

| Grand Valley State University Institutional Review Board | |
|--|---|
| Title: <i>Research Involving Participants with Questionable Consent Capacity and/or Legally Authorized Representatives [Pre-Revised Common Rule Version]</i> | |
| Section: 813a. | This policy and procedure supersedes those previously drafted |
| Approved by HRRC: 04/10/2012 Revised: 08/01/2012 Reviewed: 10/28/2014 Revised by HRRPPC: 03/28/2018 Revised by IRBPPC: 02/03/2025 | Approved by RIO/HRPA: 04/18/2012 Revisions Approved: 08/01/2012 Revisions approved by AIO/RIO: 04/10/2018 Revisions approved by IO: 06/15/2025 |
| Effective Date: 06/15/2025 | |
| Related Sections: 710: <i>Assessing Risk to Research Participants</i> 720: <i>Assessing Risk to Vulnerable Participants</i> 810a: <i>Informed Consent: General [Pre-Revised Common Rule Version]</i> 812: <i>Research Involving Children</i> 814: <i>Informed Consent for Persons Not Fluent in the Primary Language of the Study</i> 820a: <i>Waivers, Alterations and Exceptions to Informed Consent Process and Documentation [Pre-Revised Common Rule Version]</i> G-10: <i>Guidance on Working with Older Adult Participants</i> | |

Policy

1. Research studies that target or are likely to include persons who may lack ethically valid capacity to provide consent or assent at the time of enrollment in the research or while enrolled in the research must include a detailed plan for initial and ongoing assessment of participants' capacity. Absence of refusal to participate is not sufficient; affirmative consent or assent is required, as appropriate.
2. The plan must address the need to provide both initial and ongoing assessment and monitoring throughout the study duration, as well as procedures to follow if the determination of capacity to consent or assent to enroll, remain in, or withdraw from the research is reasonably uncertain.
3. The plan should clearly indicate who will conduct the assessments and what their qualifications and training are for doing so. In addition, the plan should include how the subjects' responses will be monitored and the plans to withdraw or discontinue the study temporarily or permanently if indicated.

Procedures

1. Assessing consent capacity to enroll, continue and withdraw participation in research activities.

A standardized plan to assess for consent capacity should be identified in the research protocol. The plan should address relevant assessment instruments and processes and the timeline for assessment, in addition to a plan to obtain consent from a legally authorized representative and assent from the research subject (if appropriate) when consent capacity is lacking.

2. Identifying appropriate legally authorized representatives (LARs)

- a. It is generally accepted that when individuals lack consent capacity the most ethically justified mechanism for enrolling them in research is through the use of a surrogate decision maker, specifically a LAR. The definition of a LAR is identical for both the Department of Health and Human Services (DHHS) at 45 CFR 46.102(c)) and the Food and Drug Administration (FDA) at 21 CFR 50.3(l): “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.”
- b. In Michigan, there is an established judicial review process for identifying and appointing a LAR for medical care and other important decisions. The authority of an LAR to make medical care decisions, financial management authority, residence decisions and related protections are individually specified at the time of appointment, but participation in research typically is not included. It is reasonable to permit someone who could consent to medical care for that person to serve as the LAR and provide consent for their participation in the research.
- c. Consistent with Michigan law, the following individuals, in descending order of priority, may serve as LAR for medical care decisions:
 - i. Durable power of attorney for healthcare (i.e., the individual identified in a written patient advocate designation)
 - ii. A guardian or conservator with the authority to make health care decisions for the patient
 - iii. The spouse of the patient
 - iv. An adult child of the patient
 - v. An adult grandchild of the patient
 - vi. A parent of the patient
 - vii. An available adult relative familiar with the patient and with the closest degree of kinship to the patient

Note: Depending upon the situation, Michigan law may specify a different order of priority when the patient has a terminal illness.

- d. When a study requires an LAR, the investigator may wish to seek opinions from legal counsel to determine whether an individual is an appropriate LAR under the law in a given jurisdiction.
- e. The IRB determines when the use of an LAR to obtain research consent is appropriate for a given study. The researcher(s) and the LAR shall honor any of the participant's previously expressed wishes concerning participation in research.
- f. If an adult participant regains the ability to provide legally effective informed consent after their participation in a research study has begun, and the study intervention(s) or interaction(s) are continuing, the researchers must re-consent the participant at that time in order for them to remain in the study, unless the IRB grants a waiver of consent.
- g. Laws regarding LARs are location/locale specific (state, country, territory, etc.). When conducting research in other locations, the laws regarding LARs for that location should be followed and must be described in the research protocol.

3. Obtaining consent, assent and permission

The consent document and any other written information that is normally provided to study participants must be provided to the participant's LAR who should participate fully in the consent process. The LAR must indicate permission to enroll the participant with diminished consent capacity in the research by signing and dating the consent/permission document. The prospective participant should be present for the consent discussion and asked to assent to participate. Any objection by the prospective participant to involvement in the study should be respected, even if the participant has diminished mental capacity to provide legally effective consent. Use of the short consent form for communicating with the participant may be helpful. See IRB Policy 820: *Waivers, Alterations and Exceptions to Informed Consent*.

Background

1. Informed consent in the research context is based on the principle that adult individuals should be allowed to make their own decisions about participation so long as it is reasonable to presume that the balance of risk to benefit is either neutral or potentially favors benefit to the participant. The Belmont Report principle of respect for persons is the ethical touchstone for all research: "*first, ... individuals should be treated as autonomous agents, and second, ... persons with diminished autonomy are entitled to protection.*" Persons with diminished autonomy in this context refers to persons who lack consent capacity. The absence of consent capacity is made apparent by the individual's inability to demonstrate one or more of the following:
 - a. to understand information pertaining to the research purpose and procedures,
 - b. to reason about that information,

- c. to formulate a judgment and/or make decisions regarding their own participation in the research based on that reasoning, and
 - d. to effectively communicate that judgment.
2. Consent capacity may be affected by one or more factors, for example, “*mental disorders, neurological disorders such as stroke or dementia, metabolic impairments, psychoactive medications, substance abuse, and head trauma*” (UDHHS, 2009). Proper assessment of consent capacity requires ongoing vigilance because of its highly variable nature. Capacity may manifest rapidly or slowly, and increase or decrease episodically, intermittently or progressively; it may be caused by or respond to changes in medications, environmental factors, interpersonal interactions, fatigue and other factors. In general, consent capacity required to refuse to participate in research activities is lower than the capacity required to assent to participate.

Additional Information

1. A wide range of literature is available about this subject. Researchers should consider searching the literature for valid and reliable consent capacity assessment tools.
2. The level of safeguards appropriate for research participants should be related to the anticipated level of risk. Higher risk studies require more extensive safeguards to protect the participants from both harm and loss of benefits. Commonly employed safeguards include some or all of the following: frequent or ongoing monitoring and documentation of consent capacity assessment; pre-established stopping points for participants with inadequate consent capacity; and/or an independent review of the consent capacity assessment process.
3. Methods to enhance the consent or assent process (i.e. visual aids, simplified language, scheduled repetitions, etc.) should be considered and written into the protocol plan as appropriate.
4. For additional resources concerning Michigan laws related to LARs, please see the following sections of Michigan Compiled Laws: MCL 330.1707, MCL 333.5127, MCL 333.5653, MCL 333.6121, MCL 333.9132, MCL 700.2103, MCL 700.3206, MCL 700.5506 to 700.5515, and MCL 722.4.