

Guidance and Procedures Number: 54

Title: Consent Monitoring

Date of Last Revision: July 5, 2007

I. General Overview

The first principle of the Nuremberg Code indicates “the voluntary consent of the human subject is absolutely essential.” To ensure the rights of a subject is to acknowledge their dignity and autonomy. The Belmont Report highlights that the process of informed consent should include the following principles: (1) Information, a complete disclosure of the purpose, procedures, risks, benefits, alternatives, (2) Comprehension, the manner and context in which the information is conveyed, and (3) Voluntariness: conditions free from coercion and undue influence

The regulations of both the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) provide that an IRB “will have authority to observe or have a third party observe the consent process and the research” [45 CFR 46.109(e) & 21 CFR 109(f)].

Monitoring is implemented by the IRB to ensure the protection of the rights and welfare of human research subjects. Monitoring of the informed consent process may involve passive observation/witness or subject advocacy. The IRB determines the necessary level of monitoring, documentation, and reporting timelines. The informed consent monitor will be an individual who does not have a conflict of interest and does not have a direct relationship to the research subject or to the project.

II. Policies

- A. The IRB will determine if a specific research project requires the additional safeguard of a monitor to observe the consent process and/or serve as an advocate for the research subjects to ensure the protection of the rights and welfare of the subjects. This may include, but is not limited to the following:
1. Research where coercion or undue influence, though minimized through appropriate protocol procedures, remain concerns, such as when the investigator also has a professional relationship with the subject, (e.g., clinician/investigator). Examples include but are not limited to the following:
 - a. Situations where participation in research is the only available medical option and no standard care is available or proven effective.
 - b. Subjects who may be uncritically compliant to participate in research due to their illness or the prospect of receiving relief or “treatment” through research.
 - c. Research where the risk is such that a second party (i.e. consent monitor) functions as a subject advocate to enhance the informed consent process.

2. Potential subjects may include vulnerable populations. Examples include but are not limited to the following:
 - a. Subjects with limited or no resources.
 - b. Subject population (e.g., runaway minors) where sensitive surveys, interviews, interactions and/or interventions may pose more than minimal risk.
 - c. Subjects with diminished decision making capabilities.
 3. Situations where the IRB is concerned about the conduct of the study or the process of obtaining informed consent. Examples include but are not limited to the following:
 - a. Complaints from subjects or others regarding the conduct of the study.
 - b. Complaints from subjects or others regarding the consent process with the investigators.
 - c. Audit report to the IRB identifying problems with the execution of the consent process and document.
 - d. Review of violations or events of non-compliance identifying problems with the consent process or conduct of the study.
- B. The IRB may determine at any stage of the research review process the need for a consent monitor.
- C. The determination to remove the requirement of a consent monitor for specified research will be made by the IRB.
1. Reports from the consent monitor of the observations made during the consent process and/or "Summary of Consent Monitoring for Research" documents will be provided to the IRB.

III. Procedures

- A. The IRB will determine if a research project requires the use of a consent monitor to observe the consent process in order to provide additional protections to the rights and welfare of research subjects.
- B. Formal correspondence to the principal investigator will describe the IRB determination of the need and reasons for the requirement to use a consent monitor for the respective research project.
 1. The IRB will determine whether the principal investigator or the IRB will identify a consent monitor. The IRB will determine the time frame for the response from the principal investigator and must approve the suggested consent monitor candidate.
 2. If the principal investigator cannot identify a potential consent monitor within the prescribed response time, selected trained OPRS staff may serve as a consent monitor in the interim period.

- C. The IRB Approval Notice will have a codicil outlining the required utilization of the consent monitor.
- D. All potential consent monitor candidates will receive training from the OPRS. Training will include a review of the following:
 - 1. Monitoring Informed Consent
 - 2. Evaluation to Sign a Consent Form for Research
 - 3. Summary of Consent Monitoring for Research
- E. Consent Monitoring Process
 - 1. The principal investigator or designee will contact the consent monitor in advance of a consent session with a potential subject.
 - 2. The principal investigator or designee will provide (in advance) to the consent monitor a copy of the current approved informed consent document.
 - 3. The consent monitor has five principal duties (a) Listen (b) Observe, (c) Ask questions, (d) Document, and (e) Decide:
 - a. Listen: The consent monitor should listen to the consent process and exchange between the investigator and the subject and the subject's family.
 - b. Observe: The consent monitor should closely observe the communication between the investigator and the subject. The monitor should use her/his knowledge of the consent document and be prepared to ask questions of the investigator or the subject if it appears that things are not clear.
 - c. Ask Questions: The consent monitor should be prepared to ask questions in order to facilitate comprehension on the part of the subject. In order to understand whether the subject fully comprehends the research and is making a knowledgeable decision about participation, questions should elicit a response from the subject that requires some deliberation and thought about the research rather than yes/no questions.
 - d. Document: Document the interactions, questions, answers, and the decision making process.
 - e. Decide: Decide with the investigator and the subject whether the subject should be enrolled in the research, provided additional time to consider participation in the research, or should not be enrolled. The consent monitor may determine that a subject does not understand the consent process or the research and request that the investigator re-review the materials with the subject. If the monitor does not think the subject understands the research or all items of the consent document, then the subject should not be enrolled in the research.
 - 4. The investigator will introduce the consent monitor to the potential subject and provide an explanation for the consent monitor's presence.

5. The consent monitor will utilize a copy of the approved informed consent document during the consent process to assure that all elements of the consent document are addressed by the investigator.
 - a. At any time during the consent session, the consent monitor may request that the investigator review or clarify information for the potential subject and/or seek clarification of comprehension from the potential subject.
6. At the end of the consent session, the consent monitor will utilize the Evaluation to Sign a Consent Form for Research document to assess the potential subject's comprehension of the consent process.
 - a. The potential subject will be asked the questions on the evaluation form by the consent monitor.
 - b. The consent monitor may ask additional questions, as necessary.
7. The consent monitor will prepare a brief Summary of Consent Monitoring for Research document for IRB review.
 - a. The consent monitor will forward the completed Summary of Consent Monitoring report to IRB staff.
 - b. The Summary of Consent Monitoring will be maintained in the specific IRB research protocol file.
8. The Summary of Consent Monitoring for Research report will be reviewed by the IRB at an identified interval (e.g., every five subjects) as determined by the IRB

Regulations:

45 CFR 46.109(e)
45 CFR 46.111(b)
21 CFR 56.109(f)
21 CFR 56.111(b)

References:

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979. <http://hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

U.S. Office for Human Research Protections' (OHRP, formerly OPRR) *Protecting Human Research Subjects Guidebook* (1993). http://www.hhs.gov/ohrp/irb/irb_chapter3.htm

FDA, IRB Information Sheets: Frequently Asked Questions, September 1998. <http://www.fda.gov/oc/ohrt/irbs/faqs.html>