

	Institutional Review Board	
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Responsibility: OIRB		Page 1 of 4

Research Involving Individuals with Impaired Decision-Making Ability
Policy and Procedure

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I. Policy

- A. The Institutional Review Board (IRB) gives special consideration to protecting the rights and welfare of individuals with Impaired Decision-Making Ability. The IRB regards protections from coercion, undue influence, manipulation and physical control as critically important to protecting human subjects. An individual with Impaired Decision-Making Ability refers to an individual who, for a variety of reasons, lacks the ability to understand the research, appreciate the consequences of their participation, consider alternatives, and/or make reasoned choices, such that they cannot provide informed consent for themselves.
- B.
- C. Impaired decision-making ability is protocol-specific and situation-specific.
- D. Determining when research involves individuals with impaired decision-making ability.

Populations routinely considered to have impaired decision-making ability due to regulation or policy:

- 1) Those with limited mental ability that require consideration of additional protections.
Examples include:
 - (1) Mentally handicapped
 - (2) Cognitively impaired
 - (3) Incompetent
 - (4) Incapacitated
- 2) Those with limited voluntariness that require consideration of additional protections.
Examples include:
 - (1) Children
 - (2) Prisoners
 - (3) Students

- (4) Individuals in emergency situations
 - (5) Individuals in hierarchical social structures (i.e., military personnel)
 - (6) Individuals who are economically or educationally disadvantaged
 - (7) Individuals who are marginalized in society or
 - (8) Individuals with fatal or incurable diseases.
2. The IRB shall consider whether including individuals with impaired decision-making ability in the research is appropriate by considering the following:
- 1) The research question should focus on an issue relevant to the impaired decision-making ability population (should bear some direct relationship to the population's condition or circumstances). This population should not be chosen for research that bears no relation to their situation just because it would be convenient for the researcher.
 - 2) It is not feasible to use another, non-impaired decision-making ability population. The inclusion of an impaired decision-making ability population is considered appropriate if the IRB determines that:
 - (1) the research could not be conducted without inclusion of the impaired decision-making ability population, and
 - (2) there exist compelling reasons that mitigate any additional risk.
3. The IRB should consider whether the research incorporates sufficient safeguards to ensure that the rights of the individual participants are protected, by considering the following circumstances:
- 1) Safeguards concerning mental capacity:
 - (1) In research likely to involve persons with conditions or circumstances that are associated with possible or already established impaired decision-making ability (those with documented impaired decision-making ability, incapacitated or legally incompetent), the IRB should determine whether the protocol has:
 - (a) sufficient plans to assess mental capacity; and
 - (b) whether additional protections should be included to protect this vulnerable population.
 - (2) The assessment process should include acceptable physical and mental evaluation criteria at time intervals determined appropriate, given the specifics of the study.
 - (3) In research likely to involve persons with diminished mental capacity, including those with impaired decision-making, incapacitated or incompetent the IRB shall apply additional protections required under the applicable policy (e.g., VA, state law).
 - 2) Safeguards concerning voluntariness:

- (1) In research determined to involve persons who either have (at study entry) or are likely to develop diminished voluntariness (after study entry), the IRB should determine whether additional protections should be included to protect this vulnerable population.
- (2) Presumption of capacity: Subjects with impaired decision-making ability who have not been documented to have [impaired decision-making](#) (by medical documentation), to be [incapacitated](#) (by medical or legal documentation) or to be [incompetent](#) (by legal documentation), are to be considered capable of giving informed consent for research unless and until IRB approved **plans to assess mental capacity** reveal otherwise.

II. Overview

- A. This procedure starts upon submission of a protocol involving a population expected to have impaired decision-making ability.
- B. This procedure ends when the IRB determination whether the inclusion of a population expected to have impaired decision-making ability is appropriate and whether sufficient safeguards have been incorporated into the protocol to protect the subjects.
- C. Summary of responsibilities
 1. Investigators are responsible for providing sufficient information concerning the inclusion of individuals with impaired decision-making ability.
 2. The IRB Office staff is responsible for forwarding of the draft package for IRB review for pre-review submission documents for indications of impaired decision-making ability populations.
 3. IRB is responsible for approving the inclusion of individuals with impaired decision-making ability in research.

