University of Kentucky
IMPAIRED CONSENT CAPACITY POLICY
Research studies involving adult participants with impaired consent capacity

This policy applies to research with adults who may be unable to provide legally effective informed consent because of impairment in consent capacity (i.e., decision-making capacity). An individual's consent capacity is not simply present or absent, but is best understood as occurring along a continuum. It may occur in a wide range of conditions and disease states and is task-specific. This policy employs a method to determine assessment approaches that are tailored to the study population, level of study risk and nature of consent capacity impairment. It also describes provisions for assent, dissent, process enhancements and the inclusion of legally authorized representatives for participants (subjects) with impaired consent capacity.

The following issues are considered by the IRB during its review of research involving subjects with impaired consent capacity. Any study that includes any participant who has limited or impaired consent capacity must complete a composite rating score (https://ris.uky.edu/ori/oriforms/formt/Scale.asp) and subsequent Form T and address the issues as appropriate.

The IRB should obtain a review of the project by an IRB voting member or consultant, independent of the research and investigators, with appropriate professional background, knowledge and experience in working with individuals with impaired consent capacity.

I. Studies that are most likely to include participants with limited or impaired consent capacity:

Some studies include populations that suggest a likelihood of limited or impaired consent capacity. For example, a study of individuals with traumatic brain injury, independent of individual clinical characteristics, might be assumed to include a large number of participants with impaired capacity to understand, appreciate, freely choose, and demonstrate reasoning ability about studies. Other studies are less obviously focused on high likelihood target populations. The IRB considers the following list of study populations as likely to involve a significant number of participants with limited or impaired consent capacity. Investigators with these target populations are asked to consider the likelihood of consent capacity impairment and complete the IRB Form T-*Research Involving Adults with Impaired Consent Capacity.*

This list draws from the literature and is for the purpose of increasing awareness of the influences that chronic and acute medical and situational factors have on cognitive capacities utilized when forming consent to participate in studies.

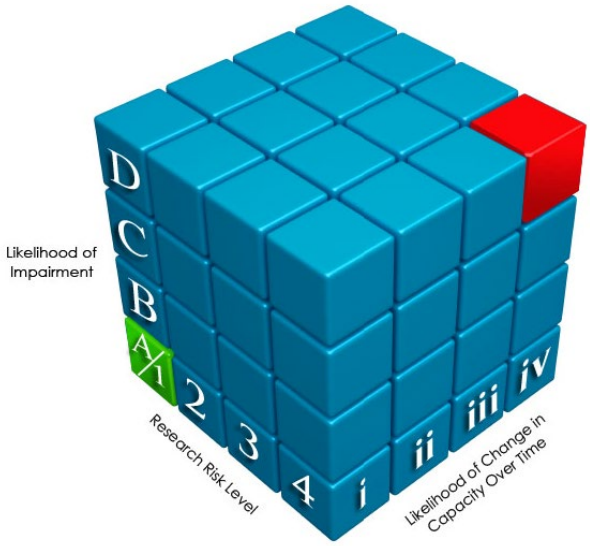
Studies with:

- Traumatic brain injury or acquired brain injury;
- Severe depressive disorders or Bipolar disorders;
- Schizophrenia and other severe mental disorders that involve serious cognitive Disturbances;
- Stroke;
- Developmental disabilities;
- Degenerative dementias;
- CNS cancers and other cancers with possible CNS involvement;
- Late stage Parkinson's Disease;
- Late stage persistent substance dependence;
- Ischemic heart disease;
- HIV/AIDS;
- COPD;
- Renal insufficiency;
- Diabetes;
- Autoimmune or inflammatory disorders;
- Chronic non-malignant pain disorders;
- Drug effects;
- Other acute medical crises.

II. Investigator obligations and duties with participants who have limited or impaired consent capacities:

The obligations and duties of investigators vary with the level of research risk and the level of impaired consent capacity. This policy implements a multidimensional model for processing studies of individuals with impaired consent capacity. This process involves assessing three dimensions of risk: (1) Research risk; (2) Likelihood that the target population for the study has impaired consent capacity; and (3) The likelihood that consent capacity might change over time. Figure 1 shows the multidimensional model of risk in research with individuals having impaired consent capacity. This cube shows all three dimensions including the research risk level in terms of harm or benefit from participating, the potential for consent impairment, and the possibility of change in consent capacity over time. The green box shows the lowest possible risk level, a 1.1.1. The red box shows higher levels of potential risk, highest level of consent impairment, and the greatest likelihood of change in capacity over time.

