Assessing Capacity to Consent in Adults: Guidance for Researchers

I. Procedures for Assessing Decision-Making Capacity

In general, the IRB will only approve research involving subjects unable to provide consent or with impaired decision-making capacity (i.e., cognitively impaired adults; participants with diminished capacity to consent) when:

1. the aims of the research cannot reasonably be achieved without inclusion of the population, and
2. there are appropriate provisions to:
    a) evaluate capacity,
    b) obtain consent (and assent if possible), and
    c) otherwise protect subjects.

Investigators must disclose to the IRB both plans and justification for including adults with impaired decision-making capacity in a given research proposal, detailing procedures for assessing capacity prior to providing informed consent and, if appropriate, for re-evaluating capacity during study participation. Plans for evaluation of capacity should be tailored to the subject population and the risks and nature of the research. This can be done with at least one of the following methods:

a) In some instances, assessment by a qualified investigator may be appropriate. However, an independent, qualified assessor (someone who's not involved in the study, nor the participants, and is only evaluating the appropriateness of the assessment plan) should evaluate subjects' capacity when the risks of the research are more than minimal risk or the investigator is in a position of authority over a prospective subject. In all cases, the person(s) evaluating capacity must be qualified to do so and use appropriate, validated tools and methods (e.g., University of California, San Diego Brief Assessment of Capacity to Consent [UBACC], MacArthur Competence Assessment Tool for Clinical Research [MacCAT-CR]). Assessments of capacity should be documented in the research record, and when appropriate, in the medical record. The assessment plan needs to be described in detail in the study protocol, and proposed assessment tools uploaded with the IRB application as available.

b) Educational measures may be employed to raise the subject's understanding to sufficient levels for them to make a meaningful choice about participating. Potential measures include orally summarizing the consent form, repetitive teaching, audiovisual presentations, and oral or written recall tests. Other measures might include follow-up questions to assess subject understanding, videotaping or audio-taping of consent discussions, use of waiting periods to allow more time for the potential subject to consider the information that has been presented, or involvement of a trusted family member or friend in the disclosure and decision-making process. Audio or videotapes, electronic presentations, or written materials used to promote understanding must be provided to the IRB for review and approval prior to use. *For examples of educational procedures and the content of such recall/assessment tests, see Appendix B.*

c) The study investigators may develop and suggest alternative procedures for evaluating the presence of decision-making capacity. Such procedures must be reviewed and approved by the IRB prior to enrollment of subjects in the protocol.

II. Surrogate consent and LAR (Legally Authorized Representative)

When a prospective subject is deemed to lack capacity to consent to participate in research, or their capacity to consent is expected to diminish, the investigator should consider requesting that the subject designate a future LAR prior to enrollment in the research, including the future LAR in the initial consent process, and obtaining written documentation of the subject's wishes regarding participation in the research. Investigators may obtain

informed consent from the individuals' surrogate or LAR (See Section 13.3 of SOP). Under these circumstances, the prospective subject should still be informed about the research in a manner compatible with the subjects' likely understanding and, if possible, be asked to assent to participate.

Potential subjects who express resistance or dissent (by word, gesture, or action) to either participation or use of surrogate consent, should be excluded from the study. Some subjects may initially assent but later resist participation or express a desire to withdraw from the research. Under no circumstances may an investigator or caregiver override a subject's dissent or resistance.

III. Reassessment of decision-making capacity

When the study includes subjects likely to regain capacity to consent (e.g., shows improvement after a stroke or traumatic brain injury) while the research is ongoing, the investigator should include provisions to inform them of their participation and seek consent for ongoing participation. Conversely, if participants may lose capacity to consent while the research is ongoing, the investigator should include provisions to reassess capacity. If the participant loses capacity, then there should be a plan to consent the LAR and obtain assent from the participant. If continued participation is not appropriate, then the participant should be removed from study.