III. Procedure

- A. Pre-review and Guidance
 1. The PI identifies the categories of vulnerable subjects (e.g., impaired decision-making, children, prisoners, fetuses, and students) involved in the research in the IRB application.
 2. The investigator completes specific forms in the IRB application which focus on ethical and regulatory issues pertaining to conduct of research involving the identified vulnerable population(s).
 3. Upon receipt of an IRB application, OIRB staff conducts a preliminary screening. When applicable, OIRB staff provides regulatory and educational materials to the IRB pertaining to impaired decision-making ability populations as outlined in the [Initial Review of Research Policy and Procedure](#), [Continuation Review Policy and Procedure](#), or [Modification and Amendments Policy and Procedure](#) policies. IRB members may also use the reviewer checklist, available on the OIRB "SharePoint", as a guide to conducting reviews.
 4. The OIRB, IRB Director, IRB Chair, or designee requests a consultant review if additional expertise is needed. (See the [Initial Review of Research Policy and Procedure](#), [Continuation Review Policy and Procedure](#), or [Modification and Amendments Policy and Procedure](#) policies).
 5. IRB membership includes representation with expertise in selected vulnerable populations routinely reviewed by the IRB, such as children, and prisoners. OIRB staff pre-review the application to ensure that designated representatives review research involving children or

prisoners. Depending upon the type of review, designated representatives may either attend the convened meeting or provide comments in writing.

B. IRB Review Process

1. The IRB reviews the IRB application to determine whether the study protocol includes enrollment of individuals with impaired decision-making ability and whether appropriate safeguards are in place.
2. As applicable, the IRB considers the following elements when reviewing research involving subjects:
 - 1) Inclusion/exclusion criteria;
 - 2) Over-selection or exclusion of certain groups based on perceived limitations (i.e., targeting prisoners as research subjects because they are a readily available “captive” population);
 - 3) Applicable or local laws that bear on the decision-making process (i.e., emancipated individuals, legally authorized representatives, age of majority for research consent).
3. The IRB follows applicable federal and state regulations and IRB policy to review and approve proposed research that involves individuals with impaired decision-making ability such as:
 - 1) Research Involving Prisoners (45 CFR 46, Subpart C) – Prisoner representatives review IRB applications involving prisoners and are present;
 - 2) Research Involving Children (45 CFR 46, Subpart D, 21 CFR 50, Subpart D and U.S. Department of Education, Subpart D) – (See the [Informed Consent Policy and Procedure](#)). Children may not be included in [VA Research](#) (e.g., conducted by VA investigators while on official duty, or at VA-approved off-site facilities) unless a waiver has been granted by the VA Chief Research and Development Officer (prior to requesting a waiver, certain criteria must be met);
 - 3) Research Involving Impaired Decision-Making Ability Subjects – (the IRB application, completion of the VA Research section of the Reviewer Checklist, and conformance with the [Informed Consent Policy and Procedure](#));
4. The IRB considers each of the specific findings discussed in the IRB application forms for research involving vulnerable subjects, as documented by IRB approval. IRB approval also documents that the IRB members acknowledge and agree with the description of safeguards and risk assessment of the protocol as described in the application by the PI. OIRB staff document discussions of controverted issues at convened meetings in the minutes.
5. OIRB staff document specific findings in the meeting minutes, or expedited reviewers document determinations in accord with applicable IRB/OIRB policy. The IRB does not reapply the categories during subsequent reviews unless changes to the protocol dictate otherwise.
6. The IRB may require more frequent review than once a year, for protocols involving vulnerable populations, based on the nature of the research and the level of risk.

IV. References

- A. Definitions (see [Glossary](#))
- B. Regulatory (see [Policy on Policies Policy and Procedure](#))