Wayne State University Human Investigation Committee	
Subject	Informed Consent Options
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Approvals	Office of the General Counsel 12/21/06; Steering Committee 01/17/07; Administrative Approval 03/19/07; Draft Revision 12/2007; Administrative Approval 08/14/2008; General Counsel 08/28/2008, Administrative Approval 09/30/10, Administrative Approval 03/07/11

Background

No investigator may involve a human being as a participant in research unless the investigator has obtained the legally effective informed consent of the individual or the individual's legally authorized representative as set forth in the federal regulations (see 45 CFR 46.116, 38 CFR 16.116, 21 CFR 50.20). An investigator shall seek such consent under the following circumstances only; the prospective participant or the prospective participant's representative has been provided sufficient opportunity to consider whether or not to participate; and the possibility of coercion or undue influence has been minimized. The information that is given to the prospective participant or his or her representative shall be in understandable language.

The Wayne State University (WSU) Institutional Review Board (IRB) has the final authority as to the content of the informed consent document presented to the prospective study participants. The IRB may require that information, in addition to that specifically required by applicable regulations or the sponsor, be given to prospective participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of the participants. The WSU IRB has the authority to observe, or have a third party observe, the consent process. No informed consent document may include any exculpatory language through which the prospective participant or his or her representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Scope

This HIC policy procedure applies to all research personnel who are involved in writing, reviewing, or providing informed consent in a research study that has been approved by WSU HIC. Personnel responsible for the informed consent process include the principal investigator (PI), co-investigator(s), key personnel, and others delegated by the investigator.

Definitions

Assent – Affirmative agreement to participate in research obtained from an individual who is not of legal age to give informed consent. Assent is obtained in conjunction with permission of the individual's parents or legally authorized representative. Mere failure to object should not be construed as assent.

Children – According to the federal regulations, children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

Emancipated Minor – A child age 16 or older who is legally recognized as an adult under Michigan law in the following instances: if child 16 or older is married; on active duty with the armed forces; or under a court order. Please refer to the HIC Policy/Procedure: "Vulnerable Participants: Children", for complete criteria and [MCLA 722.4].

Information Sheet – A document that contains all the required elements of informed consent without a signature line. The act of participation is considered consent.

Informed Consent – An ongoing process by which a participant or his/her legal representative voluntarily confirms his or her willingness to participate in a particular research project, after having been informed of all aspects of the research that are relevant to the participant's decision to participate.

Legally Authorized Representative – Defined in the federal regulations as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedure(s) involved in the research.

Oral Consent – Process of obtaining informed consent without the use of a written document.

Parental Permission – The agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

Witness – A person who is independent of the research team and cannot be unfairly influenced by people involved with the research, who does not have a coercive relationship with the participant, who attends the informed consent process when the participant or the participant's legally authorized representative is illiterate or legally blind. A witness is required when using a translated consent.

HIC Policy

Informed consent is one of the primary ethical requirements when conducting research with human participants; it reflects the basic principle of respect for persons. Informed consent seeks to ensure that prospective participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate.

The elements of informed consent are mandated in 45 CFR 46.116, 38 CFR 16.116, 21 CFR 50.25 and must include the following:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the participant;
3. A description of any benefits to the participant or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any medical treatments or compensation are available if injury occurs and, if so, what they consist of or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and
8. A statement that participation is voluntary and refusal to participate will not involve a penalty or loss of benefits to which the participant is otherwise entitled, that the participant may discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled and that the participant will receive a copy of the signed informed consent.

When appropriate, one or more of the following elements of information shall also be provided to each participant:

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the individual's participation may be terminated by the investigator without regard to the participant's consent;
3. Any additional costs to the individual that may result from participation in the research;
4. The consequences of a participant's decision to withdraw from the research and procedures for early and orderly termination of the participant's participation;
5. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant; and
6. The approximate number of participants involved in the study.

The consent form VA 10-1086 must be used for Veterans Administration research [VHA 1200.05 30.d.]. If the wording of the informed consent has been initially prepared by an entity other than the principal investigator (e.g. a pharmaceutical company or a cooperative study group), then the IRB should ensure that the wording of the informed consent meets all the requirements of the HIC policy and VA policy [VHA 1200.05 31].