III. Unexpected subjects with impaired decision making-capacity

When inclusion of adults with impaired decision-making capacity is **not anticipated** and a plan for inclusion of such subjects **has not been** reviewed and approved by the IRB, and an enrolled subject becomes unable to provide consent or impaired in decision-making capacity, the investigator is responsible for promptly notifying the IRB ***(as soon as possible but within 5 business days).*** The investigator should consider whether continuing participation is appropriate and, if so, present a plan for surrogate consent from a LAR and, if appropriate, a plan to periodically evaluate capacity and re-obtain consent if possible.

This notification needs to be provided to the IRB via the Reportable Events module in WRG:

See "HowTo: Submit Study Lifecycle Events (Amendments, Continuing Reviews, etc.)**"**

IV. What about assent?

When assent *(defined as the adult's affirmative agreement to participate in research)* is possible for some or all subjects who do not have capacity to provide informed consent, the investigator should provide the IRB with an assent plan that describes when and how assent will be obtained, provisions that will be taken to promote understanding and voluntariness, how assent will be documented, and a copy of the assent form, as needed. If the investigator intends to use audio or video recordings to document assent, provisions to ensure the security of the recordings should be described to the IRB.

V. Protocol considerations

The below are some samples of language from IRB applications that have been deemed appropriate when proposing research with adults with diminished capacity:

Prompts	Protocol-Specific Sample Language
The aims of the study cannot reasonably be achieved without the participation of adults with impaired decision-making capacity.	This study aims to assess the safety and efficacy of X using the Z system for the treatment of patients with probable Y's disease. Subjects enrolled in this study suffer from early stage effects of Y's disease and may be experiencing some cognitive impairment.
Inclusion is not based purely on convenience or availability.	Patient's diagnosed with probable Y's disease, according to the National Institute of A's criteria will be eligible for inclusion in this study. Subjects living in (i.e. nursing homes, attending senior centers) may be included in the

Prompts	Protocol-Specific Sample Language
	study, but are not being exclusively targeted based on convenience or availability.
When adults whose capacity is questionable, or may fluctuate, appropriate provisions have been provided for determining capacity to provide consent.	In order to evaluate the capacity of an individual to participate in an informed consent process, the study team will consider the subject's ability to comprehend statements of comparable complexity to those used in the consent form and whether the subject can communicate their understanding of those statements to the study team during the course of a brief and informal initial interview **(**a feedback tool could be developed and described here as well).** If the patient is determined to lack capacity, a LAR may provide surrogate consent (if this responsibility has been delegated to the LAR by the patient).
When adults whose capacity may diminish are included, appropriate provisions have been included to assess capacity on an ongoing basis and engage an LAR when needed.	Patient is deemed competent to provide their own informed consent at the time of enrollment as assessed by the Investigator based on cognitive testing (i.e. MoCA, MMSE, MacCAT-CR) and their overall clinical impression. If, during the patient's participation in the study, the investigator deems the patient to be unable to provide consent, then the surrogate/caregiver would obtain LAR status to continue to provide informed consent on behalf of the patient for the patient's continued participation.
The study is likely to improve the understanding of the condition, disease, or issue affecting the subject.	The study's technique is still being investigated, so it may offer potential benefits, though this cannot be confirmed. Other subjects may benefit from this procedure in the future, if further trials prove that it is possible to open the XYZ system in areas of (pathology being studied).
Any experimental procedures or interventions have undergone pre-clinical testing or human testing on other populations and the data supports its use in the proposed study.	The XYZ system has been used to perform T-procedure in 45 subjects for a total of 90 procedures in a clinical trial setting in USA. The clinical experience from two studies conducted at ABC Health Science Center present a favorable safety profile for (pathology being studied)'s disruption using the XYZ system in patients with malignant brain tumors and Y's disease.
Assent is required of:	Subjects with a MoCA of 26 or above (i.e. as described in protocol inclusion criteria) have capacity to understand the protocol and to provide informed consent, therefore no assent would be needed. OR Assent will be obtained from all those subjects who are capable, in addition to LAR consent
Documentation of assent:	Documentation of assent would be recorded in the subject's research records

