**Request for IRB Approval of a Study Modification**

UH requires the submission of this form with all proposed changes to IRB-approved research and IRB-approved documents associated with the research. Please review the attached instructions for completing this form. For additional information, refer to policy document [SOP 115](https://www.hawaii.edu/researchcompliance/policies-guidance#SOP).

CHS #       Study Title:       Most recent IRB approval date:

PI Name       PI email:

Contact Person:       Contact phone:       Contact email:

**1. Enrollment Status**  **[ ]  Check if not applicable**

[ ]  Study is open to enrollment The number of locally enrolled participants is:

[ ]  Study is closed to enrollment, but participants are undergoing treatment / intervention

[ ]  Study is closed to enrollment and no participants are undergoing treatment / intervention

**2. The following change(s) is/are being proposed: (please check all that apply)**

[ ]  Change in study title, design, methods, or procedures (attached revised protocol as applicable)

[ ]  Addition or removal of PI, co/sub-PI, key personnel, or cooperating institutions

[ ]  Addition, deletion or change in questionnaires or other study instruments (attach revised

 documents)

[ ]  Revised informed consent process or consent / assent forms (attach revised documents)

[ ]  Revised recruitment strategy or materials (attach revised documents)

[ ]  Change in number of participants or study population (e.g. inclusion / exclusion criteria)

[ ]  Other (e.g., closing study):

**3. Modification Plan**

[ ]  Currently-enrolled participants will be notified of this modification (explain below)

[ ]  This modification is related to an unanticipated problem or protocol violation

[ ]  This modification is being initiated by the sponsor

[ ]  This modification has already been implemented to remove an apparent immediate hazard(s)

 to study participants (explain below)

**4.** Provide a narrative response to each of the following questions. Attach additional pages as necessary. Please type your answers, using a 12 point font.

1. Clearly describe the change (do not simply reference the sponsor’s documents).
2. Is this a minor modification, eligible for expedited review? [ ]  (See attached instructions or SOP 115.3 for criteria).
3. What is the reason for the change?
4. What is the likely impact of the proposed change on study participants?
5. How would the proposed change affect the level of risk to study participants?
6. If the change has been implemented, describe circumstances, dates and results.
7. Explain any answers above, as necessary.

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PI Signature Date

**Instructions for Completing the UH IRB Modification Request Form**

1. Determining eligibility for Expedited Review.

Minor modifications may qualify for expedited review. A minor modification is a change that does not materially affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study. The Human Studies Program staff will make the final determination of eligibility for expedited review. Examples of minor modifications include:

* Modifying assessment procedures and tools or adding new study tools when the change(s) do not increase the level of risk to participants;
* Making editorial or administrative changes to IRB-approved documents that do not alter the content or intent of the current information or statements;
* Increasing or decreasing enrollment targets supported by a reasonable justification;
* Narrowing the range of inclusion criteria or broadening the range of exclusion criteria;
* Decreasing the number or volume of biological samples, provided that the change does not affect the nature of the information to be collected; and
* Adding or deleting study sites or qualified investigators.

Modifications that do not qualify as “minor” are considered to be “major” and require review by the convened IRB at a scheduled meeting. For more information, see policy document [SOP 115](https://www.hawaii.edu/researchcompliance/policies-guidance#SOP).

1. Attachments

For all modification requests, please attach a copy of the current consent form as applicable to the study. If the consent form is being revised, append a red-lined (using track changes) version of the currently-approved consent form instead of a clean copy. For changes in study objectives, design, methods, procedures, targeted population, inclusion/exclusion criteria, etc., please submit a revised protocol or protocol amendment. Attach all revised study documents affected by the proposed changes with specific changes clearly indicated, using “track changes” or comparable method. If there is more than one consent form for the study, only the main consent form is required with the modification request unless the other consent forms are being changed.

1. Instructions for Submitting your Request

Please email your modification request to uhirb@hawaii.edu. In the subject line, write “Modification Request” and the CHS number.

Also, please submit two (2) hard copy modification requests to the UH Human Studies Program, 2425 Campus Road, Sinclair 10, Honolulu, HI 96822.

All modification requests must include the signature of the PI, and all required attachments must be attached.

Please do not include this instruction page with your submission. If you have questions, call the UH Human Studies Program at 956-5007. Thank you.