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Consent Form Guidance

The following guidance is provided, in no particular order, to assist investigators in drafting consent forms that are likely to be approved by the IRB. It also includes summary information on oral consent (#13) and use of a short consent form (#14).

1. The consent form 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**. Use a 12 point font or greater, and leave sufficient margins and other white space on the consent form so that prospective subjects can write notes.

2. For children ages 7 through 17, in addition to a parental consent, an assent form is generally required. Sometimes, one assent form is provided for children ages 7 through 12 (or some other age), and a separate assent form is provided for older youths. The assent form does not need to include all of the elements that are required in a consent form. The content of the assent form should be dictated by the age/maturity of the prospective minor subjects.

3. Federal regulations permit **oral informed consent** in certain situations and with prior approval by the IRB. In this process, the investigator may obtain informed consent through use of an oral consent script. Similar to written consent, the script should include information regarding the nature and duration, risks and benefits, alternatives, and costs to prospective subjects. The subject will either verbally agree or not agree to participate in the study. Investigators are not required to secure written documentation of consent obtained orally. However, depending on the circumstances, a **handout** with consent information may be required.

   In order to approve a consent form that does not include the subject's signature (or the signature of the legally-authorized representative), one of the following criteria must be met:

   a. The research is determined by the IRB to be minimal risk AND involves no procedure(s) for which written consent is normally required outside of the research context; or
   b. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

4. Federal regulations also permit the oral presentation of informed consent information in conjunction with a "**short form consent**" and a written summary or script of what is presented orally. This process and associated documents require prior approval by the IRB.

   The short consent form is a document stating that the required consent form elements have been presented orally to the subject or his/her legally authorized representative (LAR). When this method is used, there must be a witness to the oral presentation. The short consent form must be signed by the subject (or the LAR); the witness must sign

the short form and a copy of the summary; and the person obtaining consent should sign a copy of the summary. A copy of the summary and consent form should be given to the subject, and the investigator should retain a copy of the documents with the study records.

When this procedure is used with subjects who do not speak English, the oral presentation and the short consent form should be in a language understandable to the subject, and the witness should be fluent in both English and the language of the subject.

5. In general, consent forms should contain all of the federally-required elements. (**See below for the listing of requirements**) 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. In order to alter any of the required elements of informed consent, all criteria (a,b,c below) must be met. These are:

    a. The research involves no more than minimal risk to participants;
    b. The alteration will not adversely affect the rights and welfare of participants; and
    c. The research could not practicably be carried out without the alteration.

6. Contact information for the IRB is required in all consent forms. In addition to contact information for the investigator, please include the following language:

    For questions about your rights as a research participant, contact the University of Hawaii Human Studies Program by phone at 808.956.5007 or by email at uhirb@hawaii.edu.

7. 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.

8. If you will be compensating subjects for their participation in your study (e.g., cash, gift cards, course credit, or other), explain the compensation in your consent form, under "compensation." Compensation must not be presented as a benefit of study participation in the consent form, and it should not be the focus of study recruitment materials.

9. The consent form must address issues relating to the confidentiality of study information. The following sentence is generally considered to be acceptable:

    All personal information will be kept confidential to the extent allowed by law. Several public agencies with responsibility for research oversight, including the UH Human Studies Program, have authority to review research records.

    As appropriate, include the following language:

Research records will be kept in a locked file in the investigator's office for the duration of the study. All personal information will be destroyed upon completion of the research project.

10. Effective March 7, 2012, **if your study is being conducted under an IND or IDE** or otherwise requires registration in **ClinicalTrials.gov**, the FDA requires the following statement in the consent form:

    "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

11. **For research involving audio or video recordings** of subjects, include a statement in the consent form, informing subjects of such recordings. Explain if the recordings will be erased upon transcription or upon completion of the project. If the recordings will not be destroyed, explain why they will be kept and how they will be protected after the study is complete. **In the absence of a valid research-related reason for maintaining audio or video recordings, the IRB is likely to require that they be destroyed.**

12. If you plan to store **tissue specimen**(s) for **unspecified future research use**(s), consult the Human Studies Program staff on language required by the IRB.

13. If your study involves venipuncture of study participants, the suggested consent form language is:

    You are being asked to give __ cc of blood (about __ tablespoons). The risks of this procedure may include mild pain or a bruise at the place where blood is taken. Occasionally, a person may faint or feel faint after blood is drawn. Risk of infection is slight since only sterile one-time equipment will be used.

14. Make sure that the title of the study is included on the signature page (in case the signature page gets separated from the rest of the consent form) .

15. As part of the consent process, plan to provide a copy of the informed consent document for research participants to keep, so they can refer to it if they have questions and easily find contact information for the investigator and the IRB.

Federally-required Consent Form 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, required by federal regulation, 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 all investigator(s) with their contact information

Identification of the sponsor of the research

The reason these prospective subjects are 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

Others as determined to be appropriate by the IRB.

16. If your research is subject to the requirements of the HIPAA Privacy Rule, you should append HIPAA Privacy Authorization language as a separate section at the end of your consent form, or you can submit a separate Privacy Authorization form. Template privacy authorization language can be found in the Model Forms and Guidance section of this website, under *Informed Consent: Helpful Documents*.

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