VI. IRB app completion and ICF considerations:

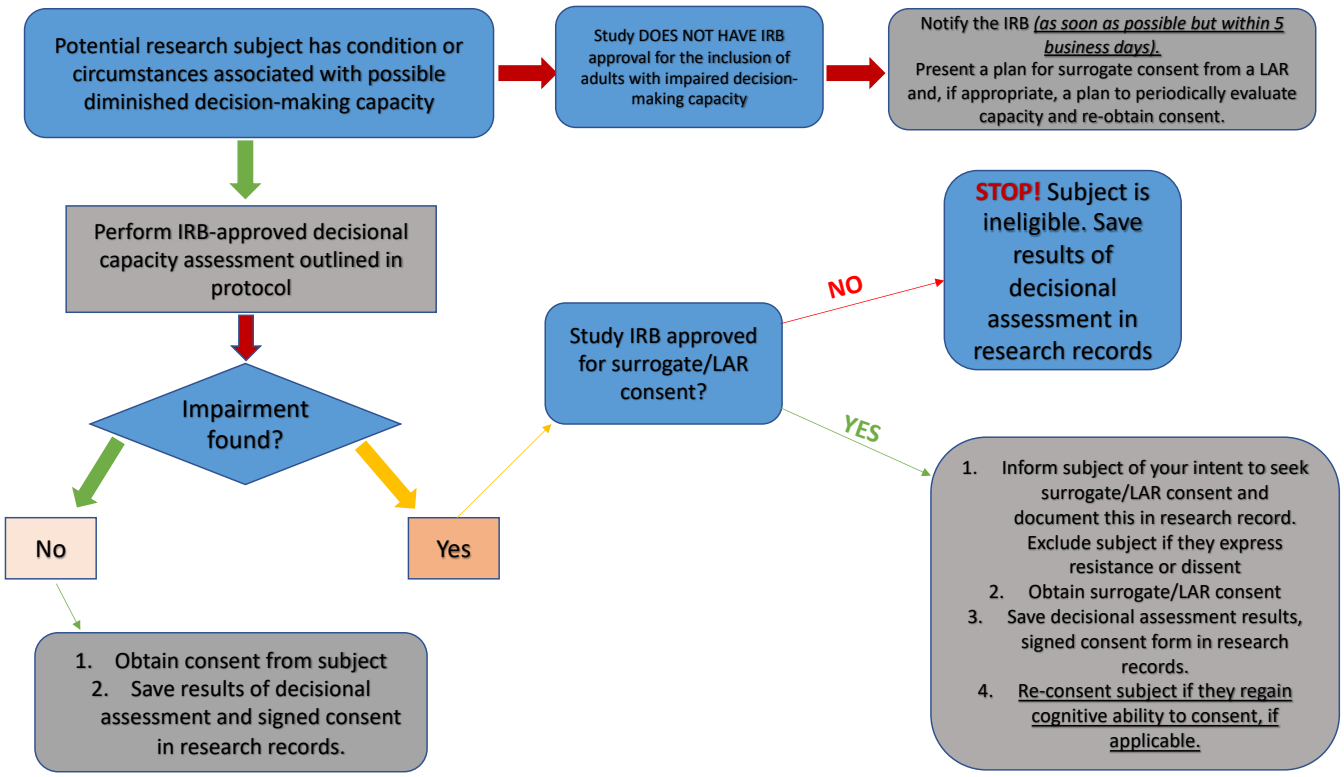
New study application	***Target enrollment section, Q. 7***: Please select "Cognitively-impaired adults". A "cognitively impaired" section will now show requesting rationale to include persons with impaired decision-making capacity as participants, and description of protections in place to ensure subject's safety (i.e. assessment of capacity to consent). ***Risks and Risks Minimization section***, **Q. 1.2**:

