

**SAMPLE INFORMED CONSENT FORM**  
For Biomedical Intervention or Clinical Trial

**The University of Hawaii does not have a standard template for consent documents. Informed consent documents should be tailored by the investigator to the subject population of the individual research project. This sample form is intended to provide investigators with guidelines for the language and formatting of a clinical trial consent form that the UH Institutional Review Board would find acceptable. Investigators are encouraged to adjust the text and heading titles to be more readable by their target audience.**

- Model text is in **bold**.
- Instructions are in *[italics]*.
- “ \_\_\_\_\_ ” Indicates that the investigator should fill in the appropriate information.
- Use at least a size 12 font in all parts of the text.
- All sections of the Informed Consent, except for the Statement of Consent, should be written in the 2<sup>nd</sup> or 3<sup>rd</sup> person voice. The Statement of Consent **may** be written in the 1<sup>st</sup> person voice.
- All sections outlined as headings (*the Roman numerals*) should appear in the consent. For studies with minimal risk to participants, some flexibility may be allowed. Investigators are encouraged to include other headings that are appropriate to their project.
- For protocols that include storage of specimens for future, as yet undefined research, a separate consent form specifically explaining this should be included as an addendum.
- UH is not currently a covered entity under HIPAA. However, if the research in question is being conducted at a covered entity, and will involve the use of protected information, the investigator may need to develop a HIPAA authorization form approved by that covered entity. Unless an authorization is included within the consent, the UH IRB does not review these forms.

## RESEARCH PARTICIPANT INFORMED CONSENT

I. **Investigator in Hawaii** (*Include name, address and phone number. Also list co-investigators if any*)

II. **Title of Study:** “\_\_\_\_\_”. (*Should be consistent with protocol*).

Sponsor (*If any*)

### III. Informed Consent

You are being asked to participate in a research study\_\_\_\_\_. This is a consent form. It is to provide you with information about this study. The research staff will talk with you about this information. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this clinical trial and you may discuss it with your regular doctor, friends and family before you make your decision. If there are any words or sections in this consent form that you do not understand, please ask the research staff to explain them. If you agree to take part in this study, you will be asked to sign this consent form.

It is important that you understand that taking part in this study is of your own free will. You may decide not to participate, or you may decide to stop being in the study at any time, and it will not affect your regular medical care now, or in the future.

### IV. Why is this Study Being Done

This Clinical Trial is being conducted to study \_\_\_\_\_ name of disease or what is being studied. You are being asked to take part in this study because you have (*list applicable eligibility requirements*). A total of \_\_\_\_\_ participants will participate in this study.

The purpose of this study is to \_\_\_\_\_ see below for text examples \_\_\_\_\_.

*Phase 1 studies: .....test the safety of name of drug/intervention and see what effects (good and bad) it has on you and your name of disease or what is being studied.*

or

**Find the highest dose of name of drug that can be given without causing severe side effects.**

*Phase 2 studies: .....find out what effects (good and bad) name of drug/intervention has on you and your name of disease or what is being studied.*

*Phase 3 studies: .....compare the effects (good and bad) of the new drug, intervention with name of commonly-used drug/intervention on you and your name of disease or what is being studied to see which is better.*

**This research is being done because ...** \_\_\_\_\_

*[Explain in one or two sentences. Examples are: "...currently, there is no effective treatment for this disease," or "...we do not know which of these two commonly-used treatments is better."]*

**V. Study Procedures**

*(Include a description of screening or pre-entry procedures)*

*(For randomized studies)*

**In this study, you will be "randomized" into one of [insert #] study groups described below. "Randomized" means that you are put into a group by chance, like flipping a coin. You will have an equal, one in three, etc chance of being placed in any group.**

*(Describe the treatment groups (treatment arms) of the study, the medication dose and form (pills, injections, etc.), and how the participant will be randomly placed into a group)*

*(For studies with placebo controls, explain what a placebo is and if appropriate, what form the placebo will take in this study. e.g. a sugar pill)*

*(For non-randomized studies: describe the treatment group(s), the medication dose and form (pills, injections, etc.), and how the participant will be placed into a group)*

*(For non-randomized and randomized studies, describe who will be blinded or not blinded to the treatment groups and a statement that the blind can be broken in the event of an emergency. For example, for double-blinded studies you may add the following: **Neither you nor the study doctor will know which arm of the study you are in. In an emergency, this information will be made available.**)*