Figure 1. Multidimensional Model of Risk Among Individuals with Impaired Consent Capacity



III. Specific Risk and Consent Capacity Assessment Duties:

This policy guides investigators to take a structured approach to the question of consent capacity that is protocol-specific and tailored to the study population.

The investigator selects the applicable category for each of the three dimensions as listed in **Table 1**. His/her selection results in a composite score which is associated with a set of recommended assessment options (**Appendix I**). This activity may be accomplished manually or by using the automated web-based tool found in Form T. Investigators can either use the recommended assessment or provide rationales for alternative protections.

This tailored approach reserves the most formal and validated assessments for situations in which impairment is more likely to be present, capacity fluctuations are likely, anticipated benefits are fewer, and foreseeable risks are greater.

For example, the suggested action for protocols with any research risk level 1 is to "***do an informal participant assessment during routine interview procedures to determine consent capacity and change over time if indicated."***

In this case, no other special assessment procedures must be considered. However the investigator may choose to incorporate consent enhancements as described in section IV particularly if the study requires extensive time or task commitments.

Conversely, the recommendations for a protocol receiving a composite score of 3Ciii would entail obtaining an independent assessment by a qualified mental health professional or use of a validated assessment instrument.

Sample informal discussion questions:

- *Can you tell me what will happen if you agree to be part of this study?*
- *How might this study help you?*
- *Can anything bad happen to you? Tell me about that.*
- *What will happen if you decide not to be in the study?*

Table 1 Research Dimensions and Categories

Research Risk: (This dimension is the same across all studies and is the fundamental risk level assignment)
Category 1. The study does not involve greater than minimal risk.
Category 2. The study presents greater than minimal risk *and* prospect of direct benefit to the participants.
Category 3. The study presents greater than minimal risk *and* no prospect of direct benefit to the subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition
Category 4. The study does not fall under Category 1, 2, or 3, listed above.

Likelihood of impaired consent capacity: (This is an anticipated level of consent capacity impairment that is likely for the target population)
Category A. The target population for the study has a low to no likelihood of impaired consent capacity.
Category B. The target population for the study has a minimal likelihood of impaired consent capacity.
Category C. The target population for the study has a moderate likelihood of impaired consent capacity.
Category D. The target population for the study has a high likelihood of impaired consent capacity.

Likelihood of changes in consent capacity over the duration of the study
Category i. The target population for the study has a low to no likelihood of changes in consent capacity over the duration of the study. This applies to participants who have impaired consent capacity but with conditions that are static or chronic and progressive and that show little likelihood of improving or to participants who are intact and have little likelihood of having diminished consent capacity. It is used when the consent capacity is expected to remain stable over the time period of the study duration.
Category ii. The target population for the study has a minimal likelihood of changes in consent capacity over time. This applies to participants who either have impairments that might be expected to improve over time or that might diminish over the time period of the study duration.
Category iii. The target population for the study has a moderate likelihood of changes in consent capacity over the study duration. This applies to participants who either have impairments that can be expected to improve over time or that are more likely to diminish over the time period of the study duration.
Category iv. The target population for the study has a high likelihood of changes in consent capacity over time. This applies to participants who either have impairments that most likely will improve over time or that most likely will diminish over the course of the study. Or, this level might apply to participants with waxing and waning capacities that fluctuate during the course of the study.

IV. Other safeguards:
For studies with risk level 2 and moderate or greater likelihood of impaired consent capacity (2 C i –iv), investigators describe and provide examples of safeguards or tools they intend to employ in conducting the research. Specific enhancements to the consent form and process may serve to improve a prospective participant's understanding and enable individuals who otherwise have limitations in consent capacity, to make competent decisions.

a. Use of guidance for a legally authorized representative to provide informed consent on behalf of the participant: When potential participants have been assessed as having impaired consent capacity, the investigator must engage a Legally Authorized Representative (LAR) to provide informed consent on the potential participant's behalf. Investigators should present information on how this selection will be made and how the LAR will be educated about making the consent decision. The IRB has the following electronic documents that can be provided to LARs to help them understand their special role.

