WAYNE STATE UNIVERSITY

HIC Policy/Procedure

Wayne State University Human Investigation Committee	
Subject	Obtaining Permission from Legally Authorized Representatives or Family Members
Form Date	June 2008 (Rev. 03/07/11)
Approvals	Steering Committee 08/12/1998; All IRB Committees 09/03/1998; Administrative Approval 10/30/1998; General Counsel 02/2008, Administrative Approval 9/30/10, Administrative Approval 03/07/11.

Background

When prospective research participants are unable to give consent, they may only be enrolled in a research project if permitted by an advance directive (e.g., living will, durable power of attorney for proxy consent) or if consent is obtained from the legally authorized representative. In the case of a child, only the parent(s) or the legal guardian can provide consent. Proxy consent may only be requested and permitted when the prospective research participant is incompetent or has an impaired decision-making capacity: (1) as documented in the potential participant's medical record and based on a previously verified determination; or (2) as determined by the Investigator using an IRB-approved method of determination; and (3) according to all pertinent federal, state, and local laws and regulations (see also, "Vulnerable Subjects: Children", and "Vulnerable Subjects: Cognitively Impaired and Mentally Disabled").

Definitions

Advanced Directive – Legal statements that allow persons to articulate values and establish treatment preferences to be honored in the future when capacity has lapsed.

Incapacitated Individual – An individual who is impaired by reasons of mental illness, mental deficiency, physical illness or disability, chronic use of rugs, chronic intoxication, or other cause, not including minority, to the extent of lacking sufficient understanding or capacity to make or communicate informed decisions.

Legally Authorized Representative – As defined by DHHS and FDA regulations means 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.

Legally Authorized Representative – Michigan - When the research is limited to medical procedures, the individuals who meet the definition of Legally Authorized Representative are, in descending order of priority:

1. The person's agent pursuant to an advance health care directive or power of attorney;
2. The conservator or guardian with the authority to make health care decisions for the person;
3. The spouse of the person;
4. An adult son or daughter of the person;
5. A custodial parent of the person;
6. An adult brother or sister of the person;
7. An adult grandchild of the person;
8. An available adult relative with the closest degree of kinship to the person.

If the proposed research is non-medical, the Legally Authorized Representative may be:

1. The conservator or guardian with the authority to make all decisions regarding the incapacitated or developmentally disabled individual;
2. The spouse of the person'
3. An adult son or daughter of the person;
4. A parent of the person;
5. Any adult brother or sister of the person'
6. Any adult grandchild of the person;
7. An available adult relative with familiarity with the patient with the closest degree of kinship to the person.

The highest ranking proxy has the final decision making authority. Documentation of that authority must be provided to the IRB and maintained in the record. If there is conflict between equally ranked proxies, a legal decision by the court may be necessary.

VA recognizes a close friend as the lowest ranking Authorized Person [HA Handbook 1200.05 36.c.(d)].

Guardian DHHS – An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care [45 CFJT 46.402(e)].

Guardian FDA – An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. For purposes of Subpart D of this part, a guardian also means an individual who is authorized to consent on behalf of a child to participate in research [21 CFR 50.3(s)].

In Michigan, a guardian is a person who:

1. Has accepted a written parental appointment to be a guardian and there are no surviving capacitated parents with parental rights; or
2. Has accepted a court appointment to be a guardian.

For purposes of the DHHS regulations, a guardian does not include a limited guardian unless the limited guardianship expressly allows the guardian to consent to medical care.

For purposes of the FDA regulations, a guardian does not include a limited guardian unless the limited guardianship expressly permits the guardian to consent to participation in research.

Living Will – A living will lists the interventions the patient would request, accept, or reject in the future – usually at the end of life.

Durable Power of Attorney (Michigan) – A document by which an individual designates, in writing, another individual to act as their agent or attorney in fact. The document or designation gives the agent the power to act on the individual's behalf regarding their physical care and management (MCLA 700.5501 et seq.). Along with the durable power of attorney, an individual may designate an individual as a patient advocate.

Patient Advocate – An individual who is 18 or older who has been designated, in writing, by a patient, 18 or older, to exercise powers concerning care, custody, and medical or mental health treatment decisions for the individual making the patient advocate designation (patient) (MCLA 700.5506). The patient advocate's restrictions do not specifically exclude research decisions [MCL 700.5501-5512].

Research Conducted Outside of Michigan

When a research subject is unable to provide consent and the research is conducted outside of Michigan, investigators must describe how pertinent laws and regulations in that jurisdiction apply to their research and provide supporting documentation to that affect (e.g., copies of national, state, or local law, or opinion of legal counsel). The Office of General Counsel or attorney representatives on the IRB must review the documentation and determine if the research complies with DHHS/FDA based on the law of the jurisdiction in which the research is conducted and provide the IRB with verification of approval.

HIC Policy

Investigators' Responsibilities

If a legally authorized representative 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, 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. All research studies involving consent by Legally Authorized Representatives or Guardians will receive a full board review.

- The IRB will require a complete and standardized evaluation of the capacity of the subject's ability to understand the consent process and sign an informed consent. The evaluation method should be one that has been referenced for use in the particular field of medicine. The explicit method for the evaluation should be provided to the IRB, and results should be documented in the medical and research record.
- When determined appropriate the IRB will allow a legally authorized representative of guardian authorized to make decision about medical care, to sign the consent. The PI must document in the medical and research record who is legally authorized to make medical decisions.
- Whenever possible, the subject should be approached concerning research assent and the assent submitted to the IRB. The IRB must determine whether the assent of the subject is a requirement and, if so, whether the plan for assent is adequate.
- The wishes of the research participant take precedence regardless of proxy consent.
- 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.