

Guidelines for Developing an IRB Application

The quality of the research application is likely to determine the timeframe for IRB review and approval of your study. If you have questions about any aspect of your application, you may consult with the Human Studies Program staff prior to submitting your application to the IRB. The following guidelines have been developed to assist you in writing an IRB application that is more likely to be reviewed in a timely manner.

1. Make sure that your application and all appendices are typed and the information provided is written clearly and succinctly. Do not cut-and-paste from your dissertation proposal or your grant application. In general, the IRB wants different information that focuses on the experience of prospective study subjects.
2. The IRB must be able to determine that an application for initial or continuing review meets the federally-required approval criteria. Make sure you provide information in your application that will enable the IRB to assess your project's compliance with these criteria:
 - a. Risks to subjects are minimized;
 - b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result;
 - c. Selection of subjects is equitable;
 - d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative;
 - e. Informed consent will be appropriately documented (generally by a signature on the consent form);
 - f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
 - g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
 - h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
3. Describe your enrollment criteria. The IRB will carefully review your criteria for including or excluding prospective research subjects. If it is possible that you will be enrolling vulnerable populations, explain the additional safeguards you will use to protect them from undue influence or coercion. Vulnerable populations may include children (up to age 18), pregnant

women and fetuses, and prisoners; people with grave illness, substance abuse problems, developmental, cognitive or emotional deficits, etc. are also considered to be vulnerable.

4. If you will be relying upon existing information or specimens for your study, describe your source(s). Explain any information from which it will be possible to identify individuals, either directly (names, social security numbers, etc.) or indirectly through codes linked to individual identifiers. Explain whether anyone on the research team will have access to identifiers or codes. If you have prior informed consent from subjects to use their data or specimens, provide a copy of the consent form to the IRB.
5. If you will be working with private information from which individuals may be identified, describe your plan for protecting the confidentiality of this data.
6. Append to your application all documents that will be seen or used by study participants. This will include consent (and assent) forms, questionnaires, recruitment documents (e.g., flyers, advertisement text, etc.), diaries (used in some drug studies), etc. These documents cannot be used until the IRB has approved them.
7. If you are applying for approval from the **UH Biomedical IRB**, append a written protocol that is separate from the IRB application. [Guidelines for Developing a Clinical Research Protocol](#) are posted on this website.
8. If you will be compensating subjects for their participation in your research project, the IRB will evaluate the compensation to determine that it is:
 - Nominal in value so that it is not likely to unduly coerce subjects into study participation. The amount of the compensation should be commensurate with the time and effort likely to be required by participants.
 - Not provided to participants only upon completion of the study, thus providing an incentive for study completion.
 - Not included in the “benefits” section of the consent form. It should be described in a separate section labeled, “compensation.”
 - Allocated fairly to all study participants. Lotteries and chance-based drawings are not allowed.
9. If there will be a cost to research participants or a third-party payer for participation in the research, explain what those costs will be in the consent form. If you don’t know the exact cost, estimate to the best of your ability, or provide a range.

10. When you are requesting IRB approval for a change in an IRB-approved document (e.g., protocol, consent form, questionnaire, etc.), include with your completed [Request for IRB Approval of a Study Modification](#) a copy of the IRB-approved document with changes marked, using track changes (or otherwise clearly indicating insertions and deletions).
11. Make sure that all applications are signed. If you are submitting an application by email, scan the signed application and forward it to uhirb@hawaii.edu.
12. The process for obtaining informed consent must be clearly and fully described. The informed consent process begins with the recruitment procedures and continues throughout the research project.
13. The consent form will be one of the most important documents in your IRB application. It must be written to be easily comprehensible by your prospective study population. The general rule is that it should be written at an 8th grade reading level. It should contain all of the required elements. If a required element does not make sense for your study, you can explain this to the IRB and request that the IRB approve an alteration.
 - a. Required Elements:
 - A statement that the study involves research
 - An explanation of the purpose(s) of the research
 - The expected duration of the subject's participation
 - A description of the procedures to be followed and identification of any procedures that are experimental
 - A description of any reasonably foreseeable risks or discomforts to the subject
 - A description of any benefits to the subject or to others that may reasonably be expected from the research (monetary compensation is not a benefit)
 - A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject
 - A statement describing the extent, if any, to which confidentiality of records identifying subjects will be maintained
 - For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

- An explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

Additional Elements, when appropriate to the study:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that the Principal Investigator will notify subjects of any significant new findings developed during the course of the study that may relate to the subject's willingness to continue participation
- The approximate number of subjects involved in the study

Optional Consent Form Elements that may be required by the IRB:

- A statement concerning an investigator's potential financial or other conflict of interest in the study
- Identification of the institutions involved in the performance of the research
- Identification of the protocol on the signature page
- Identification of the principal investigator(s) with his/her contact information
- Identification of the sponsor of the research
- The reason this person is being asked to participate in the study
- The right to compensation for commercialization from genetic information

- The right to receive research results
- The right to determine if and how their biological samples will be used for future research
- The consent form is formatted to meet IRB requirements (e.g., pages are numbered, the IRB approval date is in the footer, etc.)
- Others as determined to be appropriate by the IRB.

Note: For more information on informed consent and consent /assent forms, see the [Informed Consent: Model Forms and Guidance](#) section of this website.

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