- Advice to Legally Authorized Representatives of Adult Participants in Medical Research
- Advice to Legally Authorized Representatives of Adult Participants in Nonmedical Research

b. Adult assent form and procedure: When potential participants have been assessed as having limited or impaired consent capacity, the investigator should obtain assent. Failure to object should not, absent affirmative agreement, be construed as assent. Where impairment is too great even for obtaining assent, investigators may need to carefully consider attention to subject dissent.

A sample assent form is available on the ORI website. Obtaining assent may not be applicable in some cases such as where participants are physiologically incapable of responding to investigator questions. Verbal assent may be appropriate in cases where a subject is unable to sign an assent form.

c. Method for assessing dissent: The investigator must describe what methods are to be used to *assess dissent* among participants with limited or impaired consent capacity. Participants may exhibit behaviors or non-verbal cues (e.g. becoming upset, moving away, facial expressions, etc.) that indicate their desire to not want to participate. In addition, they may be asked to make a defined signal or gesture (e.g. shaking the head, using "thumbs down" sign, etc.) to indicate their desire to not participate or stop participation.

d. Study overviews: Use of a study overview may enable an individual with limited consent capacity to make a decision regarding study participation. A study overview summary is written in simple language that distills the principal ideas from a consent form. Not to be used as a substitute for the full consent document, this tool provides an overview of the primary consent elements for initial consideration in the consent process. From that baseline, the process may continue with additional layers of detail.

e. If consent capacity is assessed as likely to fluctuate over time, describe intervals or conditions for re-consent. The recommended plan for participants with a higher likelihood of changes in consent capacity over the duration of the study should incorporate set timeframes for re-assessing consenting capacity. Study design implications such as timing of risky procedures, sequence of intervention and lengthy periods of no contact should be considered when determining appropriate timeframe for re-assessment and/or re-consent. The Investigator should explain why he/she does not plan to follow a specific timeframe and can describe an alternative plan.

f. Other considerations and potential safeguards. Investigators should use fair and equitable recruitment practices in research and avoid practices that place participants at risk for coercion or undue influence. The investigator should describe any other educational techniques or consent process alterations he/she plans to employ.

g. Institutionalized subjects. The impact of institutionalization may further compromise the voluntariness of an individual with impaired consent capacity. Investigators must not involve this population for convenience purposes. Investigators should justify use of institutionalized subjects and take measures to ensure decisions are voluntarily made, free of influence or potential or perceived impact on involuntary confinement.

Definitions

Minimal risk – Means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests. (i.e., daily life of healthy persons).

Consent capacity – includes the specific abilities necessary for a prospective or current research participant to understand and use information relevant to consent. The components of consent capacity are the capacity to (1) act on one's own behalf; (2) understand the study; (3) appreciate the consequences to oneself of participation; and (4) make a free choice.

Assent - is defined as a child's [*or an impaired consent capacity individual's*] affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Dissent – is defined as an individual's verbal or non-verbal disagreement or refusal to assent to participate in research. Two general categories of non-verbal dissent are recognized: (1) Behaviors that suggest dissent such as turning away from researchers or pushing away and (2) Agreed signals of dissent such as situations where a researcher tells a subject to blink the eyes once or twice to signal dissent.

Competence – "Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice." [OHRP Institutional Review Board Guidebook, Chapter VI, Section D]

Permission - is defined as the agreement of parent(s) or guardian to the participation of their child or ward in research or a clinical investigation. Permission includes the element of consent set forth in federal regulations and outlined in the informed consent template included in the IRB expedited and full review applications.

Qualified mental health professional – is defined by Kentucky statute (202A.011). It includes licensed physicians, psychiatrists, psychologists, mental health RNs, licensed clinical social workers, marriage and family therapists, and licensed professional counselors. See * below for the complete statutory language.

