Marshfield Clinic

Adults Lacking Capacity to Consent

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Coercion

- The real or perceived use of overt or implicit threat of harm, intimidation, or other pressure or force to make someone comply

2.2. Human Subject

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

2.3. Legally Authorized Representative (LAR)

- An individual or judicial or other body authorized under applicable law or institutional policy, to consent to research participation on behalf of a prospective participant who lacks capacity to consent.

2.4. Research

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

2.5. Undue Influence

- Asserting advantage of a position of authority or power or offering an excessive, unwarranted, inappropriate, or improper incentive.

3. RESOURCE GUIDE BODY

Research involving vulnerable populations must include additional protections to minimize the possibility of coercion or undue influence. Federal regulations provide specific protections for some such groups. However, other groups not specified in the regulations may also be considered vulnerable, including adults not capable of providing legally effective informed consent for research. This guidance describes how adults who lack capacity to consent (ALCC) may be enrolled in research, the types of research in which such adults can be enrolled, procedures to assess capacity to consent, and who can serve as a person's Legally Authorized Representative (LAR) for enrollment purposes. It also outlines additional protections that investigators and the Marshfield Clinic Research Foundation Institutional Review Board (MCRF IRB) may consider to protect the vulnerable population.

3.1. When Adults May Lack Capacity to Consent

a. Adults may be unable to give effective informed consent for research participation as a result of conditions or situations that impair their cognitive or emotional functions, thus diminishing judgment and reasoning abilities. Diminished decision-making capacity may be temporary, permanent, progressive, or fluctuating. Some of the conditions that might cause an individual to exhibit impaired decision-making capacity include: delirium, dementia, acquired brain injury, intoxication, psychosis, coma, and mental retardation. As a general rule, MCRF IRB considers adults who are unable to consent to their own clinical care also unable to consent to research participation. Capacity to consent must be assessed by following the procedures outlined in 3.3, below.

b. When a loss of capacity to consent is temporary, and incapacity is likely to be of short duration, whenever possible, investigators and staff should wait until the adult regains capacity to obtain consent from the adult. Moreover, if an adult is initially enrolled in research by a LAR, while incapable of providing consent, but later develops or regains capacity, verification and documentation of informed consent must be received from that adult if the research is ongoing.

3.2. Research In Which Adults Lacking Capacity To Consent May Be Enrolled

a. Subject to MCRF IRB approval, and to the other requirements outlined in this document and in the document, "Vulnerable Populations," ALCC may be enrolled in the following types of research:

- Minimal risk research that may help the individual or others;
- Research involving greater than minimal risk but holding out a prospect of direct benefit to the person when a comparison of the risks to anticipated benefits is at least as favorable as that presented by alternative standard approaches;
- Research involving greater than minimal risk and not holding out a prospect of direct benefit, but likely to yield generalizable knowledge about the person's disorder or condition to help others if:
  - The person's Legally Authorized Representative (LAR) has indication that the ALCC would have elected to participate in such research, and
  - The proposed research is reviewed and approved by MCRF IRB consistent with federal human subjects protections regulations.

b. ICH GCP guidelines state that if research does not present a therapeutic value to research participants, ALCC should only be enrolled if the study objectives of the trial cannot be met with participants who can personally give informed consent, the foreseeable risks to participants and negative impacts on their well-being are minimized and low, the research is not prohibited by law, and the approval of the IRB expressly includes such subjects, and the written IRB approval covers this aspect.

c. If, prior to incapacity, the adult indicated a preference not to participate in research, that preference prevails even if the adult's LAR wants to enroll the adult in research.

3.3. Assessing Capacity to Consent

a. Generally, any adult is presumed capable of providing effective informed consent unless there is:

- Documentation of a court-appointed Guardianship of the Person;
- Activated Power of Attorney for Health Care (two physicians, or one physician and one licensed psychologist, determine in writing that the principal lacks capacity, attached to the power of attorney instrument); or
- There is evidence that a condition or disability impairs the adults' reasoning or judgment, or there are demonstrated and documented indications that he or she is unable to understand and choose whether or not to participate. [Investigators and staff must consider the current capacity of all potential participants encountered, and should be cognizant that decision making capacity can fluctuate (see 3.1.a, above).]

b. The IRB will consider how capacity will be assessed based upon the nature of the research and the anticipated cognitive status of the population to be studied, and the contents of the proposed plan provided by the investigator. Various methods of assessment such as psychological evaluation, physician determination of cognitive status, or a less formal assessment such as personal interaction with the potential subject may be appropriate.

- An assessment must take place before investigators or staff can obtain informed consent from the person's LAR.

c. All documentation of assessments conducted must be maintained in the study records.

d. Ongoing Assessment

- During the ongoing conduct of research, investigators and staff should be cognizant of any changes in status of Guardianship or any activation of a Power of Attorney for Health Care.
- If during the course of the research a participant demonstrates signs or indications of possible diminished capacity, an assessment may be required to determine whether a LAR is required to make ongoing decisions about research participation.
  - If the research is approved for enrollment of ALCC, the IRB-approved plan for assessment should be followed.
  - If the research is not approved for enrollment of ALCC, an IRB amendment must be submitted including a plan to assess capacity.

3.4. Who Can Serve as the LAR

a. These individuals can generally serve as a LAR, in the following order of priority:

- Designated Guardian of the Person, or
- Designated Agent under an Activated Power of Attorney for Health Care, to the extent the decision to enroll in the research is consistent with the Power of Attorney document, or
- Next of kin (in the following order):
  - Spouse

- Adult child
- parent

b. The investigator or staff should instruct the LAR that he or she should make a decision about research participation based on what the adult lacking capacity would have decided if known, as well as on what is in that adult's best interest.

3.5. Additional Safeguards to Protect Adults Lacking Capacity to Consent

a. When research involves ALCC, MCRF IRB will consider additional protections to minimize the possibility of coercion and undue influence. Additional safeguards that investigators can incorporate in the study plan, and that MCRF IRB will consider, may include, but are not limited to:

- Requiring a third party to observe the consent process and/or research interventions;
- Involving in the IRB review, a member, or a consultant, who has background, knowledge, and/or experience working with the vulnerable population;
- Involving participant advocates in the research;
- Using informational/educational techniques to enhance understanding;
- Implementing waiting periods regarding when informed consent is presented and obtained; and
- Obtaining verbal assent from participants in addition to obtaining informed consent from a LAR.
  - An adult unable to give effective informed consent for research may still be able to assent to participation. MCRF IRB will consider the level and nature of diminished capacity when determining whether assent is required.
  - When assent is required, it will be verbal and will focus on what specific inconveniences or discomforts that the participant may experience as part of the research. If assent will be obtained, the IRB may require an outline of the information to be given to the participant.

b. An outward display of dissent from the participant during the assent process should be taken as an indication that enrollment should not proceed. In cases where ALCC's assent to participate in research is required by the IRB, consideration must be given to initial, as well as subsequent, expressions of dissent.

- Because expressions of dissent may occur after the research intervention has begun, LARs and researchers must attempt to recognize signs of dissent and respect the adult's right to stop participating.

c. The MCRF procedure "Vulnerable Populations" has additional information regarding IRB considerations of such additional safeguards.

4. ADDITIONAL RESOURCES

4.1. References:

- None

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #5265.1
2.0	Add hyperlinks to Vulnerable Populations policy & ICH GCP Guidelines

6. DOCUMENT PROPERTIES

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