# 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 must 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.
* Curriculum or educational practice research. Research must take place in an educational setting.
* Always have two copies of the informed consent 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 (*insert PI name*) and I am requesting your permission for your child to participate in my research project. I am your child's 9th grade math teacher at Hoku High School. I am also a graduate student at the University of Hawai’i at Mānoa (UHM), in the (*insert department affiliation*). *(If student, indicate that results will contribute to senior project, thesis or dissertation. ie: “*One requirement for earning my Master's degree is to do a research project.”)

***What am I being asked to agree to?***

As part of my 9th grade math class, your child will be using a new curriculum to learn (*brief description*).If you agree for your child to be in the study, I will use your child’s test scores, homework and class assignments as part of my research records.

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

You can choose to allow your child to take part, or you can choose not to 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 at any time. If you stop being in the study, there will be no penalty or loss to you. I recognize that I am the researcher in this project and, at the same time, your child's teacher. I assure you that your child's participation or non-participation in my research project will not impact his or her grades, class standing, relationship with me, or relationship with Hoku High School.

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

The purpose of my research project is to (*briefly* *state what the study is designed to assess or establish. ie:* I want to assess how the New Math curriculum compares with the previous curriculum.) 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 I decide that my child can take part in this study?***

The new Math curriculum will be implemented in two Hoku High school 9th grade math classes starting in January of this year. This curriculum is an accepted and approved curriculum for 9th grade students. If you and your child agree for your child to be in this study, your child will not need to do anything differently. The curriculum will take about 4 weeks. Your child’s math class meets three times a week for 1 hour per class. The curriculum being studied will involve regular coursework, tests and quizzes. Your child will be one of about 60 student participants. Participation in my project means that I will have permission to use your child’s test scores, homework and class assignments as part of my research records. If you or your child decide not to participate, I will not use your child’s records for my research.

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

*(Describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed. The primary risk for this type of research is generally loss of privacy. ie: “*I believe there is little or no risk to your child in participating in this project. There may be some risk of loss of privacy due to participation in this project.”)

*(Describe any expected benefits to participants from the research. In MOST curriculum 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. If the research will take place in a classroom setting, mask wearing is only required for the research interaction.

***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.” **OR** “I will not record your child's name or any other personal information that would identify your child in my research records.)” (*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 completing the course/curriculum, I will remove all identifiers 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* [*Consent form template 468*](https://drive.google.com/file/d/0B45cs2lc9u-vZjd2WXhhbVU4Z0U/view) *future use of biospecimens 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 below signature page and return it to: *(insert here)*

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

**Signature(s) for Consent**:

☐ I give Permission for (*Insert PI name*) to use my child’s homework, test scores and grades as part of his research records.

I give permission for my child to join the research project entitled, *(study title)*. I understand that my child can change his or her 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!