

Clinical Research Update
***“Assessing Consent Capacity in Clinical Research:
New Directions”***

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Traditional Views

- Traditionally, subjects have been seen as either “competent” or “decisionally impaired” or “decisionally challenged.”
- This black and white understanding has been refuted by research on cognitive functioning for a long time.
- In addition, the terminology has been somewhat stigmatizing.

The concept of “dementia” for ascertaining and addressing cognitive impairment has failed. It is too categorical, exclusive, and arbitrary. Creating a dichotomy between dementia and nondementia ignores the spectrum of cognitive impairment... It is time to shift the focus from thresholds to a continuum of cognitive impairment, from the late to early stages, and from effects to causes.

- Hachinski, 2008, JAMA, 300: 18, 2172-2173

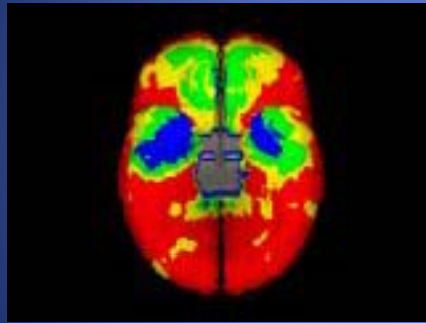
- Hachinski's comments specific to dementia also apply to a wide range of disorders and clinical conditions that result in cognitive difficulties. Decisional capacity is not a discrete, unitary condition that lends itself to easy measurement.
- In addition, empirical studies show that **study subjects presumed to be competent to give consent are, in fact, often not competent** (Berg, Appelbaum, Lidz & Parker, 2001).
- More to the point for the IRB, there is poor interrater reliability for clinical assessments of decisional capacity (Marson, McInturff, Hawkins, Bartolucci, & Harrell, 1997).
- Variation in consent capacities secondary to complex clinical conditions and variations in study risk levels means a carefully titrated approach to identifying, assessing, and consenting individuals with impaired consent capacity.

How Clinical Conditions Affect Cognitive Capacities

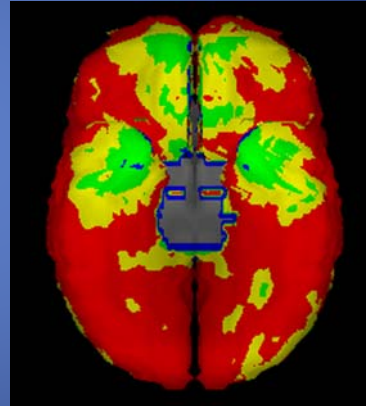
- Many clinical conditions can result in mild cognitive impairment and these mild conditions can greatly affect decisional capacity (Jefferson, Lambe, Moser, Byerly, Ozonoff, & Karlawish, 2008).

Brain images showing decreased frontal lobe activity with two clinical conditions

Depression



TBI

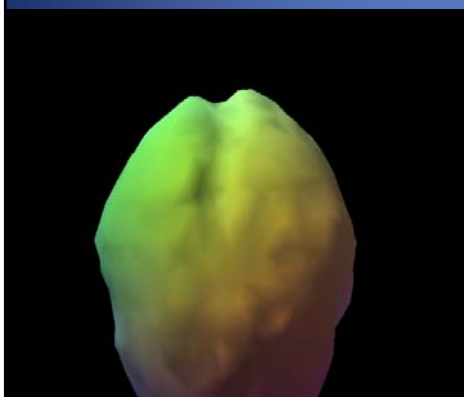


One other note:
About 15% of the population has an IQ of 85 or lower – think of a 19 page consent form in the context of this level of IQ.

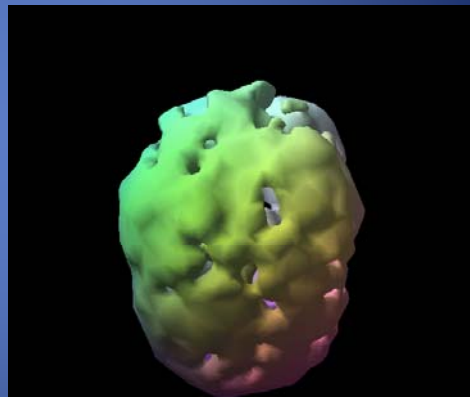
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For a reference, side by side

Healthy Control



Drug Dependent



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Variation in decisional impairment

