Consent/Cover Letter Required Elements

Directions: When drafting consent forms and cover letters for your research study or program evaluation plans, please, make sure that the following elements listed below are included. If you have any questions or need assistance in developing this form and letter, contact HIRB for assistance.

1. A statement of your affiliation with Heartland Institutional Review Board.

2. A statement that the study involves research and/or program evaluation and an explanation of the purpose of the research in terms that the potential participants can readily understand.

3. A description of procedures and an estimation of how long participation will take.

4. Criteria for subject selection.

5. A statement that the study is voluntary or a statement such as, "Completion and return of this survey indicates voluntary consent to participate in this study."

6. A statement describing the extent, if any, to which confidentiality will be maintained and the precise means of maintaining confidentiality. This statement should incorporate all of the following items listed below that pertain to your study.

    a. A description of any coding system used, and the rationale for keeping the list of subjects' names. NOTE: If you assign a number, it must not be the Social Security number.
    b. If a sheet that matches numbers and identifying information will be kept, state that the code listing and data will be kept in separate and secure locations.
    c. A statement of who will have access to the code list and data.
    d. A statement of what will happen to the code list when the study is complete. (Will it be destroyed? Will it be kept secure? How? And, for how long?)
    e. A statement such as "We will take all reasonable steps to protect your identity."

7. Contact information for a person employed with the project who is able to answer questions.

8. The Heartland Institutional Review Board approval statement: "This project has been reviewed and approved by Heartland Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to: Heartland Institutional Review Board – Ph: 866.618.HIRB – director@heartlandirb.org"

9. For studies involving children, both a parental consent form and an appropriate child assent form are needed.

10. If subjects will be recorded using either audio, video, or both, please, include the information listed below as it pertains to the type of recording to be performed.

    a. Describe recording procedures.
    b. Indicate how confidentiality will be maintained and what will happen to recordings when the study is complete.
    c. A statement such as: "I agree to participate in this activity and know that my responses will be recorded." Note: Subjects must also be given the ability on the form to either agree to be recorded or to refuse to be quoted. For example: "I agree ___I disagree___(select only one) that I may be quoted in future publications resulting from this study."
    d. State how recordings will be stored, who will be allowed to hear/view recordings, and when recordings will be erased. If the recordings will not be erased, state where recordings will be kept and how the recordings will be used in the future (e.g., future research, valuable historical data).
    e. If recording will be performed in a group setting, consent of all members present in said group must be obtained.

11. If participants will be solicited by e-mail, the "from" line should be the researcher's name and the "subject" line should be "Research Request". The message should state early how e-mail addresses were obtained. Include either a statement saying there will be no future e-mails or a message that permits addressees to opt out of any future mailings. If you plan future e-mails, add the statement, "If you do not respond to this survey or return the opt-out message, you will be contacted again with this request X times during the next X weeks." Note: A blind copy format should be used so that the list of recipients will not appear to all recipients. Please, include the following HIRB contact information in the last sentence of the HIRB approval statement:

    Heartland Institutional Review Board – Ph: 866.618.HIRB – director@heartlandirb.org

12. For focus group research, the consent form should include the following language: "All reports based on this research and written by the researcher will maintain the confidentiality of individuals in the group. Only group data will be reported and no names will be used. Since a focus group involves a group process, all members of the group will be privy to the discussions that occur during the session; therefore, absolute confidentiality on the part of the participants, themselves, may be difficult to ensure."

13. If private health records will be used, contact the agency that has the health records and ask them what procedures they require before they will release subjects' private health information.

The following may also be required for research that falls under the advanced review criteria.

1. Consent forms for all advanced research should include a statement similar to: "I have read the material above, and any questions I asked have been answered to my satisfaction. I understand a copy of this form will be made available to me for the relevant information and phone numbers. I realize that I may withdraw without prejudice at any time."

2. A statement of any foreseeable risks or discomforts or a statement that the risks are minimal.

3. A description of benefits to the subject or to others which may be expected from participation in the research.

4. For projects that may involve physical risk to the subject, include:

a. The following paragraph, verbatim: "The Department of Health and Human Services requires that you be advised as to the availability of medical treatment if a physical injury should result from research procedures. The researchers do not have funds specifically dedicated to compensate you for any adverse effects that you may experience by participating in this research. Nevertheless, you retain all your legal rights to seek compensation in the event of injury or other adverse event. Immediate medical treatment is available at usual and customary fees at _____. In the event you believe you have suffered any injury as a result of participating in the research program, please contact Heartland Institutional Review Board – Ph: 866.618.HIRB – director@heartlandirb.org"

b. A statement that a medical questionnaire must be completed and that subjects may be excluded from participation based on their responses.

c. If blood is to be withdrawn, include a statement indicating the amount of blood to be withdrawn and potential complications, including possible bruising, inflammation, and infection at the site of the puncture. Name the individual who will withdraw the blood, state his/her qualifications, and assure subjects that care will be taken to avoid any complications.