

Additional Protections for Research Involving Cognitively Impaired Individuals

Scott J. Lipkin DPM
Lehigh Valley Health Network, Scott.Lipkin@lvhn.org

Follow this and additional works at: <https://scholarlyworks.lvhn.org/network-office-research-innovation>



Part of the [Health and Medical Administration Commons](#)

Let us know how access to this document benefits you

Published In/Presented At

Lipkin, S. J. (2010). Additional Protections for Research Involving Cognitively Impaired Individuals. *LVHN Scholarly Works*. Retrieved from <https://scholarlyworks.lvhn.org/network-office-research-innovation/2>

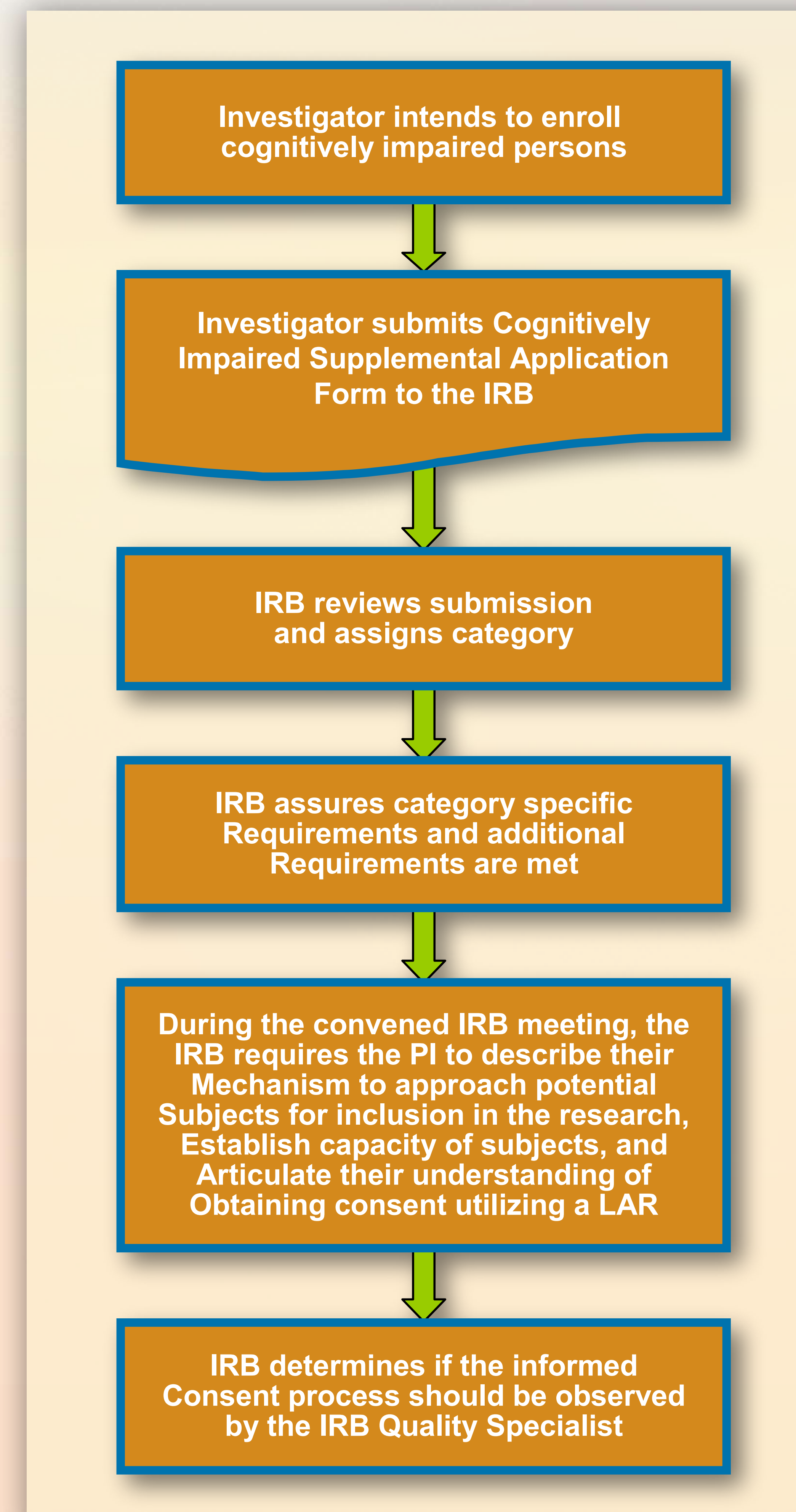
This Poster is brought to you for free and open access by LVHN Scholarly Works. It has been accepted for inclusion in LVHN Scholarly Works by an authorized administrator. For more information, please contact LibraryServices@lvhn.org.

