RESEARCH INVOLVING DECISIONALLY IMPAIRED INDIVIDUALS

HRPO POLICIES AND PROCEDURES - CHAPTER 14

https://www.hrpo.pitt.edu/policies-and-procedures/research-involving-decisionally-impaired-individuals

DECISIONALLY IMPAIRED PERSONS

Those who have a diminished capacity to understand the risks and benefits for participation in research and to autonomously provide informed consent

Causes:

- Psychiatric,
- Organic,
- Disorder (developmental or other) that affects cognitive or emotional functions, or
- From the effect of drugs or alcohol.

The impairment may be

- Temporary,
- Permanent, or
- Fluctuating

DETERMINATIONS: RESEARCH INVOLVING PERSONS WITH DECISIONAL IMPAIRMENT

INTENT (choose one):

a. The research bears a direct relationship to the decisionally impaired subject's condition or circumstance

b. The research pertains to conditions, phenomena, or circumstances that commonly or uniquely affect the research participants and may contribute in important ways to the current or future welfare of the study population

c. The research offers therapeutic or other benefits to the individual participant when standard approaches are ineffective, unproven, or unsatisfactory

RISK CATEGORIZATION (choose one):

- The research is no greater than minimal risk to the subject
- The research presents an increase over minimal risk, but offers the potential for direct benefit to the subject
- The research 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

ADDITIONAL SAFEGUARDS EMPLOYED

The IRB may consider requiring additional safeguards, as appropriate, for a given protocol. Such safeguards may include any of the following:

- Independent party to assess the capacity of the potential subject;
- Standardized assessment of cognition and/or decisional capacity;
- Informational or educational techniques;
- Independent person to monitor the consent process;
- Waiting periods to allow for additional time to consider information about the research study;
- Proxy consent;
- Assent in addition to proxy consent in order to respect the autonomy of individuals with decisional impairment;
- Use of a witness:
  - IRB determines if witness must be unbiased (not a part of study team or participant's family)
  - IRB determines if witness observes the entire consent process or just the signature.

CONSENT

- **Default position on consent**: Absent evidence of serious disability that impairs reasoning or judgement, adults should be presumed competent to consent

- **Considerations regarding compromised capacity**: The IRB determines what is sufficient
  - How will capacity be determined/measured?
  - Who will make the determination?
  - What tools will be used?
  - Will a second opinion be sought?

PROXY

When proxy consent is utilized, study teams must comply with PA law

- Adjudicated legally incapacitated with court appointed guardian*
- Health Care Proxy delegated by Power of Attorney
- When neither a court-appointed guardian nor a health care proxy exists, investigators may seek informed consent from a Legally Authorized Representative following the order listed below:
  - Spouse (unless an action for divorce is pending, and the adult children of the principal are not the children of the spouse)
  - Adult child
  - Parent (natural or adoptive)
  - Adult sibling
  - Any other adult relative known & documented to have made previous health care decisions

*The guardian may only provide proxy consent if the court order appointing them guardian specifically states that they have the authority to enroll the incapacitated person into a research protocol

PROXY CONSENT AND SUBJECT ASSENT

Proxy: Uses substituted judgment for the subject, reflecting the values and wishes of the subject

Assent: If potential subject can exercise **some** judgement, but not enough to consent, assent needs to be obtained

Objections should be noted and respected

Direct informed consent will be obtained if subjects are to regain capacity → subject can decline to continue

Note: future banking for genetic testing may not be permitted under proxy

PITTPRO: COGNITIVELY IMPAIRED ADULTS

Study Scope

Check all that apply

1. * **Will this study actively recruit any of the following populations?**
   - [x] Adults with impaired decision-making capacity
   - [ ] Children (under the applicable law of the jurisdiction in which the re
   - [ ] Children who are Wards of the State
   - [ ] Employees of the University of Pittsburgh/UPMC
   - [ ] Medical Students of University of Pittsburgh as primary research gr
   - [ ] Students of the University of Pittsburgh
   - [ ] Neonates of uncertain viability
   - [ ] Non-viable neonates
   - [ ] Non-English speakers
   - [ ] Nursing home patients in the state of Pennsylvania
   - [ ] Pregnant women
   - [ ] Prisoners
   - [ ] N/A