For all other research, the required and additional elements are addressed in the Human Investigation Committee (HIC) consent templates. It is preferred that all consent forms be developed using the WSU HIC informed consent/assent templates. When the informed consent/assent is not in the WSU template, all of the required language from the HIC informed consent/assent templates must be included. Changes proposed to the standard language of the HIC consent templates must be approved by the IRB. If participants include subjects from vulnerable populations then the following policies/procedures should also be consulted: the HIC Policy/Procedure on the appropriate Vulnerable Subject category, e.g. prisoners, terminally ill, children, for specific consent requirements. For specific consent criteria for research involving pregnant women see HIC Policy/Procedure "the Inclusion of Pregnant Women in Research" and "Research Involving Fetuses and Neonates".

Once the informed consent/assent document is approved by the HIC, all forms must have the HIC stamp of approval to be considered a valid informed consent. An IRB approved informed consent/assent document will contain the approval and expiration dates established by the IRB. The informed consent document expires when the protocol approval period expires at midnight on the date of expiration. The dates of approval and expiration are also provided to the PI on all approval memos. For VA research, if the consent document is amended during the protocol approval period, the consent document must reflect the approval date of the amendment rather than the date of the approved protocol.

Informed Consent Options

Informed consent or waiver of informed consent must be obtained for every participant in a research study before that participant begins any aspect of participation in the research. Informed consent does not stop at the simple signing of a document but continues throughout the study. See HIC Policy/Procedure: "Informed Consent Process" for guidance on the complete process.

The documents for use in the informed consent process include:

1. Written Informed Consent
2. Short Form Informed Consent for Non-English Speaking Participants
3. Parental Permission
4. Assent
5. Information Sheet
6. Oral Consent
7. Waiver of Consent/Assent in Non-Emergency Research
8. Waiver of Consent in Emergency Research

Written Informed Consent

Generally, the IRB requires informed consent to be documented by a written consent form approved by the IRB. The written consent form should be written at 6th - 8th grade reading level in language that is understandable by the research participant and must be reviewed with the research participant (or the research participant's representative) as part of the consent process. Informed consent should be obtained in person unless one of the circumstances described below occurs in which case the noted alternative method of obtaining informed consent will be permitted.

Obtaining Written Informed Consent via Fax:

Situations may arise when obtaining informed consent from participants via fax is appropriate. The following are examples of acceptable situations: (1) it is acceptable for the informed consent process to take place in person, allow the potential participant time to take the consent document home in order to consider participation, and then have the potential participant sign and fax the informed consent document back to the research site; or (2) the informed consent process takes place over the phone; or (3) if consent is obtained from a guardian. The person obtaining the informed consent should sign the informed consent document and make appropriate notes in the participant's records upon completion of the informed consent discussion. The participant may then fax a signed copy of the informed consent document to the research site. Upon receipt of the faxed informed consent, the investigator or appropriate designee should again sign and date the document as acknowledgement of its receipt and make appropriate notations to the participant's record. The participant should still return the signed original informed consent document (either at the next visit or via mail) to the research site at his/her earliest opportunity. The appropriate receipt of the signed original informed consent document should sign and date it, file it with the faxed copy, and make appropriate notes to the participant's record. The notes coinciding with the dates and signatures on the informed consent documents provide the source documentation that confirm and explain how the informed consent process occurred. All documents will be maintained in the protocol record.

Obtaining Informed Consent via Mail:

This option is used when it is not possible to complete the informed consent process in person. Generally, this option is used when the study is a minimal risk study or there has been a change to the informed consent that may affect the participant and the individual is not scheduled for a study visit. Two copies of the informed consent must be mailed so that the participant has a copy to keep and another to mail back to the site. It is strongly encouraged that a follow-up phone call be placed to ensure that the research participant understands the changes in the informed consent. A witness signature is not required for the consent process. Once the signed informed consent is received it should be signed with the date it is received. Appropriate notes to file must include the changes and if a phone call was used to answer any questions about the changes the participant may have.

Short Form for Non-English Speaking Participants

Persons that do not speak English have opportunities to join research studies using the short form informed consent option or English versions translated into the language spoken or understood by the potential participant. See HIC Policy/Procedure: “Informed Consent Involving Non-English Speaking Participants” for specific requirements and instructions.

Assent and Parental Permission

Permission from parents is usually obtained prior to approaching a child participant. If the HIC determines that the research involves greater than minimal risk without direct benefit to the child (45 CFR 46.407, HIC category 3), signatures from both parents are necessary. However, it is acceptable for only one parent to provide permission when the other parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. The circumstance for obtaining only one signature must be documented in the study records. In other cases, such as child abuse or sexually transmitted disease, parental permission may not be appropriate. The HIC can grant a “waiver of parental consent” if criteria in the “Review of Research Involving Children/Adequate Provision for Soliciting the Permission of Parents or Guardians” checklist are met.

