

 LEHIGH UNIVERSITY	UNIVERSITY RESEARCH POLICY: Research Involving Cognitively Impaired Individuals			
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Policy Statement

This policy describes the policy and procedures for Institutional Review Board (IRB) review of research involving cognitively impaired individuals as subjects in research.

Reason for Policy

This policy helps ensure that human subjects research involving cognitively impaired individuals as research subjects protects the rights and welfare of this vulnerable population, as well as meets all regulatory requirements.

Entities Affected By This Policy

This policy applies to all faculty, staff, and students of the university conducting human subjects research involving cognitively impaired individuals as research subjects; the IRB committee members and chairs; Research Integrity office staff.

Who Should Read This Policy

- Faculty, staff, and students of the university engaged in human subjects research subject to IRB review and oversight
- New and re-appointed IRB committee members
- New and re-appointed IRB committee co-chairs
- Research Integrity office staff

Responsibilities

Responsible Party	List of Responsibilities
Designated reviewers	Apply this policy when conducting reviews of IRB applications.
Lehigh University faculty, staff, and students submitting human subjects research for IRB review	Read, understand, and follow this policy when preparing applications for submission to the IRB. Read, understand, and follow this policy when conducting human subjects research.
Research Integrity office staff	Process IRB reviews and apply this policy when research involves cognitively impaired individuals as research subjects.

Principles

Cognitively impaired persons are those who have a diminished capacity to understand the risks and benefits for participation in research and to autonomously provide informed consent. This cognitive impairment may result from a psychiatric, organic, developmental or other disorder that affects cognitive or emotional functions or may result from the effect of drugs or alcohol. The impairment may be temporary, permanent or may fluctuate.

Although not specifically addressed in the regulations as a vulnerable population, the Lehigh IRB requires additional safeguards for research involving persons with cognitive impairment. The IRB assesses the potential risks and benefits for each research proposal, and the provisions for obtaining informed consent from the participant or their legally authorized representative, to determine if the activity satisfies the conditions for permitted research.

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Procedures

Initial Screening

Upon acceptance of a complete package, the Research Integrity office staff makes a preliminary determination as to whether this policy applies to the study.

Consent

In general, all adults, regardless of diagnosis or condition, should be presumed competent to consent to participation in research unless there is evidence of serious disability that would impair reasoning or judgment.

In making the determination about whether it is appropriate for investigators to utilize proxy consent, the IRB will take into consideration the following:

- the rationale for the need to obtain proxy consent;
- the criteria that will be used in determining whether a potential subject has decisional impairment sufficient to require the use of proxy consent, including any use of standardized assessment tools;
- whether any additional methods are proposed to enhance subjects' ability to achieve decisional capacity with regard to the proposed study (e.g., reading of the consent form may not be sufficient and use of other tools such as videos, educational materials, post-test, etc. might be considered to assist potential subjects in understanding what is involved with the research);
- who will be approached, and in what order, to provide proxy consent.

If a person with cognitive impairment is capable of exercising some judgment concerning the nature of the research and participation in it, the investigator should obtain the subject's assent in addition to the consent of his/her legally authorized representative.

The verbal objection of an adult with cognitive impairment to participation in the research should be binding. If the subject, at any time, objects to continuing in the research study, such objection must be respected.

Where the condition causing the subject's cognitive impairment is of an intermittent or temporary nature, the informed consent process should include a mechanism for obtaining the subject's subsequent direct informed consent to participate in the research. If a subject regains decision making capacity and declines to continue in the research, the decision must be respected.

Assent

The IRB may elect to require investigators to obtain and document the assent of cognitively impaired individuals. Assent is a participants' affirmative agreement to participate in research. Mere failure to object may not be construed as assent. The IRB has the discretion to determine the appropriate manner, if any, of documenting assent. The use of assent should be appropriate based on the degree of impairment of the participants. Written materials and a script for verbal descriptions and assent must be submitted for IRB review.

Documentation of Consent and Assent

For adult persons with cognitive impairment, the investigator should document the following before obtaining the consent and signature of the subject's legally authorized representative or guardian and the signature of the unbiased witness to this consent, if required by the IRB:

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- the conclusion that the subject is incapable of understanding the information presented regarding the research, to appreciate the consequences of acting (or not acting) on that information, and to make a choice;
- the information provided to the subject's legally authorized representative regarding the cognitive and health status of the subject, the risks and benefits of the research, and the role of the proxy.

To document obtaining the assent of a subject with cognitive impairment, a Verification of Explanation statement should appear on the consent document and be signed and dated by the Principal Investigator, listed co-investigator, or other research staff. Please refer to the Appendix in this policy for a sample Verification of Explanation statement.

Review

The IRB will approve the research only if it finds that:

- the research bears a direct relationship to the cognitively impaired subject's condition or circumstance;
- the research meets one of the following criteria:
 - presenting no greater than minimal risk to the involved subjects;
 - presents an increase over minimal risk to involved subjects, but which offers the potential for direct individual benefit to the subject;
 - presents a minor increase over minimal risk to involved subjects and which does not have the potential for direct individual benefit; provided that the knowledge sought has direct relevance for understanding or eventually alleviating the subjects' disorder or condition.

In evaluating a protocol involving the enrollment of persons with cognitive impairment, the IRB may consider requiring additional safeguards, as appropriate, for a given protocol. Such safeguards may include any of the following:

- use of an independent party (independent of the study investigator with appropriate expertise) to assess the capacity of the potential subject;
- use of standardized assessment of cognition and/or decisional capacity;
- use of informational or educational techniques;
- use of an independent person to monitor the consent process;
- use of waiting periods to allow for additional time to consider information about the research study;
- use of proxy consent;
- use of assent in addition to proxy consent in order to respect the autonomy of individuals with decisional impairment;
- use of a witness.

The IRB will determine the following when choosing this option:

 - whether the witness needs to be unbiased (which means the individual is not part of the study team nor a family member of the potential participant)
 - whether the witness will observe the entire consent process or just the signature

Web Address For This Policy

[Lehigh University IRB website](#) (IRB Standard Operating Procedures and Policies)

Related Resources

University Policies and Documents
Lehigh University IRB Glossary

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Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
Policy Clarification and Interpretation	Senior Research Integrity Specialist	610-758-2871	https://research.cc.lehigh.edu/contact-us-0

Appendix

Sample "Verification of Explanation" Statement

I certify that I have carefully explained the purpose and nature of this research study to the above-named participant in appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to participate in this study.

Investigator's Signature

Date