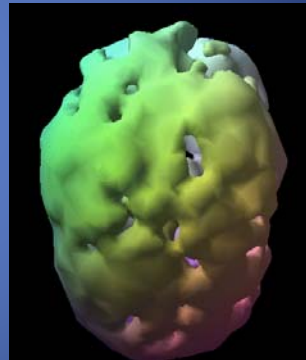
- Situational vs. disorder-related impairment
 - (e.g. emergency room, “institutions,” vs. stroke)
- Global vs. specific impairment
 - (e.g. sedative overdose vs. paranoid psychosis)
- Static vs. progressive vs. episodic vs. time limited impairment
 - (e.g. severe mental retardation vs. Alzheimer’s disease vs. manic depressive disorder vs. TBI)
- Acute vs. persistent impairment
 - (e.g. stress, or hypoxia secondary to asthma or acute pain vs. mental retardation or autism)
- Universal
 - (e.g. therapeutic misconception, inadequate disclosure)

Clinical conditions

- 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
- Other acute medical crises

What are the concerns? Back to the definitional elements for consent capacity

1. "capacity to act on one's own behalf"
2. "the ability to understand"
3. "to appreciate the consequences"
4. "to make a choice"



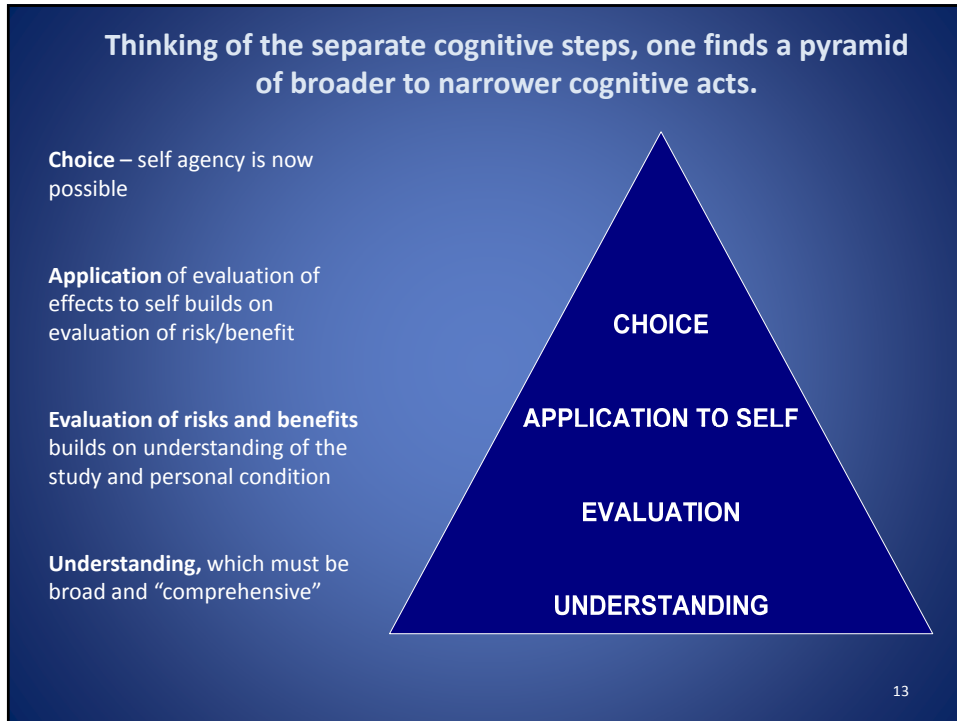
Top view, SPECT image of cortex of long-term drug abuser's brain

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Consent capacity as a composite of cognitive steps or acts

- Each of the four components of consent capacity ***are distinct cognitive acts that imply a sequence.***
- Each implies the use of intelligence, awareness, and fundamental knowledge.

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New Federal Directions

- There is growing concern about how to ethically include research subjects who have limited or impaired consent capacity as evidenced by the OHRP solicitation of ideas about new regulations and guidance.
- Furthermore, in March, 2008 the DHHS Secretary’s Advisory Committee on Human Research Protections (SACHRP) appointed a subcommittee to make recommendations about changes in consent processes with decisionally impaired subjects.
- That group, the Subcommittee on the Inclusion of Individuals with Impaired Decision-making in Research (SIIDR) presented ten recommendations, three of which are complete, four are in early stages of development and three others are planned.