In most cases once parental permission has been obtained, the assent of the child participant is required. A child’s assent can be waived in certain treatment studies where the study offers potentially lifesaving benefits. In the case where child assent is appropriate, however, if the parent(s) gives permission for the child to be in the study and the child doesn’t assent, the child cannot be enrolled in the study. See HIC Policy/Procedures: “Vulnerable Participants: Children” for guidance on submission requirements.

Information Sheet

An investigator may submit a request to the IRB seeking waiver of the requirement to obtain written documentation of informed consent and when appropriate provide participants with a written information sheet that contains all of the required elements of informed consent. The IRB may approve this request under two circumstances described in the Criteria to Waive Requirement for Written Documentation of Informed Consent checklist.

Oral Consent

Unless otherwise approved by the IRB the informed consent process is to always be explained orally to participants. Unless the IRB waivers the requirement to obtain written documentation of the informed consent process, the informed consent process must be documented in writing.

Waiver of Informed Consent

The IRB may approve an informed consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or the option to waive the requirement for informed consent provided the IRB finds and documents that the requirements in the "Criteria to Waive or Alter Requirement to Obtained Informed Consent" checklist are met.

Criteria for Waiver of Written Documentation of Consent

The IRB may waive the requirement of written documentation of the informed consent process provided the IRB finds and documents that the requirements in the "Criteria to Waive Requirement for Written Documentation of Informed Consent" checklist are met.

Obtaining Initial Consent

The PI does not have to obtain the informed consent personally but has the ultimate responsibility for the informed consent process. Any co-investigator listed on the Medical/Behavioral Protocol Summary Form (or added to the study by an amendment) may obtain informed consent from potential study participants. In addition, the PI may designate key personnel who are authorized to obtain informed consent. All persons designated by the PI to obtain informed consent must complete all required HIC training and be listed as key personnel on the Medical/Behavioral Protocol Summary Form via submission or added later via amendment before those designees may obtain informed consent.

The PI must confirm that he/she has trained the individuals who will obtain informed consent, and each of those trained must be knowledgeable about the study and capable of answering study-related questions posed by the potential participant. In addition, all persons listed as investigators or key personnel on the protocol must have completed the required HIC on-line training with the Collaborative Institutional Training Initiative (CITI) before they can obtain informed consent or participate in any other aspects of the study.

The PI is responsible for making sure that only the most current version of the HIC-approved informed consent document bearing the HIC approval stamp be used. The person conducting the informed consent process must sign the informed consent document as the "person obtaining consent," as well as obtain the signature of the participant and/or their legally authorized representative. Unless informed consent is waived or altered, the authorized person obtaining informed consent must ensure that all study participants or their legal representatives sign and receive a copy of the HIC approved informed consent document. That person must also ensure that no human being is involved as a participant in a research study unless informed consent has been obtained and documented before entering the participant into a study and/or conducting any procedures required by protocol.

The person obtaining informed consent should also ensure that the participant or legally authorized representative (LAR) enters the date of signing next to their name and prints their name on the document as well. The research participant or LAR must initial each page of the consent document where required.

Consent Form Revisions

During the course of a study, it may become necessary to change some of the information in the informed consent document. This can be done by a consent form revision, an addendum, or notification to study participant or his or her legally authorized representative. Any revisions must be submitted to the HIC as an amendment for review and approval prior to use. Immediate hazards or issues of safety should be communicated to the participant upon receipt of the new information or as directed by the sponsor. The new information communicated to the participant or his or her legally authorized representative must be reported to the HIC as soon as possible. Please see HIC Policy/Procedure: "Adverse Reactions and Unexpected Events" for reporting requirements and time lines.

When there have been changes made to the informed consent, the correct revised version of the HIC informed consent document, stamped, "approved", must be utilized when enrolling any new participants in the study. While some informed consent changes may require re-consenting with a revised consent form or an addendum for ALL participants (e.g., discovery of a previously unknown serious side effect), not all affecting the risk/benefit ratio, patients no longer receiving study treatment). In cases where participants have completed active study or follow-up procedures and new safety information is discovered that may affect a participant's further participation or long-term risks from the treatment, the participant must be informed of this new information. The timeliness of informing participants and re-consenting will depend on the seriousness of the new information.