*(For non-randomized and randomized studies)*

**If you take part in this study, you will have the following tests and procedures:**

*(Describe the visit schedule, the required procedures, questionnaires (provide examples of the question or the nature of the questions to be asked), tests and their frequency. Include any screening procedures required such as chart reviews, use of laboratory or test results, etc., to confirm eligibility. For randomized studies, list the study groups and, under each, describe categories of procedures. Include whether a participant will be at home, in the hospital, or in an outpatient setting. If objectives include a comparison of interventions, list all procedures, even those considered standard. Where blood or body fluids are required, state amounts (in teaspoons as well as ml.) and frequency. If blood, tissues or body fluids are to be stored for future analysis, a separate informed consent is required.)*

*(Provide simplified schema and/or calendar of visits and procedures to be carried out for each visit. Estimate of the amount of time required for each visit .)*

**Participation in the study will be for** (days/weeks/months/until a specific event.)

*(Where appropriate, state that the study will involve long-term follow-up.)  
(For studies including an open label extension phase indicate that a separate consent form will be signed prior to entering this phase of the study.)*

**The researcher may decide to take you off this study if \_\_\_\_\_.**

*(Explain circumstances, such as in the participant's medical best interest, funding is stopped, drug supply is insufficient, participant's condition worsens, new information becomes available, failure to take the medications as described, etc.)*

**You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study staff and your regular doctor first.**

*(Describe any serious consequences of sudden withdrawal from the study.)*

*(State how/when/whether individual or aggregate results will be provided to the participants.)*

## **VI. Risks**

**While on the study, you are at risk for certain side effects .**

*(List by regimen the physical and nonphysical risks of participating in the study in percentages and numbers whenever possible. Nonphysical risks may include such things as the inability to work, potential anxiety related to the sensitive nature of the questions asked, etc. List the known human experiences related to the treatment and procedures involved, including bruising or discomfort from blood draws, as well as any relevant animal data. Highlight or otherwise identify side effects that may be irreversible, long-term or life threatening.)*

*(When describing risks of drug regimens, list the risks in bullet format for each drug. Further, when possible the listing should be broken into easily understood categories of "more likely" or "less likely"*

*For example)*

**Drug XYZ side effects.**

**More likely:**

- **Decreased appetite**
- **Difficulty sleeping**
- **Headache, dizziness**

**Less likely:**

- **Hallucinations or delusions**
- **Nausea and/or vomiting**

*(Risks of venipuncture. If the protocol requires blood draw or IV use, this language should be included)*

**Taking blood may cause some brief soreness, bleeding, and bruising where the needle enters the body, and in a few cases swelling at the site where the needle enters the body. Rarely, fainting and infection can occur.**

*(Also, if applicable, the following should be added)*

**There also may be other side effects or discomforts that we cannot predict, especially to a fetus or embryo. Because the drugs in this study may affect an unborn baby, you should not become pregnant or father a baby while on this study. Your doctor will discuss this with you. You should not breast-feed a baby while on this study.**

**Your condition may not improve or may worsen while participating in this study.**

*(The following text should be added for trials with a placebo arm)*

**If you are in the treatment group that receives placebo (inactive substance) your symptoms or condition may worsen or not improve.**

**The study drug must only be taken by the person for whom it has been prescribed. All medication must be kept out of the reach of children and persons of limited capacity to read or understand.**

**VII. Benefits**

**By participating in this study, you will be providing information to the study doctors that will show the effects of       insert the treatment       for the treatment of name of disease or what is being studied. There may or may not be direct medical benefit to you from participating in this study. We hope the information learned from this study will benefit other participants with name of disease or what is being studied in the future.**

**VIII. Costs**

**All clinic and professional fees, diagnostic and laboratory tests which will be performed as part of this study are provided at no cost to you. There will be no cost for the study treatment that you will receive.**

**OR**

*(Describe expenses the participant may or will incur as a result of participation in the study as related to equipment, tests, services and treatment.)*

**IX. Compensation**

**You will be given \_\_\_\_\_ to compensate you for time and expenses in participating in this study.**

*(Describe any method of payment or reimbursement for participation here. If compensation is pro-rated according to study visit, this should be explained here. It should be noted that the IRB will not approve consent forms that state compensation is dependent on completion of the research. In addition, the IRB will not approve lottery, or other chance-based forms of compensation.)*