SIIDR Recommendations

1. *A use of “consent capacity” rather than “decisionally challenged” or “not competent.”*
2. *Development of detailed guidance for IRBs and investigators on the nature of consent impairment, including:*
 - a. *An individual’s consent capacity is not simply present or absent – capacity is best understood as occurring along a continuum;*
 - b. *Impaired consent capacity occurs in a wide range of conditions and disease states – policies should recognize the many manifestations of impaired consent capacity and not be limited to specific disorders;*
 - c. *Consent capacity is task-specific and depends on the nature and complexity of the relevant decision-making process; and*
 - d. *Guidance should encourage development of policies to reflect the fluctuations in consent capacity over time.*

SIIDR (continued)

3. *Development of detailed approaches for identifying and assessing individuals who may have impaired consent capacity and approaches for both should be tailored to the study population, the level of study risk and the likelihood of subjects with impaired consent capacity.*
 - a. *Formal assessment methods can be used.*
 - b. *The level of capacity needed for consent depends on study characteristics.*
 - c. *Investigators and research staff responsible for the consent process should be appropriately trained and qualified.*
 - d. *Enhancements to the consent forms may improve subjects’ understanding and may improve consent capacity.*

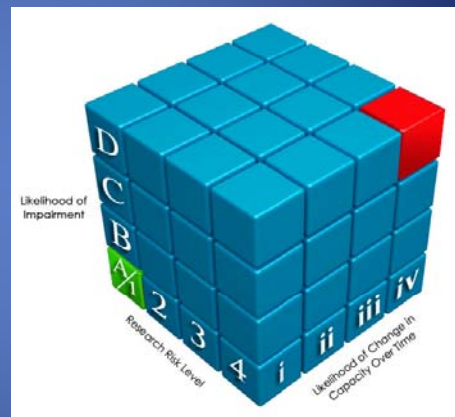
The Task for the UK IRB

- **The Goal** was to develop a new policy that would put us in accord with national trends
- **The Objective** was to design procedures that would do two things:
 - Stimulate thinking about the role of consent capacity, and
 - Accommodate study differences and not tie investigators hands

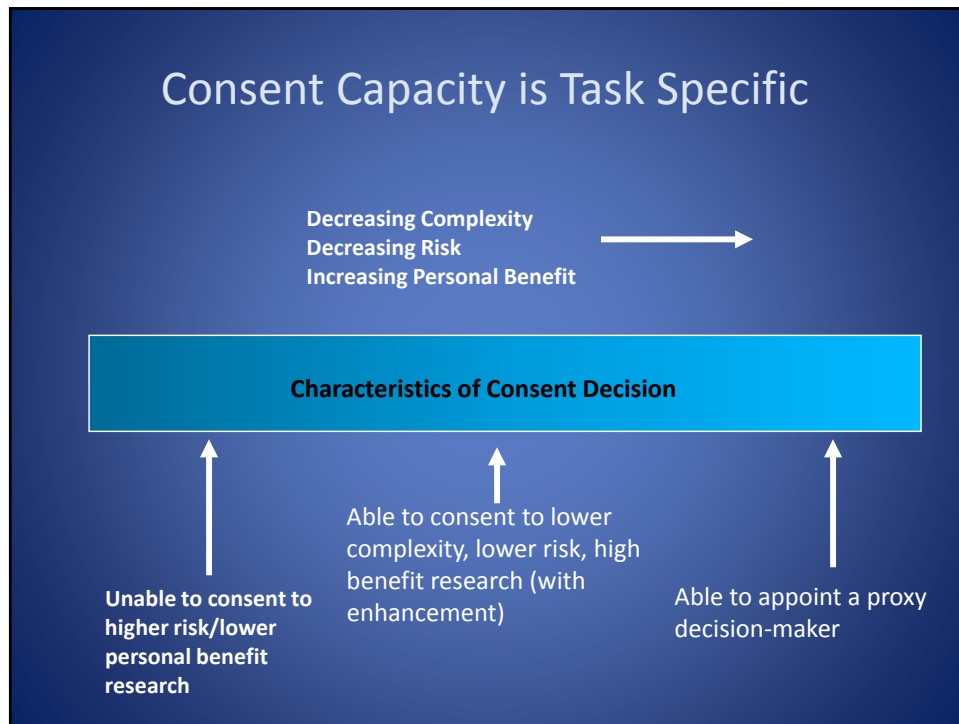
The UK multidimensional model

This approach factors in:

1. Research risk level
2. Likelihood of impaired consent capacity
3. Likelihood of changes in consent capacity over the duration of the study



