Wayne State University Human Investigation Committee	
Subject	Informed Consent Process
Form Date	October 23, 2006 (Rev. 03/07/11)
Approvals	Office of the General Counsel 2/8/07, Steering Committee 03/21/07, Administrative Approval 03/28/07, Administrative Approval 09/30/10, Administrative Approval 03/07/11

Background

Informed consent is one of the primary ethical requirements when conducting research involving humans; it reflects the basic principle of *respect for persons*. According to the federal regulations (45 CFR 46.116, 38 CFR 16.116, and 21 CFR 50.20), 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 (LAR). An investigator shall obtain consent only under circumstances that provide the prospective participant or his/her LAR with sufficient opportunity to consider whether or not to participate and has minimized the possibility of coercion or undue influence. The information that is given to the participant or the LAR shall be in language understandable to the participant or the LAR. See Human Investigation Committee (HIC) Policy/Procedures: "Informed Consent Options" for information about the informed consent document and "Obtaining Permission from Legally Authorized Representatives or Family Members" about who can serve in this capacity when a potential participant is not able to consent for him/herself.

Informed consent is a process that goes far beyond asking for the participant's signature on an informed consent document. It is an ongoing, interactive exchange of information that begins with recruitment of the participant and continues through the completion of the study.

Scope

This policy/procedure applies to all personnel who will be obtaining informed consent for research studies approved by the HIC, although the ultimate responsibility for informed consent lies with the Principal Investigator (PI) (see HIC Policy, "Principal Investigator: Roles and Responsibilities"). Personnel responsible for obtaining informed consent may include the principal investigator, co-investigator(s), and any key personnel that the principal investigator has delegated authority to obtain informed consent. For Veterans Administration Research, the PI must use VA Form 10-1086 and the informed consent must be reviewed by the John D. Dingell VAMC Clinical Investigation Committee.

HIC Policy/Procedure

The first step in the informed consent process is to provide potential participants with general information about the nature of the study and why they might be suited to participate. The recruitment flyers, websites, and phone scripts may be part of this process. All study specific recruitment materials must be reviewed and approved by an Institutional Review Board (IRB) prior to implementation. (See HIC Policy: "Advertising".)

Steps in the Informed Consent Process

Once a potential participant indicates an interest in joining a research study, the following must occur:

1. Details are presented by study personnel who are knowledgeable about both the study and the HIC requirements of informed consent process.

2. Adequate information is given concerning the research via the HIC approved informed consent document in a language that is as non-technical as possible.

3. Ample time and opportunity are provided for the potential participant or his/her LAR to inquire about the details of the research project and to decide whether or not to participate in the research, as well as to consider other available options, if applicable.

4. Potential participants or his/her LAR have asked questions and received answers to their satisfaction.

5. It is ensured, to the degree possible, that the potential participant has comprehended the information provided about the research.

6. The potential participant or his/her LAR voluntary consent is obtained by way of a signature on the informed consent document or as otherwise authorized.

7. Documentation is provided about the research that the participant can refer to later. This includes a signed copy of the informed consent document, calendars, instructions, etc. Note that all materials provided to participants require IRB approval.

8. Documenting that the informed consent process has occurred. This may be done in the research record, a narrative note in the medical record, or an entry onto a research worksheet kept in each participant's research file.

The HIC may at any time request that the informed consent process be observed and/or monitored [38 CFR 16.109(e), 45 CFR 46.109(e), 21 CFR 56.109(e)]. This activity may be carried out by the Sr. Research Compliance Specialist for the HIC or another individual as directed by the HIC.

The principal investigator and all research personnel are responsible for continuing the informed consent process throughout the individual's participation in the study, providing ongoing opportunities to reaffirm participation through the study, reminding the participant about important information and data collection points, and providing new information as it becomes available. All interactions with the participant are to be documented as appropriate.

At each study visit, participants are encouraged to ask questions about the study and their participation, and to raise any and all concerns. Thus, informed consent becomes an ongoing, interactive process, rather than a one-time information session.