Informed Consent

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Policy Statement

No investigator may involve a human being as a subject in non-exempt research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representatives (legal guardian or durable power of attorney for health care). Exceptions must be approved by the IRB.

Description and Procedures

A. Documentation of Informed Consent

In most cases, informed consent must be documented by use of a written informed consent form, to be signed by the subject or the subject's legally authorized representative. Electronic signatures may be used, but a written copy must always be given to the person signing the informed consent form. The IRB must approve all consent documents to be used, and approve all study personnel who will obtain consent. Approval must also be obtained from the IRB for each modification made in the form thereafter, before instituting the change. The version of the consent document being used should match exactly with the version given final IRB approval in the protocol file. The IRB office will issue the approved version of the consent form stamped with "University of the Incarnate Word IRB Approved," the application number, and date of approval. Electronic surveys not requiring written informed consent must have the IRB approval number inserted into the survey before they are used.

The consent document is a legal document containing sufficient information to allow the prospective research subject to make an informed decision about whether or not to participate in the research. It is not intended to be a protection for the investigator and does not constitute any waiver of liability. The signed consent document provides documentation of a subject's consent to participate in a study.

B. Process of Obtaining Consent

The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. The federal regulations mandate the following features be included in the informed consent process:

- The prospective subject or the legally authorized representative must be provided with sufficient opportunity to discuss or consider whether or not to participate. The possibility of coercion or undue influence must be minimized.
- The prospective subject or legally authorized representative must be provided with information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- The informed consent document must present information in sufficient detail, but worded in a manner that can be readily understood by the potential subjects.
- No informed consent document may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

C. Required Elements of Informed Consent

Each of the following points must be covered in the consent document, except in cases where the point is irrelevant to the research (45 CFR 46.116[b]):

1. at the beginning of the consent document, a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research;

2. a statement that the study involves research, an explanation of the purposes 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 non-standard and/or developed specifically for this research;

3. a description of any reasonably foreseeable risks or discomforts to the subject, their frequency and severity, to include (but not limited to) hazards of procedures, withholding methods of proven value, financial risk, and loss of privacy, and a description of what will be done to minimize risks;

4. a description of any benefits to the subject or to others which may reasonably be expected from participation along with a disclaimer that the investigator cannot guarantee there will be any benefit derived from taking part in the study;

5. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

6. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

7. for research involving more than minimal risk, an explanation as to whether there will be any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

8. identification including the full name(s) and 24-hour phone number(s) of the investigator(s) the subject may contact for answers to questions about the research, the contact information for the Institutional Review Board (should subjects have any questions regarding their participation, rights and/or research procedures), and whom to contact in the event of a research-related injury to the subject;

9. 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; and

10. one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    a. a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
    b. a statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

D. Additional Elements of Informed Consent

The following additional elements of informed consent should be included when appropriate (45 CFR 46.116[c]):

1. a statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

2. anticipated circumstances under which the subject's taking part may be terminated by the investigator;

3. any additional costs to the subject that may result from participation in the research;

4. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue to take part will be provided to the subject;

6. the approximate number of subjects involved in the study;

7. a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

8. a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

9. for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.

E. Distribution and Storage of Signed Consent Documents

Both the subject and the investigator will sign two copies of the consent form. A complete, signed copy of the consent document must be given to each subject. A copy with original signatures must be retained in the investigator's file for a minimum of five years after completion of the study.

F. Waiver of Consent

The IRB may waive the requirement to obtain informed consent in some circumstances. Such a waiver may be given when the following conditions exist:

1. The research involves no more than minimal risk to the subjects.
2. The research could not practicably be carried out without the requested waiver.
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

G. Waiver of Requirement for Signed Consent

The IRB may waive the requirement of signed consent in some circumstances, and may require instead that a written statement describing the research be given to the subject. Such a waiver may be given when **one** of the following conditions exists:

1. The only record linking the subject and the research would be the consent document and the principal risk would be resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

3. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided that there is an appropriate alternative mechanism for documenting that informed consent was obtained.