Consent Capacity is Task Specific

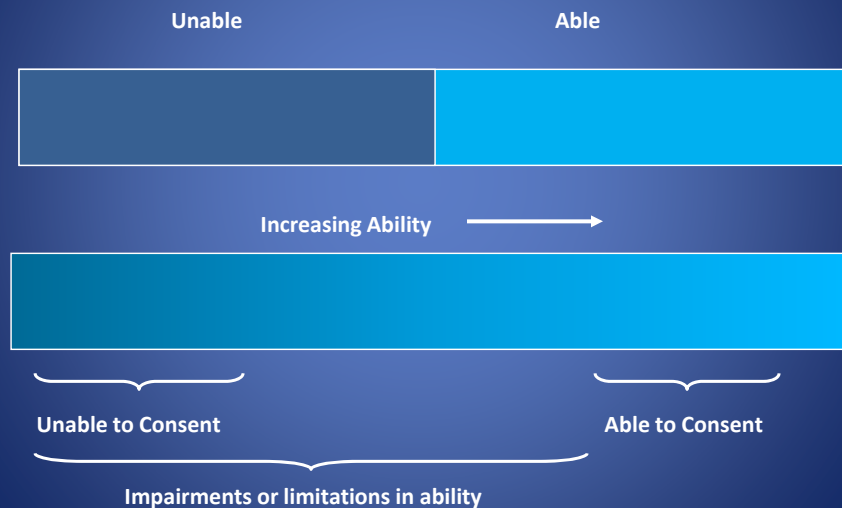


1st Dimension

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 subjects.
- **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, because
- **Category 4.** The study does not fall under Category 1, 2, or 3, listed above.

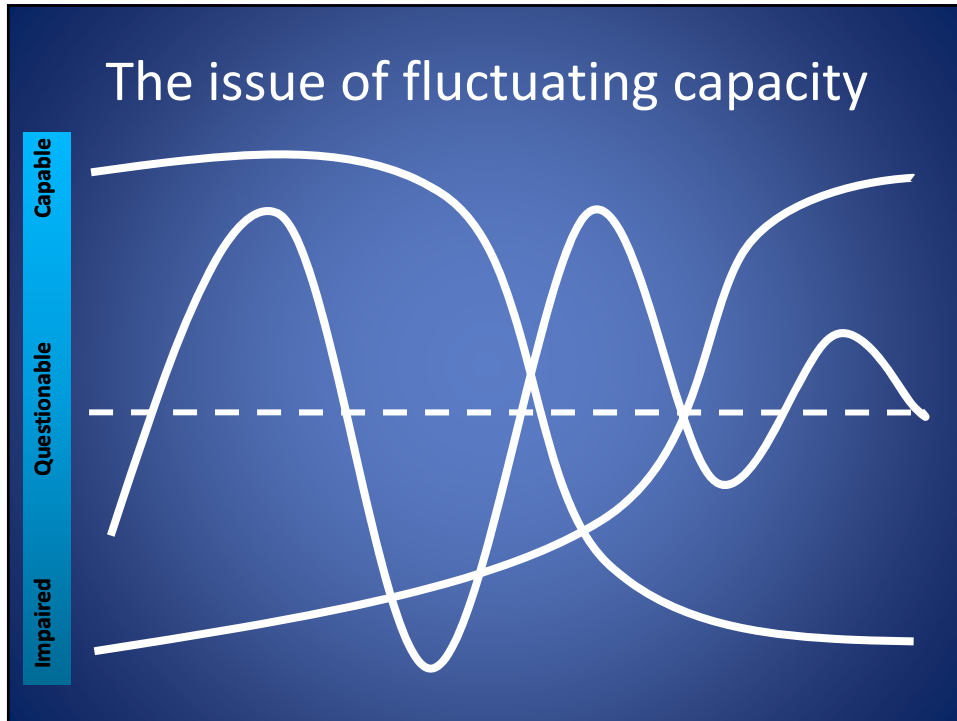
Consent capacity occurs along a continuum



2nd Dimension

Likelihood of impaired consent capacity: (This is an anticipated level of consent capacity impairment that is likely for the target population)

- A. The target population for the study has a **low to no likelihood** of impaired consent capacity because: (Here the investigator supplies a rationale for why a likely population does not in fact have risk of consent capacity impairment).
- B. The target population for the study has a **minimal likelihood** of impaired consent capacity because: (Here the investigator supplies a rationale for why a likely population does not in fact have risk of consent capacity impairment).
- C. The target population for the study has a **moderate likelihood** of impaired consent capacity related to: (Here the investigator supplies information about the population and its likely impairment in consent capacity).
- D. The target population for the study has a **high likelihood** of impaired consent capacity related to:



3rd Dimension: Fluctuation

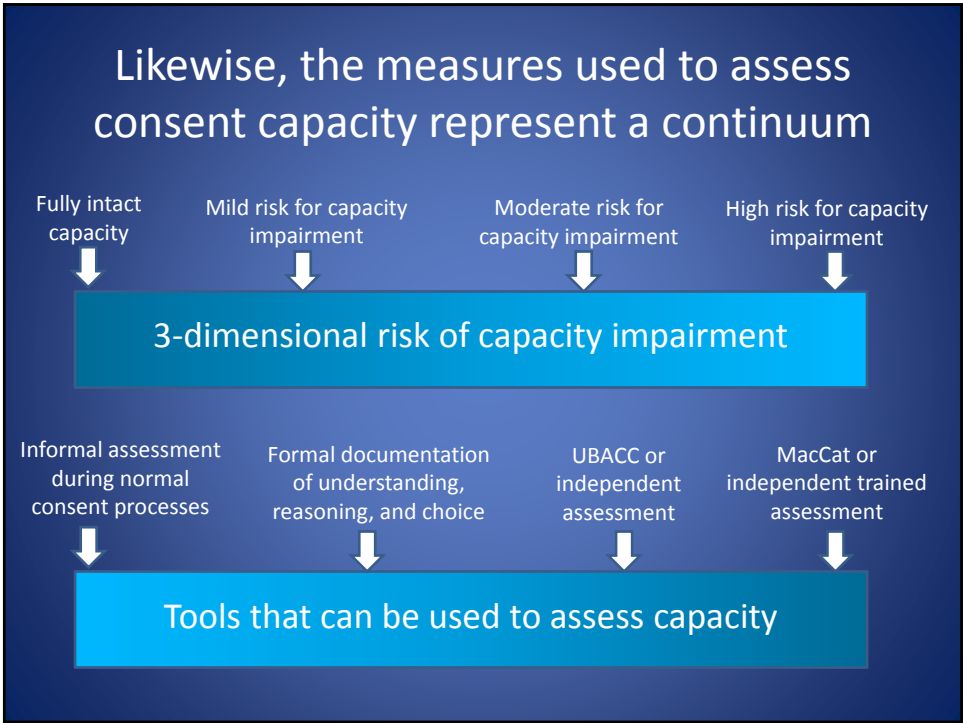
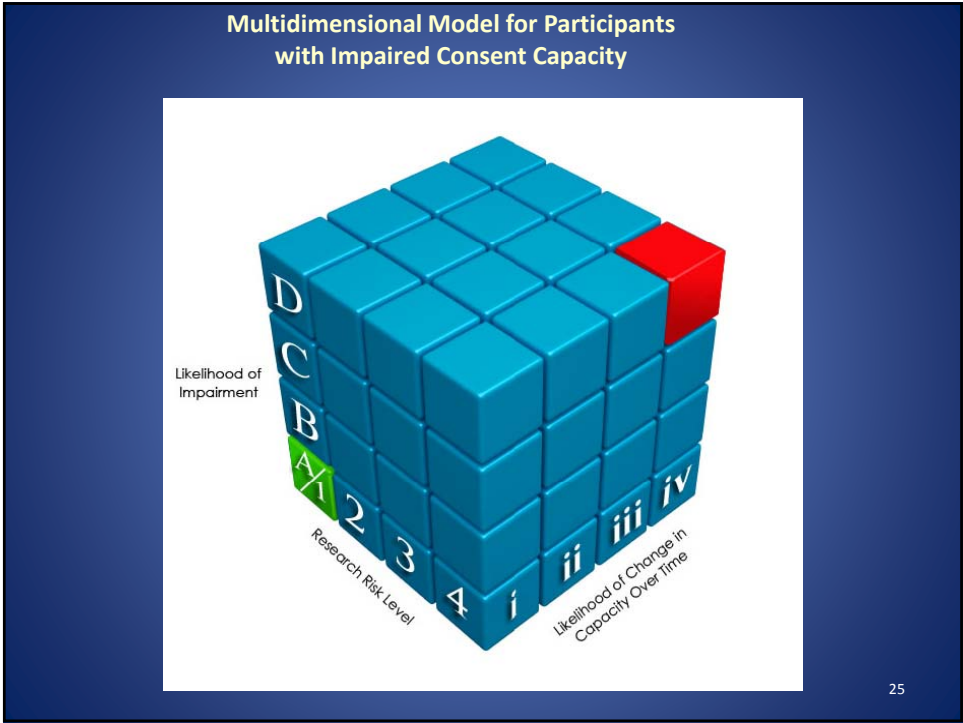
Likelihood of changes in consent capacity over the duration of the study

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.