Legally authorized representative - is an individual, judicial or other body authorized to make research participation decisions on behalf of another. In accord with state law and federal regulation, individuals who can serve as legally authorized representatives are as follows:

Consent and/or Authorization by a Legally Authorized Representative
Consistent with Kentucky health care decision statutes for choosing a legally authorized representative for adult subjects unable to consent, one of the following responsible parties, in the following order of priority (if no individual in a prior class is reasonably available, willing, and competent to act), is authorized to make research participation decisions on behalf of the person: (a) the judicially-appointed guardian of the person, if the guardian has been appointed and if the decisions to be made under the consent are within the scope of the guardianship; (b) the attorney-in-fact named in a durable power of attorney, if the durable power of attorney specifically includes authority for the decisions to be made under the consent; (c) the spouse of the person; (d) an adult child of the person, or if the person has more than one (1) child, the majority of the adult children who are

reasonably available for consultation; (e) the parents of the subject; (f) the nearest living relative, or if more than one of the same relation, a majority of the nearest living relatives.

Consent by a legally authorized representative should involve all the same considerations that informed consent from a competent subject involves.

***KRS 202A.011, Section (12)(a)-(12)(g)* "Qualified mental health professional" means**:
(a) A physician licensed under the laws of Kentucky to practice medicine or osteopathy, or a medical officer of the government of the United States while engaged in the performance of official duties; (b) A psychiatrist licensed under the laws of Kentucky to practice medicine or osteopathy, or a medical officer of the government of the United States while engaged in the practice of official duties, who is certified or eligible to apply for certification by the American Board of Psychiatry and Neurology, Inc.; (c) A psychologist with the health service provider designation, a psychological practitioner, a certified psychologist, or a psychological associate, licensed under the provisions of KRS Chapter 319;
(d) A licensed registered nurse with a master's degree in psychiatric nursing from an accredited institution and two (2) years of clinical experience with mentally ill persons, or a licensed registered nurse, with a bachelor's degree in nursing from an accredited institution, who is certified as a psychiatric and mental health nurse by the American Nurses Association and who has three (3) years of inpatient or outpatient clinical experience in psychiatric nursing and is currently employed by a hospital or forensic psychiatric facility licensed by the Commonwealth or a psychiatric unit of a general hospital or a private agency or company engaged in the provision of mental health services or a regional community mental health and mental retardation program; (e) A licensed clinical social worker licensed under the provisions of KRS 335.100, or a certified social worker licensed under the provisions of KRS 335.080 with three (3) years of inpatient or outpatient clinical experience in psychiatric social work and currently employed by a hospital or forensic psychiatric facility licensed by the Commonwealth or a psychiatric unit of a general hospital or a private agency or company engaged in the provision of mental health services or a regional community mental health and mental retardation program; (f) A marriage and family therapist licensed under the provisions of KRS 335.300 to 335.399 with three (3) years of inpatient or outpatient clinical experience in psychiatric mental health practice and currently employed by a hospital or forensic facility licensed by the Commonwealth, a psychiatric unit of a general hospital, a private agency or company engaged in providing mental health services, or a regional community mental health and mental retardation program; or (g) A professional counselor credentialed under the provisions of KRS Chapter 335.500 to 335.599 with three (3) years of inpatient or outpatient clinical experience in psychiatric mental health practice and currently employed by a hospital or forensic facility licensed by the Commonwealth, a psychiatric unit of a general hospital, a private agency or company engaged in providing mental health services, or a regional community mental health and mental retardation program.

Appendix I. Assessment actions and instruments by composite risk score

1	Any level	Any level	Do you plan to do an informal subject assessment during routine interview procedures?
2	A	i	Do you plan to do an informal subject assessment during routine interview procedures?
2	A	ii	
2	A	iii	
2	A	iv	Do you plan to do an informal subject assessment during routine interview procedures *and repeat as needed?*
2	B	i	Do you plan to do an informal subject assessment during routine interview procedures?
2	B	ii	Do you plan to do an informal subject assessment and document all of the following: 1) subject understanding; 2) subject understanding of the study; 3) subject choice to participate; and 4) subject's evidence of reasoning? For iv – *and repeat as needed?*
2	B	iii	
2	B	iv	
2	C	i	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study?
2	C	ii	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at appropriate intervals– every year recommended?*
2	C	iii	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at appropriate intervals– every 6 months recommended?*
2	C	iv	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at*

