

Wayne State University Human Investigation Committee	
<b>Subject</b>	<b>Vulnerable Participants: Cognitively Impaired and Mentally Disabled</b>
<b>Form Date</b>	January 4, 2010 (Rev. 03/07/11)
<b>Approvals</b>	08/11/99 – Revision Approved by Steering Committee Version 0.2, 09/02/99 – Approved by all IRB Committees, 10/25/06- OGC Approval, 11/17/06- Revision Steering Committee, 12/05/06-Revision Administrative Approval, 01/04/10 Revision Administrative Approval, 9/30/10 Administrative Approval 03/07/11

## Background

There are no specific federal regulations concerning the inclusion of cognitively impaired or mentally disabled participants. These vulnerable participants have the same rights as other individuals to participate in research, but special care must be taken to avoid coercion.

The purpose of some research protocols involving cognitively impaired or mentally disabled participants will specifically focus on their special problems. Some examples include, but are not limited to, some patients with dementia, schizophrenia, delirium, mental retardation, bipolar disorder and stroke. Other protocols may include a variety of participants and only incidentally include vulnerable participants. In either case, special considerations must be made to ensure that the informed consent process is adequate and appropriate. For research following Good Clinical Practice (ICH-GCP guidance E6) guidelines, as with all research conducted at WSU, clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with GCP and the applicable regulatory requirements.

## Definitions

For the purposes of the HIC policy, two groups of cognitively impaired/mentally-disabled participants are recognized:

***Institutionalized*** – non-voluntary and/or dependent residence in an "institution" (including hospitals, group homes, etc.), who may not be competent to give informed consent.

***Non-institutionalized*** – inpatients and outpatients who are free-living but who may not be competent to give informed consent

## HIC Policy

It is important but not always obvious to recognize a prospective participant who is cognitively impaired/mentally disabled. If a Principal Investigator (PI) either knows or suspects that a participant falls into these categories, he/she or his/her designee must determine whether the individual is able to give informed consent.

The specific procedures to be used to determine competence to give informed consent must be described in the protocol. If the participant is not able or legally authorized to give informed consent, then the PI must determine whether there is a legally authorized representative for the participant. For most institutionalized participants and some inpatients, this information will be part of the medical record or patient file. In many cases, the legally authorized representative may already be present at the interview. If neither is the case, the investigator or designee must ask the participant, with a reasoned and sensitive approach, whether he/she has a legally authorized representative or family member who is usually involved in decisions about his/her health and other important matters.

Another issue is whether assent (written or oral) must be obtained from a cognitively impaired or mentally disabled participant whose legally authorized representative is willing to give consent for the participant to participate. The final decision should include considerations of the risks and benefits expected from participation in the proposed research as well as the ability of the research participant to give written or oral assent.

If a PI identifies a research participant that is cognitively impaired or mentally disabled on a research protocol that had not been identified in the HIC submission as using cognitively impaired or mentally disabled research participants, the PI may enroll up to three research participants in the research protocol under the policy involving "Obtaining Permission from Legally Authorized Representatives or Family Members". After the third patient, the PI must amend his/her HIC protocol to include the enrollment of research participants that are cognitively impaired or mentally disabled. For VA research, there must be a prior IRB determination that criteria are met before any surrogate consent may be obtained.

## HIC Procedure

If the HIC Medical/Behavioral Protocol Summary Form indicates that cognitively impaired or mentally disabled persons are to be included in the research, then the investigator must: (1) describe any special procedures or circumstances that apply to the recruitment of a prospective participant, (2) describe the method for identifying his/her legally authorized representative, if any, and the method for obtaining their consent, (3) include in the submission the specific instrument/assessment tool that will be used to determine a person's ability to consent and (4) describe any special precautions that will be taken when obtaining informed consent. Additionally, the consent form must include the following:

1. A signature line for the legally authorized representative (if not available, see policy on "Obtaining Permission from Legally Authorized Representatives or Family Members When Participants Themselves are Unable to Give Consent"),
2. Documentation by investigator that the participant has assented when he/she is functionally able to assent as described by the following rules:

- a. If there is a reasonable probability of benefit to the participant from participation in the research, OR there is little direct benefit but minimal risk, the legally authorized representative's consent is sufficient and written assent is not necessary. Oral assent would be sufficient.
- b. If there is no reasonably expected benefit to the participant and more than minimal risk, the participant's written assent, whenever possible, must be obtained in addition to the consent of the legally authorized representative.
- c. At the end of the informed consent document, in addition to the signature line for the PI or his/her designee, the PI must document whether the participant is or is not competent to sign the informed consent and indicate this determination with his/her signature.
- d. If, during the course of the research, the cognition of the participant changes and he/she becomes able to consent for themselves, the participant should be re-consented and the process noted in the research record. The method used to assess the change in decision making capacity should be the same procedure described in the initial submission.

For Veteran Administration Research [1200.05 49]:

1. Limit consent by a legally authorized representative to situations where the prospective participant was incompetent or had impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note
2. When feasible, the practitioner must explain the proposed research to the prospective participant even when the surrogate gives consent
3. Prohibit participants from being forced or coerced to participate in a research study
4. Require the determination that a participant was incompetent or had an impaired decision-making capacity be made by a legal determination or a determination by the practitioner, in consultation with the chief of service, after appropriate medical evaluation that the prospective participant lacks a decision-making capacity and is unlikely to regain it within a reasonable period of time.
5. If the determination that the prospective participant lacks decision-making capacity is based on a diagnosis of mental illness, require consultation with a psychiatrist or licensed psychologist to be obtained.
6. If the participant's decision making capacity changes during the course of the study, the participant should be given the opportunity to re-consent.
7. When there is a possibility that a subject may lose the capacity to consent during research participation (e.g., with early Alzheimer's or unstable schizophrenia) the IRB may require a timeline to reevaluate the capacity of the subject's ability to understand the consent process and sign an informed consent since the subject's capacity may fluctuate.
8. The IRB will determine whether the medical record has to be flagged to protect the participant's safety by indicating participation in the study and the source of more information on the study. However, the IRB may not require the medical record to be flagged if the following are met:
  - Participation in the study involves only one encounter.
  - Participation in the study involves the use of a questionnaire or previously collected biological specimens.
  - Identification as a participant in a particular study will place the participant at greater than minimal risk.
9. The IRB must find and document the following when research involves persons with impaired decision making capacity:

- Only incompetent persons or persons with impaired decision making capacity are suitable as participants.
- Competent persons are not suitable for the proposed research.
- The investigator has demonstrated to the IRBs that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as participants.
  - Incompetent persons or persons with impaired decision-making capacity are not being proposed as participants simply because they are readily available.
  - The proposed research entails no significant risks, tangible or intangible, or if the research presented some probability of harm, there has to be at least a greater probability of direct benefit to the participant.
  - The research does not impose a risk of injury, unless the research is intended to benefit that participant and the probability of benefit is greater than the probability of harm.
  - Procedures are devised to ensure that participants' legally authorized representatives are well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. Legally authorized representatives are told that their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant's wishes could not be determined, what they think is in the incompetent person's best interest