GUIDELINE FOR INSTITUTIONAL REVIEW OF RESEARCH INVOLVING ADULTS WITH DECISIONAL IMPAIRMENT

OHSP Policy 604 Research Involving Adults with Decisional Impairment indicates that additional institutional review is required if the RSRB approves research under Category C for research involving persons with decisional impairment and the subject does not have the capacity to designate a research proxy. This guideline outlines the procedures followed by the RSRB for obtaining the additional approval by the appropriate institutional designee.

Note: Proposals that only include activities utilizing existing data do not require this additional institutional review.

Procedures for Obtaining Institutional Approval:

1. Based on the protocol and application materials, the convened board confirms that the research involves adults with decisional impairment and documents the following determinations:
   - The study constitutes a minor increase over minimal risk with no possibility of direct benefit to the subjects who are participating, but may produce knowledge about the subjects' disorder or condition; **and**
   - Subjects in the study **might not** have the ability to designate a research proxy.

2. The research study was reviewed by the convened board and considered to be otherwise approvable under Category C involving subjects who are unable to designate a research proxy. The RSRB will stipulate that approval is contingent upon institutional approval.

3. The RSRB Specialist sends all appropriate study materials, including but not limited to the RSRB application, protocol, and plan for capacity assessment to the appropriate institutional reviewer(s) and the University of Rochester Medical Center Office of Counsel, in preparation for a protocol review meeting.
   - In cases where the institutional reviewer has a conflict of interest, the materials will be forwarded to the Senior VP for Research (or designee) for review.

4. A protocol review meeting is conducted with the study Investigator, study Coordinator, RSRB Chair, RSRB Specialist, RSRB Director, University of Rochester Medical Center Office of Counsel, and institutional reviewer (and other staff or study personnel as appropriate).

5. Once the meeting is completed, the institutional reviewer sends a letter to the Investigator acknowledging the meeting and review determination, summarizing the discussion, and documenting any other pertinent information relevant to the protocol review discussion and any special circumstances that need to be addressed (see page 3 for a sample letter).

6. The letter is uploaded into the RSRB application (ROSS) by the study team (i.e., Investigator or Coordinator), along with any changes to the protocol and additional study materials that may have resulted from the meeting.

7. The RSRB Specialist will review the revised documents (as applicable) and ensure that any changes or issues noted by institutional review have been addressed. Once this is completed, and no new issues remain, the RSRB Chair completes the stipulation review for study approval.

SAMPLE LETTER INVOLVING SUBJECTS WITH DECISIONAL IMPAIRMENT UNDER CATEGORY C

[INSERT INSTITUTIONAL LETTERHEAD]

Date: [INSERT]

TO: Study Investigator

FROM: **[**INSERT INSTITUTIONAL REVIEWER NAME]
[INSERT INSTITUTIONAL REVIEWER TITLE]

CC: CEO URMC
Dean of School
Board Chair
OHSP Director
RSRB Director
RSRB Specialist
Office of Counsel
Senior Vice President for Research

RE: **RSRB #XXXXX: STUDY TITLE**

This memo will document our meeting of [INSERT DATE] regarding the inclusion of persons with decisional impairment who are unable to designate a research proxy, in your study noted above, as requested by the RSRB. I am writing to confirm my concurrence with the board's decision that this study constitutes a minor increase over minimal risk with no prospect of direct benefit to individual subjects who participate, but may produce knowledge about the subjects' disorder or condition (Category C) and is consistent with institutional policy permitting the inclusion of persons with decisional impairment. My concurrence is based upon the following information discussed during our meeting.

The purpose of this study is [INSERT PURPOSE AND SUMMARY OF STUDY ACTIVITIES].

The following consent process will be used in this study to protect individuals who are initially determined to have consent capacity. Individuals will be assessed for consent capacity for the study using [INSERT ASSESSMENT METHOD], which is consistent with the OHSP "Guideline for Assessing Consent Capacity in Decisionally Impaired Adults". This process is approved by the RSRB, and requires assent from any individual with decisional impairment. As eligible subjects will have varying levels of cognitive function, this process includes the following possible situations:

- If a subject is capable of providing consent for the study, he/she will sign the study consent form and will be offered the option to identify an individual to serve as a research proxy on the attached "Advance Directive for Research Participation" form. If the subject elects not to identify a research proxy and loses consent capacity during participation, he/she will be withdrawn from the study based upon an inability to provide continued consent.

- If the subject is not capable of providing consent for the study, but is capable of providing assent and designating the appointment of a research proxy, he/she will be asked to identify a research proxy on the "Advance Directive for Research Participation" form. The research proxy will be contacted, the study discussed, and that individual will make the determination about the subject's participation in this study.

The following additional protections are in place for those individuals participating in this study:

- An advocate, independent of the study team, will be available to assist the subjects who participate and their identified research proxies with the consent process and throughout the study. This research advocate will be from the [insert location], and is familiar with the clinic population. The advocate's contact

information will be specifically listed in the consent document and will be separate from the study team's contact information.

- The site-specific consent process will include language that, if a subject resists any procedure or study activity, such resistance should be seen as termination of "assent", and the subject should be withdrawn from study, regardless of the decision of the research proxy.

Attachments: Advance Directive for Research Participation