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| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer. This checklist can be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)   * For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer may complete this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer can then this checklist to “Submit Non-Committee Review” activity. * For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained. 2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the protocol file.  * Use a separate checklist for each waiver or alteration of informed consent determinations for a study | |
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| 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 | |
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| 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 |
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| 1. Level of Risk (Choose only one) | |
|  | The research is no greater than minimal risk to the subject  *Provide protocol specific findings justifying this determination:* |
|  | The research presents an increase over minimal risk, but offers the potential for direct individual benefit to the subject  *Provide protocol specific findings justifying this determination:* |
|  | Any risk is the least possible for achieving the objectives of the research.  *Provide protocol specific findings justifying this determination:* |
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| 1. 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:* |
| 1. 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](https://www.hrpo.pitt.edu/policies-and-procedures/chapter-14-considerations-special-subject-populations))  *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:* |