H. Posting of Clinical Trial Consent Form

For clinical trials supported by the Federal funding, one IRB-approved informed consent document must be posted by the Principal Investigator on a publicly available federal website repository, such as clinicaltrials.gov. Redactions of certain information, such as confidential commercial information, may be made to the document before public posting, as required by the Federal funding agency. The informed consent document must be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

I. Non-English Speaking Subjects

If the research subject does not understand English sufficiently to be able to give informed consent, consent should be obtained in the language readily understood by the subject. Translations of consent documents should be available at the outset of a study if it is anticipated that non-English speaking subjects will be enrolled.

J. Format of the Informed Consent Document

Templates for adequately detailed, stylistically acceptable consent documents are available on the IRB's website. The templates include the required and recommended elements of consent, with additional elements recommended by the UIW IRB and suggested language for each section. It is strongly recommended that UIW investigators use the templates to develop informed consent documents, modifying them as appropriate for their specific studies.

Language

The informed consent form should be written in the second person, which addresses the prospective subject directly and emphasizes his/her voluntary decision making. It must be written in language that is simple enough to be readily understood by the least educated of the subjects to be utilized (normally this should be simple enough for an eighth grade student). Scientific terms should be avoided when possible. If scientific terms must be included, the lay definition should be provided.

Unnecessary mixing or repetition of the informational content should be avoided whenever possible. This helps the prospective subject focus on each individual element of consent thereby enhancing the comprehension of the information presented.

Two or More Consent Documents

It sometimes is necessary to use two or more consent documents when procedures are to be performed on subgroups of subjects or when reasons for subject selection differ. The most common example of this situation is studies which involve a treatment and a control population.

If there is more than one consent document, place a label after the title indicating the subject population to which each is addressed.

Technical Elements

At the top of the first page, the consent document should bear the title of the study, e.g., "Subject Consent to Take Part in a Study of...(give title of study)," and the name(s) of the institution(s) at which it is to be conducted. Pages should be numbered "1 of 4," "2 of 4," etc. At the end of the consent document there should be statements that the subject will be given a signed copy of the form to keep and that his/her signature means he or she has read the document and been given the chance to discuss it and ask questions.

Spaces should be provided for: (a) the signature of the subject who consents to take part; or in the case of a minor, of the parent or guardian who consents on behalf of the subject and a line for the assent of the subject if age 7 or older; (b) the signature of the investigator or other approved person who enrolls the subject; and (c) the date consent is obtained.

K. Guardian Consent

Unless he/she is also a court appointed guardian or has durable power of attorney to consent for medical treatment, a "next-of-kin" usually cannot give consent for research on an adult subject. Consent for a child to take part in research must be obtained from a parent or legal guardian. Generally, age 7 is accepted as the age at which assent is sought. Emancipated minors (those under 18 years of age and married, or those for whom minority status has been court-removed) may consent on their own to take part in research. Although some minors may consent to certain types of medical treatment, there is no legal precedent that they, by themselves, may consent to take part in research.

Regarding enrollment of subjects who are incompetent, incapacitated, or otherwise cognitively impaired, Texas state law permits the adult next-of-kin to consent to medical treatment, including that given in the context of a research proposal. This is only permitted if the IRB finds that it is appropriate and that sufficient safeguards have been incorporated into the protocol to protect the subject.

Generally, the IRB must consider: (i) whether there is a compelling reason to include incompetent individuals in the research (i.e. the research could not otherwise be completed due to inadequate numbers of eligible competent subjects; generally surrogate consent is reserved for evaluation of life saving measures which could not otherwise be tested); (ii) whether there is a favorable risk/benefit ratio (the research must be intended to benefit the individual subject and the probability of benefit is greater than the probability of harm); (iii) that under no circumstance will subjects be forced or coerced to participate; and (iv) that the subject's representatives will be well informed about the nature of the study and that their obligation is to try to determine what the subject would do if competent or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interests. Information that would allow the Board to evaluate these criteria must be provided.