Additional Protections for Research Involving Cognitively Impaired Individuals

Scott J. Lipkin, DPM, Director, Research Participant Protection Office

Lehigh Valley Health Network, Allentown, Pennsylvania

Although there are no federal regulations specifically written to address the needs of cognitively impaired research participants, the Lehigh Valley Health Network IRB follows and applies a modified version of the recommendations governing the conduct of research in children made by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.



Investigator Responsibilities

When applying to the IRB, the investigator must submit a Cognitively Impaired Supplemental Application Form and address the following:

- Explain why it is necessary to involve persons who are cognitively impaired as research subjects.
- Provide sufficient protocol specific justification for the use of cognitively impaired persons as research subjects.
- Explain the procedures proposed for evaluating the mental status of prospective subjects to determine whether they are capable of consenting.
- Explain how the Principal Investigator will identify persons authorized to give legally valid consent on behalf of any individual(s) judged incapable of consenting on their own behalf.
- Describe if the patient's physician or another health care provider will be consulted before any individual is invited to participate in the research.
- Describe if it is reasonable to expect that during the course of the study, subjects may lose their capacity to consent or their ability to withdraw (e.g., research involving administration of or withdrawal from psychotropic agents).
- Describe if the research is likely to interfere with ongoing therapy or regimens.
- When applicable, explain why the research pertains to aspects of institutionalization.
- When applicable and if the intent is to enroll institutionalized subjects, explain why non-institutionalized subjects are not appropriate for the research and why they may not be reasonably available.

LVHN IRB Designates One of the Following Categories

Category #1: Research not involving greater than minimal risk.

Category #2: Research involving an intervention or procedure that presents an increase over minimal risk to involved subjects, but offers the potential for direct benefit to the subject and is available only in the context of the research study.

Category #3: Research involving an intervention or procedure that presents an increase over minimal risk and no potential for direct individual benefit, but likely to yield generalizable knowledge for understanding or eventually alleviating the subject's disorder or condition.

IRB Required Findings per Category

Category #1:

- Adequate provisions are made for soliciting consent of a capable subject or assent of an incapable subject and consent of the subject's representative

Category #2:

- Adequate provisions are made for soliciting consent of a capable subject or assent of an incapable subject and consent of the subject's representative; and
- The risk is justified by the anticipated benefit to the subject(s); and
- The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Category #3:

- Adequate provisions are made for soliciting consent of a capable subject or assent of an incapable subject and consent of the subject's representative; and
- The risk represents a minor increase over minimal risk; and
- The intervention(s) presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, physiological, social, or educational situations; and
- The intervention(s) is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for understanding/amelioration of the disorder or condition.

Additional IRB Required Findings

- An IRB member who is independent of the research and the investigator, and who is knowledgeable about and experienced with decisionally impaired adults is present at the IRB meeting.
- There are adequate procedures for evaluating the mental status of prospective subjects to determine if they are capable of giving informed consent.
- There are adequate procedures for identifying persons authorized to give legally valid consent on behalf of any individuals who are incapable of consenting on their own behalf.
- If the research proposes to involve institutionalized subjects with decisional impairment, sufficient justification is provided for using this population.
- The IRB may require:
 - Use of an independent party to assess the capacity of a potential subject
 - Use of an independent monitor to observe the recruitment, assessment, and/or the informed consent process
 - Use of informational or educational techniques to assess and enhance comprehension at each stage of the research
 - Use of a waiting period to provide additional time for subjects to consider participating in the research