OR

**You will receive no payment or reimbursement for any expenses related to taking part in this study.**

**X. Alternatives**

**Instead of being in this study, you may request the standard medical treatment for *(name of disease or what is being studied. List alternatives including commonly-used therapy)***

**You do not have to participate in this study to receive treatment for your condition. Please talk to your regular doctor about all your treatment options.**

**XI. Confidentiality**

**All research information about you will be held confidential to the extent allowed by state and federal law. Your personal information will not be given to anyone without your written permission. A code, which will be known only to study personnel, will be used instead of your name on medical records in this study. Research records which may be identifiable to you will be kept in a secure locked file when not being used. *(If there is a Certificate of Confidentiality for the study, it should be stated here. If not, it should be stated that research records are subject to subpoena.)***

**Information gathered in this research study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. Agencies with research oversight, who may review your records include: the University of Hawaii Committee on Human Studies (IRB), U.S. Food and Drug Administration (FDA), the National Institutes of Health (NIH), study staff, drug companies supporting this study, and study monitors. Confidentiality does not prevent you from releasing information about yourself and your participation in the study. You will be asked to sign an authorization form to release personal health information.**

**XII. Voluntary Participation**

**Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your other medical care at this site. If your study doctor feels that it is in your best interest to withdraw you from the study, your study doctor will remove you without your consent.**

**We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.**

*(When a Data Safety and Monitoring Board exists):*

**A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.**

*(Also, in studies where students or employees are potential research subjects, they should be informed that their performance evaluation, grades or class standing will not be affected by their decision not to participate.)*

**XIII. Injury Related to the Study**

**In the case of injury or illness resulting from this study, necessary medical treatment will be available at no additional cost to you.** *(Describe the costs that are covered by the Sponsor and explain whether the Sponsor will compensate the participant in the event of an adverse event.)*

Or

**If you are injured as a result of being in this study, you will be provided what immediate treatment is available for your injuries. You will then be told where you may get other treatment. The cost for this treatment will be charged to your insurance company or to you. Your insurance company may not pay for these costs. If your insurance will not pay for these costs, they will be your responsibility. The University of Hawaii has no program to pay you or compensate you in any way for your injuries.**

**XIV. Questions**

**You are free to ask questions that you may have about your treatment and your rights as a research participant at any time. If you have questions about this study, or a research-related injury you should contact the investigator name at phone #. If you have questions about your rights as a research subject, contact the UH Committee on Human Studies at (808) 956-5007, or (808) 539-3955.**

**XV. Statement of Consent**

**I have read the above information, or it has been read to me. I have had the opportunity to discuss this research study with name of Investigator and/or his/her study staff, and I have had my questions answered by them in language I understand. I take part in this study of my own free will, and I understand that I may withdraw from participation at any time and this will not affect my medical care. My consent to participate in this study does not take away any of my legal rights in the event of negligence or carelessness of anyone working on this project. A copy of this consent form has been given to me.**

**I agree to take part in this study.**

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**Subject's Name (print)**

**Signature**

**Date**

OR

*(For studies with children, consent should be obtained from the parent or legal guardian and assent should be obtained from the child. UH IRB policy is that investigators should obtain assent from minors 7 years of age and older. Assent may not be obtained using a parental consent form. Minors must be allowed to review and sign a separate assent form.)*

**Minor subject's printed name:** \_\_\_\_\_

**Parent/legal guardian's signature** \_\_\_\_\_ **Date** \_\_\_\_\_

**Parent/legal guardian's printed name:** \_\_\_\_\_

OR

*(For studies involving persons who are incapable of giving consent, consent should be obtained from their legally authorized representative. The Hawaii Revised Statutes do not authorize surrogate decision-making for medical treatment unless it has been legally formalized. Consent forms with signature lines for "legal guardian", "legal representative" or "representative" will not be approved.)*

**Subject's printed name:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Legally Authorized Representative's printed name:** \_\_\_\_\_

\_\_\_\_\_  
**Legally Authorized Representative's signature**

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

*(The IRB does not endorse inclusion of a witness signature line on consent forms, unless it is explained who the witness is, and what the witness is to attest to. If the investigator wishes to identify the person administering the consent, this may be included. It is not, however, a requirement of the CHS.)*

*Optional:*

**I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent**

**Printed Name:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Role in the study:** \_\_\_\_\_ *[This must be done by an authorized/qualified member of the research team i.e. investigator, study nurse, etc.]*