Cognitively Impaired Adults

1. * **Provide a justification for the inclusion of adult subjects who are unable to provide direct consent for study participation:**

2. * **Specify the criteria used to determine that a given potential adult subject is not able to provide direct consent for participation and identify who wi responsible for that determination:**

PITTPRO: CONSENT PROCESS

Consent Process

Since participants with impaired decision-making capacity to consent will be enrolled, address the following questions:

* Describe the process for identifying the appropriate person to act as proxy for the participant:

* Will assent be obtained from the participant who has impaired decision-making capacity?

● Yes ○ No Clear

* Describe the assent process and documentation of assent:

In order for the IRB to approve a study involving individuals with decisional impairment, the research must have appropriate intent as well as an acceptable level of risk

1	**Intent (Choose only one)**	
☐	The research bears a direct relationship to the decisionally impaired subject's condition or circumstance	
☐	The research pertains to conditions, phenomena, or circumstances that commonly or uniquely affect the research participants and may contribute in important ways to the current or future welfare of the study population	
☐	The research offers therapeutic or other benefits to the individual participant when standard approaches are ineffective, unproven, or unsatisfactory	
2	**Level of Risk (Choose only one)**	
☐	The research presents no greater than minimal risk to the involved subjects *Provide protocol specific findings justifying this determination:*	
☐	The research presents an increase over minimal risk to the involved subjects, but offers the potential for direct individual benefit to the subject *Provide protocol specific findings justifying this determination:*	
☐	The research 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 *Provide protocol specific findings justifying this determination:*	
3	**Additional Safeguards (choose all that apply as determined by the IRB)**	
☐	Use of an independent party (independent of the study investigator with appropriate expertise) to assess the capacity of the potential subject. *Provide protocol specific findings justifying this determination:*	
☐	Use of standardized assessment of cognition and/or decisional capacity *Provide protocol specific findings justifying this determination:*	
☐	Use of informational or educational techniques *Provide protocol specific findings justifying this determination:*	
☐	Use of an independent person to monitor the consent process *Provide protocol specific findings justifying this determination:*	
☐	Use of waiting periods to allow for additional time to consider information about the research study *Provide protocol specific findings justifying this determination:*	
☐	Use of proxy consent *Provide protocol specific findings justifying this determination:*	
☐	Use of assent in addition to proxy consent in order to respect the autonomy of individuals with decisional impairment *Provide protocol specific findings justifying this determination:*	
☐	Use of a witness. The IRB will determine the following when choosing this option: ☐ The study team must use an unbiased witness (i.e. not part of the study team or a family member) ☐ The witness will observe the entire consent process ☐ The witness will observe just the signing of the consent form *Provide protocol specific findings justifying this determination:*	
4	**Consent/Assent Issues (Choose all that apply)**	
☐	If subjects' decisional making capacity is expected to return, provisions have been included to obtain direct consent for continued participation *Provide protocol specific findings justifying this determination:*	
☐	For proxy consent, the investigator has appropriately indicated the order in which LARs will be approached that conforms to PA state law (See Chapter 14 of the HRPO Policy and Procedure Manual) *Provide protocol specific findings justifying this determination:*	
☐	For subjects capable of exercising some judgment concerning the nature of the research and participation in it, the investigator should obtain the subject's assent include provisions as to how assent will be documented *Provide protocol specific findings justifying this determination:*	
☐	A signature line for a witness is included on the consent document, if required above *Provide protocol specific findings justifying this determination:*	

Use the Checklist: Research Involving Persons with Decisional Impairment

https://www.hrpo.pitt.edu/guidance-forms#d

Please reach out to askirb@pitt.edu with questions