			appropriate intervals– every 6 months recommended?
2	D	i	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study?
2	D	ii	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at appropriate intervals– every year recommended?*
2	D	iii	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at appropriate intervals– every 6 months recommended?*
2	D	iv	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at appropriate intervals– every 6 months recommended?*
3	A	i	Do you plan to do an informal subject assessment during routine interview procedures?
3	A	ii	Do you plan to do an informal subject assessment during routine interview procedures *and repeat as needed – every year recommended?*
3	A	iii	Do you plan to do an informal subject assessment during routine interview procedures *and repeat as needed – every 6 months recommended?*
3	A	iv	Do you plan to do an informal subject assessment during routine interview procedures *and repeat as needed – every 6 months recommended?*
3	B	i	Do you plan to do an informal subject assessment during routine interview procedures?
3	B	ii	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at appropriate intervals– every year recommended?*
3	B	iii	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at appropriate intervals– every 6 months recommended?*
3	B	iv	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at appropriate intervals– every 6 months recommended?*
3	C	i	Do you plan to do an informal subject assessment during routine interview procedures?
3	C	ii	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at appropriate intervals– every year recommended?*
3	C	iii	Do you plan to obtain an independent assessment by a qualified mental health professional* with experience in consent capacity assessment OR the MacArthur

			Competence Assessment Tool *and repeat at appropriate intervals – every 6 months recommended?* **See ORI Policy on assessing consent capacity or KRS 202A.011, Section (12)(a)-(12)(g). This includes: licensed physicians, licensed psychiatrists, psychologists, RNs with master's degree in psychiatric nursing or certified mental health BSN, RNs, licensed clinical social workers, marriage and family therapists, and licensed professional counselors.*
3	C	iv	Do you plan to obtain an independent assessment by a qualified mental health professional* with experience in consent capacity assessment OR the MacArthur Competence Assessment Tool *and repeat at appropriate intervals – every 6 months recommended?* **See ORI Policy on assessing consent capacity or KRS 202A.011, Section (12)(a)-(12)(g). This includes: licensed physicians, licensed psychiatrists, psychologists, RNs with master's degree in psychiatric nursing or certified mental health BSN, RNs, licensed clinical social workers, marriage and family therapists, and licensed professional counselors.*
3	D	i	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study?
3	D	ii	Do you plan to use the UBACC or comparable assessment instrument OR independent assessment by personnel not affiliated with the study *and repeat at appropriate intervals– every year recommended?*
3	D	iii	Do you plan to obtain an independent assessment by a qualified mental health professional* with experience in consent capacity assessment OR the MacArthur Competence Assessment Tool *and repeat at appropriate intervals – every 6 months recommended?* **See ORI Policy on assessing consent capacity or KRS 202A.011, Section (12)(a)-(12)(g). This includes: licensed physicians, licensed psychiatrists, psychologists, RNs with master's degree in psychiatric nursing or certified mental health BSN, RNs, licensed clinical social workers, marriage and family therapists, and licensed professional counselors.*
3	D	iv	Do you plan to obtain an independent assessment by a qualified mental health professional* with experience in consent capacity assessment OR the MacArthur Competence Assessment Tool *and repeat at appropriate intervals – every 6 months recommended?* **See ORI Policy on assessing consent capacity or KRS 202A.011, Section (12)(a)-(12)(g). This includes: licensed physicians, licensed psychiatrists, psychologists, RNs with master's degree in psychiatric nursing or certified mental health BSN, RNs, licensed clinical social workers, marriage and family therapists, and licensed professional counselors.*
4	A,B,C,D	i-iv	What methods will you use to assess consent capacity for this study?

While some investigators may choose to use adaptations of validated tools, other studies may require use of the published original tool. The following provides information regarding use and access to validated consent capacity assessment tools:

- The MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR; Appelbaum & Grisso, 2001)
  - Semi-structured interview, tailored to protocol
  - Administration takes 15-30 minutes, and substantial training is required for valid administration and interpretation
  - Available from Amazon.com
- The University of California, San Diego Brief Assessment of Capacity to Consent (UBACC; Jeste et al., 2007) is available on line
  - 10-item scale; may be tailored to protocol
  - Less than five minutes to administer, minimal training needed
  - AMA terms of use for the UBACC