Marshfield Clinic

Informed Consent of Illiterate or Legally Blind Research Subjects

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Engaged in Research:

- To intervene or interact with human subjects, or obtain individually identifiable private information about human subjects, for purposes of research.

2.2. Human Subject:

- A living individual about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information.

2.3. Illiteracy

- The condition of being unable to read and write.

2.4. Legally Authorized Representative:

- An individual, judicial body, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in research.

2.5. Research:

- A systematic investigation, the including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

3. RESOURCE GUIDE BODY

Investigators and staff who are engaged in research at Marshfield Clinic may encounter the occasional individual who wants to participate in research, but who is unable to take part in the standard informed consent process due to blindness or illiteracy. Procedures must be in followed to ensure that informed consent obtained from such subjects is effective, and that the subjects are able to comprehend study information, evaluate the risks and benefits of participation, and document approval to participate. This guidance outlines the procedures that investigators and staff must follow to obtain effective informed consent from individuals in these populations for the occasional and unanticipated subject.

3.1. Federal Regulations and Guidance

a. Informed Consent Documentation

- Federal regulations at 45 CRF 46.117 and 21 CFR 50.27 require documentation of informed consent, either in the form of:
  - A written consent document embodying all of the required elements of informed consent; or

- A short form written consent document including a statement that the informed consent elements have been verbally presented to the subject or legally authorized representative. When a short form is used with verbal presentation, the following must occur:

  The IRB must approve a written summary of what is to be said;

  There must be a witness to the oral presentation;

  The witness must sign both the short form and a copy of the summary;

  The subject or legally authorized representative must sign the short form;

  The person obtaining consent must sign a copy of the summary; and

  A copy of the summary and short form must be given to the subject or legally authorized representative.

b. Food and Drug Administration Guidance on Illiterate Subjects

- The FDA has issued guidance stating that a person who speaks and understands English, but who does not read and write, can be enrolled in research by "making their mark" on a consent document, if consistent with applicable state law. Based on cases from the late 1800s, Wisconsin law appears to accept the "making of a mark" as a valid signature, so long as the person understands what they are signing, or in the case of research, what they are consenting to.
- FDA guidance also clarifies that a separate short form or narrative statement is not required in order to enroll subjects who cannot read or write. However, an impartial witness must attest to the adequacy of the consent process and the subject's voluntary agreement. Three signatures are also required to be on the informed consent document (21 CFR 50.27(b)(2)): that of the subject or legally authorized representative, the witness, and the person obtaining informed consent.
- Further, FDA guidance confirms that a person who can understand and comprehend spoken English, but who is physically unable to talk or write, can be enrolled in research if they are competent and able to indicate approval or disapproval by other means. This means they may be enrolled if they can understand the study's concepts, evaluate the risks and benefits of entry when explained verbally, and indicate approval or disapproval to entry. The consent form should document the method used to communicate with the prospective subject, and the specific means by which the subject communicated agreement to participate. An impartial third party should witness the entire consent process and sign the consent document. A videotape recording of the consent interview is also recommended.
- FDA guidance cautions investigators considering to enroll subjects who may not truly understand what they have agreed to. It directs IRBs to consider illiterate persons as likely to be vulnerable to coercion and undue

influence, and should determine that appropriate safeguards are in place when enrollment of such subjects is anticipated.

- The DHHS Office for Human Research Protection (OHRP) has not released guidance on the enrollment of subjects who cannot read or write.

c. FDA and OHRP have no regulations or guidance specific to the circumstance of obtaining informed consent from legally blind research subjects.

3.2. Procedures for Obtaining and Documenting Informed Consent

a. All investigator and research staff participating in the informed consent process must be aware that he or she is not to enroll any subject if they feel that the potential subject's illiteracy, blindness, or physical inability to write or speak, creates such a barrier that truly informed consent cannot be obtained.

b. Unless otherwise noted at the time of IRB review and approval of a study, investigators must use the following procedure to enroll potential research subjects who are illiterate or legally blind:

- As part of the informed consent process, the IRB-approved consent document must be read to the prospective subject in its entirety.
- An impartial third party witness must witness the reading of the IRB-approved consent document and the subsequent conversation about the information contained within. The witness may not be a family member of the subject. The role of the witness is to attest to the apparent understanding of the prospective subject and their willingness to participate.
- The IRB-approved consent form must be used to document the informed consent process.
- The subject and the person obtaining consent must sign the consent form if they are able to do so. The subject may use an "X" or other mark in place of an actual signature if he or she is unable to sign, so long as the subject understands what has been read to them.
- The witness must also sign the consent form, attesting that the document was read in its entirety to the subject, and that the subject agreed to participate.
- The subject and the witness must both be given a copy of the signed consent form.
- The IRB's determination regarding assent requirements for subjects who are younger than 18 years old must be followed for illiterate and legally blind subjects. The assent form must be read to the minor subject, and the subject must sign or make their mark on the assent form.

3.3. If an investigator wants to enroll a person who can understand and comprehend spoken English, but who is physically unable to speak or write, the investigator must consult the Office of Research Integrity & Protections.

4. ADDITIONAL RESOURCES

4.1. IRB Forms for Submission
- IRB Consent Template

4.2. References:
- Informed Consent
- Vulnerable Populations

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #701.3 (no changes made)
2.0	Add hyperlink to applicable IRB forms and other policies referenced in this document.

6. DOCUMENT PROPERTIES

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