	Please provide a description of the risks and benefits to persons with impaired decision making capacity. If the research poses greater than minimal risk to the participants, please provide justification why the probability of benefit is greater than the probability of harm ("Benefits", Q. 2). ***Informed Consent, Minor Assent, and Parental/Guardian Permission section**:* In **Q. 1.3** and **1.4**, please describe how the subjects inform consent will be obtained and how the team will ensure the information presented is understood, respectively. ***In Q.4***, please select "Use of a legally authorized representatives (LAR)" to indicate if you intend to use a Legally Authorized Representative (LAR) as a part of your consent process. Please explain when the use of an LAR may arise in this study population and what the frequency of an LAR might be during the enrollment period (i.e. all subjects, or some) ***Additional consent considerations?*** Please discuss whether obtaining assent from the adult with impaired decision-making capacity and informed consent from an LAR is appropriate for the study. Please also discuss whether periodic re-consenting or re-assenting is appropriate to ensure a participant's continued involvement is voluntary and to accommodate fluctuating decision making capacity. **INFORMED CONSENT FORM** ***LAR signature block:*** please add/keep the LAR Signature Block to the end of your consent document. See the ICF template for language/placement: WCM ICF

References:

1. SOP link
2. Association for the Accreditation of Human Research Protection Programs (AAHRPP): Reviewing Research Involving Adult Participants with Diminished Functional Abilities Related to Capacity to Consent www.aahrpp.org
3. Appelbaum, PS, and Grisso, T: MacArthur Competence Assessment Tool for Clinical Research (MacCATCR), Professional Resource Press, Law and Psychiatry Program, University of Massachusetts Medical School, Worcester, MA, 2001.
4. Appelbaum, PS, and Candilis, PJ: A Direct Comparison of Research Decision-making Capacity: Schizophrenia/Schizoaffective, Medically Ill, and Non-Ill Subjects, 2009.
5. Cullen et al. (2007). "A review of screening tests for cognitive impairment." Journal of Neurology, Neurosurgery & Psychiatry, 78: 790-9.
6. Dunn et al. (2006). "Assessing decisional capacity for clinical research or treatment: a review of instruments." American Journal of Psychiatry, 163: 1323-34.
7. Food and Drug Administration (FDA): Informed Consent Information Sheet: Guidance for IRBs, Clinical Investigators, and Sponsors http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm
8. Jeste DV et al. (2007). A New Brief Instrument for Assessing Decisional Capacity for Clinical Research. Arch Gen Psychiatry 64(8):966-74.
9. National Institutes of Health: Research Involving Individuals with Questionable Capacity to Consent http://grants.nih.gov/grants/policy/questionablecapacity.htm
10. Sturman ED. (2005) The Capacity to Consent to Treatment and Research: A Review of Standardized Assessment Tools. Clinical Psychology Review. 25:954-974
11. 45 CFR 46
12. 21 CFR 50 and 56
13. The Belmont Report: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Appendix A: Flowchart



Appendix B: Sample tool templates

Sample 1: ICF feedback tool, provided by Dr. Czaja's research team

Date (M D Y)	ID#	Location

Informed Consent Feedback Tool
for Decisional Making Capacity in Minimal Risk Research

Project Title: _____
Research Project #: _____
Principal Investigator: _____

1.	I am agreeing to take part in a research study.	True	False
2.	I can stop being in the study at any time.	True	False
3.	I am volunteering to take part in this study.	True	False
4.	There are few risks associated with being in this study.	True	False
5.	The main risk of being in this study is that:* _____ _____	True	False
6.	I do not have to answer any questions that I don't want to answer.	True	False
7.	I will not be penalized for refusing to participate in this study.	True	False
8.	A possible benefit of taking part in this study is that:* _____	True	False
9.	Information obtained from this study will be kept private.	True	False
10.	I can ask the researcher questions at any time during the study	True	False

Adapted for use by the Weill Cornell Neuropsychology Service from a questionnaire developed by a sub committee of the Mount Sinai School of Medicine Institutional Review Board Committee on Human Rights in Research, New York, N.Y.

* Information pertains to risks and benefits specific to protocol being studied.

