

Wayne State University Human Investigation Committee	
SUBJECT	Obtaining Permission from Legally Authorized Representative or Family Members (When Participants (Subjects) Themselves are Unable to Give Consent)
Section	
Form Date	
Approvals	Approved by Steering Committee 8/12/98, Approved by All IRB Committees 9/3/98, Administrative Approval 10/30/98

Background

There are circumstances in which informed consent may be waived when subjects are unable to give informed consent to participate in research (due to poor medical condition, etc., see below). Michigan state law is silent on this issue, so deference is given to federal law. Sections of 45 CFR 46 (116 and 117) state that an IRB may waive or alter a requirement for informed consent procedure--in IRB-approved research--under specific circumstances. These are discussed below. In all instances covered in this policy and procedure, informed consent must be sought from a legally authorized representative of the subject, although in some circumstances, a family member's consent may suffice (see Definitions). In "Emergency Care" protocols, covered under a separate policy, (See HIC Policy and Procedure: Planned Emergency Research") subjects who are anticipated to be both unable to give consent and unlikely to be accompanied by a legal representative or family, may be enrolled in the study when certain conditions are met.

Scope

It is essential to differentiate between the issues discussed in this policy/procedure and those included under the HIC Policy/Procedure: "Single Time Emergency Use of a Test Article". The latter concerns the single time use of a test article in situations where the proposed use has *not* received prior IRB approval. In contrast, the issues discussed in this policy, "Obtaining Consent from Legally Authorized Representatives or Family Members (When Subjects Themselves are Unable to Give Consent)", relate to *research studies that have already been approved* by the IRB. In both cases consent must be documented.

Definitions

Legally Authorized Representative – an individual or judicial 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 the research (45 CFR 46.102). In the case of children, this would be a parent or legal guardian. For adults, a legally authorized representative would have durable power of attorney for health care for the subject or some other court order authorizing him/her to be the legal representative.

Family Member – Includes the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship

HIC Policy

There are two types of research protocols that may involve subjects who are unable to give consent :

- Where their medical condition resulting from disease, trauma, foreign substance(s), or
- Other causes of cognitive impairment that render them incapable of giving true informed consent.

The first category, which is specifically covered by this policy, includes HIC-approved research protocols in which most subjects are expected to be able to give informed consent, but in which one or more subjects who are eligible for the protocol are incidentally unable to give informed consent. Requirements for obtaining informed consent in this category of protocols are described below.

The second category, covered in a separate policy, includes protocols that are anticipated to involve a majority of subjects who will be unable to give informed consent (See HIC Policy/Procedure: "Planned Emergency Research). The latter protocols require prior community hearings and approval as well as HIC and WSU administrative approval.

A legally authorized representative may consent to enrollment in any research protocol that has had prior HIC approval. If the risk is minimal, and there is no legal representative, then a family member may "consent" (although strictly speaking, the family member cannot give true informed consent but must participate in the informed consent process and then be given an opportunity to object to the subject's participation.) If the risk is more than minimal, but there is a reasonable expectation of a direct benefit to the subject, then a family member's "consent" is sufficient. *If neither a legal representative nor a family member is available, then a subject may not be enrolled in any research protocol covered by this policy.* Guidelines for waiver of consent in Emergency Care Research are distinct from this policy.

Investigators' Responsibilities

If a legally authorized representative or family member is told about the research and the subject's condition improves, the subject is also to be informed as soon as is feasible. The investigator must also inform the subject or, if the subject remains incapacitated, a legally authorized representative or a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. These procedures must be described, for each subject enrolled in a protocol with waiver of consent, in the application for Continuation of a Research Protocol (annually, or as otherwise directed by the HIC at the time of approval.)

Additional HIC Responsibilities

The IRB is responsible for ensuring that procedures for the requirements described above are followed appropriately. Protocols that are known to include subjects unable to give consent may be reviewed for Continuation by the HIC more often than every 12 months. In addition, the Steering Committee of the HIC may review the continuation reports in order to monitor compliance with HIC policies.

Waiver of Consent of Participants (Subjects) in Research

Informed Consent must be obtained from all adult subjects who are mentally capable of providing their effective informed consent to participate in the proposed research. For adult subjects who are **not** capable of providing effective informed consent due to mental incapacity, there are four possible avenues that may allow their participation in research trials. (See HIC Policy/Procedure: "Informed Consent Options".)

1. A legally authorized representative* may consent to enroll a subject in any research protocol that has had prior approval by the Human Investigation Committee (HIC).
2. If there is no legal representative* present, a family member** who is involved with medical decision making for the subject, may consent to HIC approved research if the risk is minimal (benefit irrelevant)
3. If there is no legal representative* present, a family member** who is involved with medical decision making for the subject may consent to HIC approved research if there is greater than minimum risk involved but the research potentially has direct benefit to the subject
4. Subjects who are anticipated to be both unable to give consent and unlikely to have a legal representative or a family member present to give consent, may be enrolled in a Planned Emergency Research Protocol if the protocol has had prior community hearings and approval, and HIC and WSU administrative approval.

NOTE: if there is no Legally Authorized Representative* or Family Member present and if the research is not covered under "Emergency Care Protocols" (see # 4 above), THE SUBJECT CANNOT BE ENROLLED IN ANY RESEARCH PROTOCOL.**

* Legally Authorized Representative refers to an individual or judicial 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 the research (45 CFR 46). In the case of children, this would be a parent or legal guardian. For adults, a legally authorized representative would have durable power of attorney for health care for the subject, court-appointed *legal guardianship for the subject* or *some other court order authorizing him/her to be the legal representative*.

*** Family member includes the following legally competent persons: spouses; parents; children (including adopted children); brothers, sister, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.*