In addition, for those studies approved by the IRB to enroll subjects by surrogate consent, there should be provisions for informing the subject immediately if he/she becomes competent and for obtaining the subject's signature to indicate he/she was informed about having been enrolled in the study. If the subject becomes competent and there are study activities to continue (such as

follow-up visits), the subject should also be asked whether or not he/she consents to continue in the study.

L. Assent

Adequate provisions must be made for soliciting the assent of children, when the children are capable of providing assent. The ages, maturity, and psychological state of the children involved should be taken into account. Generally, age 7 is accepted as the age children should give assent. If the procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, assent of the children is not a necessary condition for proceeding with the research. Regarding the involvement of adults who are mentally disabled, in addition to the consent of a legally authorized representative or guardian, the feelings and expressed wishes of the incompetent person should still be respected. Investigators should both inform the subject and solicit his/her assent to take part in the study. (45 CFR 46.408)

M. Deception

The IRB recognizes that in some cases, informing the subject of the hypothesis being tested may result in a biased response. Under these circumstances, the nature of some studies requires that the full purpose not be revealed to a subject until the study has been completed. The deception to be employed must be: (a) explained and justified in the protocol (b) explained in a debriefing statement required in the protocol which describes the true intent of the study and which must be read to the participant at the close of the study. Studies which use deception but impose no more than minimal risk to participants qualify for expedited review provided they adhere to the requirements described herein.

N. Guidelines for Subject Consent in Exempt Survey Research

Survey research involving the use of self-administered questionnaires and telephone and face-to-face interviews generally places subjects (respondents) at minimal risk. Minimal risk could involve possible invasion of privacy and disruption of normal routine. Further risks could include possible legal risks, possible inconvenience, embarrassment, and other kinds of psychological discomfort. Such risks may become more than minimal when sensitive information (such as sexually transmitted diseases, AIDS, alcohol and drug abuse) is requested. Survey or interview-based research involving minimal or no risk is usually categorized as Exempt from federal regulations, including requirements for informed consent. However, information about the research and the voluntary nature of the study should still be provided. Guidelines for such cases are provided below.

Self-Administered Questionnaires in Exempt Research

A cover letter or introductory statement containing the following information should accompany a self-administered questionnaire:

1. an explanation of the purpose of the questionnaire;
2. an explanation of how and/or why the subject was asked to participate;
3. a statement of the amount of time the questionnaire will require;
4. a description of any stresses associated with sensitive information elicited;
5. a description of any benefits reasonably to be expected;
6. an offer to answer any inquiries concerning the questionnaire;

7. an instruction that the subject is free to refuse to fill out the questionnaire; and
8. an assurance of confidentiality, including how confidentiality will be provided and maintained.

In the instance that there will be no way of tracing respondents, return of the questionnaire to the investigator will be considered to be adequate informed consent provided the cover letter including the above information accompanied the questionnaire.

Surveys or Interviews in Exempt Research: Telephone, Face-To-Face, or Electronic

Whenever possible, a letter should precede an interview to inform the subject of the impending interview. The letter should contain the following information:

1. an explanation of the purpose of the interview and the kinds of questions to be asked,
2. an explanation of how and/or why the subject was chosen to participate in the study,
3. a statement of the amount of time the interview will require,
4. a description of any benefits reasonably to be expected,
5. an instruction that the subject is free to discontinue the interview at any time without prejudice, and
6. an explanation of confidentiality.

At the beginning of the interview or electronic survey, the information contained in the letter should be reiterated to the subject again by the interviewer.

In the instance of telephone interviews, and assuming that the information letter is part of the process, the oral consent of the interviewee to continue the interview will be considered to be informed consent.

In the instance of face-to-face interviews, the informed consent document should be in writing. Informed consent should be obtained prior to the interview. The signatures of the subject and the approved person obtaining consent should be contained in the consent document. Like the letter and spoken introduction, the informed consent document should include all the relevant information listed in the Required Elements Informed Consent section.

Effective Date

August 24, 2020

Revision History

References

OHRP Guidance on the Use of Electronic Informed Consent
45 CFR 46