Sample 2: Determination of consent capacity tool, Rochester U

DETERMINATION OF CONSENT CAPACITY FOR ADULTS WITH DECISIONAL IMPAIRMENT

Study Title: X
RSRB #: XXXXX
Subject Name: _____

Instructions: All potential subjects should be recruited and informed of the study as outlined in the study protocol. To determine whether the subject has the capacity to provide consent, ask the following questions at the conclusion of the consent process. Use the corresponding 5-point scale to document the potential subject's level of understanding as below.

Level of Understanding 5-Point Scale

1	2	3	4	5
None	Poor	Unclear	Good	Excellent

Assessment Questions	Level of Understanding
Why is this study being done?	1 2 3 4 5
If you decide to participate in the study, what are some of the things you will be asked to do?	1 2 3 4 5
What parts of the study are being done as part of your regular care and what parts of the study are being done only for the research?	1 2 3 4 5
Describe some of the risks or discomforts that people may experience if they participate in this study.	1 2 3 4 5
What are the benefits of participating in this study?	1 2 3 4 5
Do you have to be in this study?	1 2 3 4 5
If you are in the study and stop your participation, will you still be able to receive regular care?	
Who will pay for your medical care if you are injured while in this study?	1 2 3 4 5
What will happen if you decide not to be in the study?	1 2 3 4 5
Who should you contact if you have questions or experience a problem while in the study?	1 2 3 4 5
Additional Comments:	

Potential subjects scoring a 4 or 5 on all questions have demonstrated an understanding of the study and are determined to have capacity to provide informed consent. Potential subjects scoring less than 4 on any question have not demonstrated a full understanding of the study and therefore must designate a representative (research proxy) to provide permission on his/her behalf to be enrolled. The assent of the subject should be obtained.

_____

Printed Name of Investigator Signature of Investigator Date

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Sample 3: Determination of consent capacity tool v. 2, Rochester U

DETERMINATION OF CONSENT CAPACITY FOR ADULTS WITH DECISIONAL IMPAIRMENT

Study Title: X
RSRB #: XXXXX
Subject Name: _____

Instructions: All potential subjects should be recruited and informed of the study as outlined in the study protocol. To determine whether the subject has the capacity to provide consent, ask the following questions at the conclusion of the consent process.

- Why is this study being done?
- If you decide to participate in the study, what are some of the things you will be asked to do?
- What parts of the study are being done as part of your regular care and what parts of the study are being done only for the research?
- Describe some of the risks or discomforts that people may experience if they participate in this study.
- Will this study help you?
- Do you have to be in this study?
- What will happen if you decide not to be in the study?
- If you are in the study and stop your participation, will you still be able to receive regular care?
- Who will pay for your medical care if you are injured while in this study?
- Who should you contact if you have questions or experience a problem while in the study?

Individuals who achieve a demonstrated understanding of the study are determined to have capacity to provide consent. However, if in answering these questions, the potential subject is unable to demonstrate understanding, reasoning, or appreciation of the study, and the Investigator still wishes to enroll the subject, the consent should be reviewed further and the above questions repeated. If, after a second review, the potential subject is still unable to demonstrate consent capacity, he/she must not be enrolled or may designate a representative (research proxy) to provide permission on his/her behalf to be enrolled. The assent of the subject should be obtained.

Consent Capacity Assessment Checklist:

- ☐ Potential subject was able to convey the purpose of the study.
- ☐ Potential subject was able to convey the study procedures.
- ☐ Potential subject was able to convey the potential risks of the study.
- ☐ Potential subject was able to convey the potential benefits of the study.
- ☐ Potential subject was able to convey alternatives to participation.
- ☐ Potential subject recognized the voluntary nature of the study.

OR

- ☐ Potential subject does not have capacity to consent.

Additional Comments:

_____

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Printed Name of Investigator Signature of Investigator Date

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Note: These templates should be modified as applicable to the needs of the study.

604a_GDL_Assess_Consent_Capacity_Decisional_Impaired.pdf (rochester.edu)