state what the study is designed to assess or establish*). I am asking your permission for your child to participate in this project because (*explain succinctly and simply why the prospective participant is eligible to participate*).

***What will happen if you decide your child can take part in this study?***

If you and your child agree for your child to be in the study, the interview/survey will be held (*describe where the interview will take place*). The interview/survey will take *(describe how long the interview will take. If multiple interviews, also include total time commitment*). Your child and I and (*describe other personnel or state:* no one else) will be present in the room during the interview/survey. If your child participates, he or she will be one of *(describe the number of participants)* that I will interview/survey separately. One example of the kind of question I will ask is, *(provide a sample question or two)*. If you would like to see a copy of all of the questions that I will ask, please contact me via the phone number or email address listed near the end of this consent form.

(*If the interview will be recorded state*: With your and your child's permission, I will record the interview using an audio-recorder). (*If transcribing state*: I am recording the interview so I can later type a written record of what we talked about during the interview. I will evaluate the information from the interview.

***What are the risks and benefits of taking part in this study?***

*(Describe any reasonably foreseeable risks, discomforts, inconveniences, and how these will be managed. If there are significant psychological risks to participation that might cause the researcher to terminate the study, please describe them and the possibility that the researcher may terminate the study without prior notice to participants. If potential risk is minimal, such as minor discomfort, it is appropriate to state this. ie: “*I believe there is little or no risk to your child in participating in this project. There is a possibility your child may become uncomfortable or stressed by answering an interview/survey question or questions.”) If that happens, we will skip the question, take a break, or stop the interview/survey. Your child may also withdraw from the project altogether at any time.

*(Describe any expected benefits to participants from the research. In MOST interview/survey research, the participant will not benefit from participation. This should be clearly stated. ie: “*There will be no direct benefit to you or your child for participating in this project*.”* The results of this project might help me, other teachers, and researchers *(describe more general benefits the research may generate)*.

***In-Person Research Risk:***

For the safety and protection of your child, you, the research team and others, we strongly recommend that your child wear a well-fitting mask that covers nose and mouth [(CDC guidance)](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html) during each research-related encounter to reduce the spread of common respiratory diseases such as the Rhinovirus (common cold), the Influenza (Flu), Respiratory Syncytial Virus (RSV), and Coronavirus Disease of 2019 (COVID-19). Members of the research team will wear a well-fitting mask that covers nose and mouth at all times.

***Results of Research:***

*(Indicate if any test results (i.e. clinically relevant research results) will be disclosed to participants and if so, under what conditions).*

***Privacy and Confidentiality:***

Any information that is obtained in connection with this study and that can be identified with your child will remain confidential and will be disclosed only with your permission. (*Describe procedures to safeguard data. ie*: “All study data will be secured in encrypted files on a password protected computer.”) (*Describe who will have access to identifiable records. ie*: “My University of Hawai'i advisor and I will have access to the information.)

Other agencies that have legal permission have the right to review research records. The University of Hawai‘i Human Studies Program has the right to review research records for this study.

***Future Research Studies:*** (*Insert this language as appropriate*)

After I write down the interviews, I will destroy the audio-recordings. Identifiers will be removed from the research records. When I report the results of my research project in my typed paper, I will not use your child's name or any other personal information that would identify your child. Instead, I will use a pseudonym (fake name) for your child. If you would like a copy of my final report, please contact me at the number listed near the end of this consent form.

After removal of identifiers, the research records may be used for future research studies or distributed to another investigator for future research. We will not seek further approval from you or your child for these future studies.

(*If planning to archive identifiable records for future research* *also refer to* [*Model Consent form guide 468*](https://drive.google.com/file/d/0B45cs2lc9u-vZjd2WXhhbVU4Z0U/view) *for additional checkboxes that must be inserted in the Signature line section)*

***(OR)***

Even after removing identifiers, the data from this study will not be used or distributed for future research studies.

***Compensation:***

*(Describe any compensation for participation here, such as: “*You (*OR*) Your child will receive a $5 gift certificate to either Starbucks or Jamba Juice for your time and effort in participating in this research project*.”)*

***Questions:***

If you have any questions about this study, please call or email me at *[insert phone number & or email address – do not use personal numbers]*. *(If this is a student project, add:* You may also contact my advisor, *[insert name]*, at *[phone # & email address])*. You may contact the UH Human Studies Program at 808.956.5007 or uhirb@hawaii.edu to discuss problems, concerns and questions, obtain information, or offer input with an informed individual who is unaffiliated with the specific research protocol. Please visit <http://go.hawaii.edu/jRd> for more information on your rights as a research participant.

If you agree to your child’s participation in this project, please sign and date the following signature page and return it to: *(insert here)*

Keep a copy of the informed consent for your records and reference.

**Signature(s) for Consent**:

I give permission for my child to join the research project entitled, *(insert study title)* I understand that my child can change their mind about being in the study at any time. I understand that I may change my mind about my child being in the study at any time.

**Name of Child (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Parent/Guardian (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Parent/Guardian's Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Mahalo!