# 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 ADULTS (age 18 and older)
* With the exception of clinical trials, use this template for Intervention studies, both medical and social & behavioral. **Intervention** includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes. Use model consent form 460 for clinical trials.

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 for review.**

Aloha! You are being asked to participate in a research study conducted by *(insert names and degrees of all investigators)* from the *(insert department affiliation)* at the University of Hawai‘i. *(If student, indicate that results will contribute to senior project, thesis or dissertation).*

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

If you participate in this project, you will be asked to *(provide a brief description of the intervention here).*

***Taking part in this study is your choice.***

Your participation in this project is completely voluntary. You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. If you stop being in the study, there will be no penalty or loss to you.

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

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

***What will happen if I decide to take part in this study?***

If you decide to participate in this study, you will be asked to do the following: *(If there is more than one step, describe each step and how much time each step will approximately take. For example, first, you will be asked to\_\_\_which will take about 10 minutes. Then, etc.... Your participation will take [45 minutes to an hour].* Only you and I will be present during the *[fill in here].* You will be oneof about *(#)* people in this study*.*

***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 physical or 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).*

*(Describe any expected benefits to participants from the research. If the participant will not benefit from participation, clearly state this fact.) For example:* There will be no direct benefit to you for participating in this project.The results of this project may help *(fill in here).*

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

For the safety and protection of yourself, the research team and others, we strongly recommend that you 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 you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of *(describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc.)*

*(Insert here whether any information will be released to any other party for any reason, state the person/agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure.)*

*(If participants are to be audio- or videotaped, describe who will have access, if they will be used for educational purposes, and when they will be erased).*

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. When I report the results of my research project, I will not use your name. I will not use any other personal identifying information that can identify you. I will use pseudonyms (fake names) and report my findings in a way that protects your privacy and confidentiality to the extent allowed by law.

***Future Research Studies:* *(Insert one of the following statements:)***

Identifiers will be removed from your data or identifiable biospecimens *(choose one)* and after removal of identifiers, the data or biospecimens *(choose one)* may be used for future research studies or distributed to another investigator for future research studies and we will not seek further approval from you for these future studies. *(If using this statement, also refer to* [*Consent form template 468 for future use of specimens*](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 or biospecimens collected for this study *(choose one)* will not be used or distributed for future research studies.

***Whole Genome Sequencing:*** ***(For research involving biospecimens - Delete this section if not relevant)***

All your genetic information makes up your genome. Genomic sequencing is a test that records all or part of the pieces of DNA that are in your genes, piece by piece. This is usually done to look for changes in your genome that may cause health problems. Future research studies may use all or part of your DNA. For future research studies using your DNA, you will not get reports or other information about any research that is done using your samples.

***Compensation:***

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

The research may lead to new tests, drugs, or other products for sale. If this research does, you will not get any payment.

***Questions:*** If you have any questions about this study, please call or email me at *[insert phone number & 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 participate 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 to join the research project entitled, *(insert title here)*

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

**Participant’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of the Person Obtaining Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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

Mahalo!