

RESEARCH WITH SUBJECTS LIKELY TO MANIFEST OR DEVELOP DECREASED DECISIONAL ABILITY

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Unit: Human Research Protections Program (HRPP), Office of Research review Board Committees

2. Not all research projects proposing to involve decisionally impaired persons should be approved, and not all such persons should be enabled to participate in research projects. The MCW IRB should exercise heightened vigilance in the review of protocols involving persons with decreased decisional ability, in accordance with 45 CFR 46.111(b).
3. Safeguards for human research subjects should be proportional to the degree of decisional impairment, the magnitude of risk, or both. Provisions for additional safeguards should be in place prior to involving individuals with decreased decisional ability in research that poses greater than minimal risk.
4. When reviewing a project focusing on groups of subjects likely to show decreased decisional ability, the IRB will evaluate, determine and record in its minutes, the following:
 - a. Which projects invoke application of the IRB policy on "decreased decisional ability;"
 - b. If the research project poses greater than minimal risk (or: risk represents a minor increase over minimal risk).
 - c. If the project does pose greater than minimal risk, a finding as to whether the research project poses a prospect of direct benefits to the individual subject (if so, specify those benefits); or is likely to yield "generalizable knowledge about the subjects' disorder or condition which is of VITAL importance for the understanding or amelioration of the disorder/condition (if so, specify why the knowledge may be vital).
 - d. The specific "additional safeguards" judged appropriate.
 - e. Recommend that the Investigator to become thoroughly familiar MCW IRB policy on who can be Legally Authorized Representatives (LAR) for research consent purposes and any other applicable state laws, and to consider consultation with the MCW, FH, Versiti or CW General Counsel (as applicable) before or during the project.

IRB Review

1. The IRB Committee will review the project using the *IRB Member Form: New Protocol Reviewer Checklist* to determine if it meets the criteria for approval.
 - a. Additionally, if the project involves subjects with decreased decisional ability, the Committee will also complete the *IRB Member Form: Research involving Subjects with Decreased Decisional Ability Checklist*.
2. If one or more of the required criteria described in this policy are not present or are deemed not sufficient, IRB Committee or designated reviewer will request modifications to the project.

REFERENCES:

45 CFR 46.107(a)
45 CFR 46.111(b)

SUPPORTING DOCUMENTS:

IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability

IRB SOP: Legally Authorized Representatives (LARs): Who Can Consent to Research on Behalf of an Adult Subject with Decreased Decisional Ability

IRB Member Form: New Protocol Reviewer Checklist

IRB Member Form: Research involving Subjects with Decreased Decisional Ability Checklist

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