Category ii. The target population for the study has a minimal likelihood of changes in consent capacity over time.

Category iii. The target population for the study has a moderate likelihood of changes in consent capacity over the study duration.

Category iv. The target population for the study has a high likelihood of changes in consent capacity over time.



MacCAT-CR

- MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR) (Appelbaum & Grisso, 2001).
 - It consists of Four Sections with clinician ratings of participant's responses in each section:
 - Understanding
 - Appreciation
 - Reasoning
 - Expressing choice
- Paul Appelbaum & Thomas Grisso developed this for the MacArthur Foundation – two tools one for treatment, one for clinical research.

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MacCAT-CR

- No sum scoring.
- Items are to be tailored for the specific study.
- Probes are used to make the tool more adaptable.
- Scoring for each section consists of 3 options – (2) giving complex answers, (1) a single response that is correct and (0) no viable response.
- Failure to have a response to any one section can lead to assessment of decisional incapacity.
- It takes between 20-30 minutes to complete.

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The UBACC

- University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) has been shown to have reliability and concurrent validity and high sensitivity (Jeste, Palmer, Appelbaum, Golshan, Glorioso, Dunn, Kim, Meeks, & Kraemer, 2007).
- Takes less than 5 minutes to administer.
- 10 items – tailored to the specific study.

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Sample items from the UBACC

- What is the purpose of the study that was just described to you?
- What makes you want to consider participating in this study?
- Do you believe this is primarily research or primarily treatment?
- Do you have to be in this study if you do not want to participate?
- If you withdraw from this study, will you still be able to receive regular treatment?
- If you participate in this study, what are some of the things that you will be asked to do?

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How this all works in your research...

1. Selection of capacity criteria based on the three-dimensional model
2. Input selections in the automated web-based form
3. Receive direct guidance from IRB on appropriate measures for assessing consent capacity (you can propose alternatives!)

(Illustrative examples)

Proposed changes to Form A - GIS

New Screening Items for Form A-1

Study Population
There are two kinds of studies that need Form T: (1) studies of subjects with impaired consent capacity and (2) studies that target populations with clinical conditions that suggest a great likelihood of impaired consent capacity. If this study does not fall into one of these two criteria and you do not answer "yes" to questions 1 or 2 do not use Form T.

1. Does this study focus on subjects with impaired decision making capacity?

Yes No
If yes, proceed to Form T.

2. If no, does this study target a population whose clinical condition suggests a great likelihood of impaired decision making capacity including conditions listed below?

Traumatic brain injury or acquired brain injury
Severe depressive disorders or Bipolar disorders
Schizophrenia or other 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
Other acute medical crises

Yes No
If yes, proceed to Form T.
If no, do not complete this form.
If yes, but you do NOT think your study subjects will have limited consent capacity, please explain and do NOT complete Form T:

Retrospective chart review and questionnaire of persons with well-controlled diabetes investigating self-report of diet and HgbA1c levels

1st Dimension

Research Risk:

- **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, because
- **Category 4.** The study does not fall under Category 1, 2, or 3, listed above.

2nd Dimension

Likelihood of impaired consent capacity: (This is an anticipated level of consent capacity impairment that is likely for the target population)

- A. The target population for the study has a **low to no likelihood of impaired consent capacity.**
- B. The target population for the study has a **minimal likelihood of impaired consent capacity.**
- C. The target population for the study has a **moderate likelihood of impaired consent capacity.**
- D. The target population for the study has a **high likelihood of impaired consent capacity.**

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3rd Dimension: Fluctuation

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.

Category ii. The target population for the study has a minimal likelihood of changes in consent capacity over the duration of the study.

Category iii. The target population for the study has a moderate likelihood of changes in consent capacity over the duration of the study.

Category iv. The target population for the study has a high likelihood of changes in consent capacity over the duration of the study.

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Section 1: Research risk level.
Rate the overall risk level posed by this study according to the categories listed below.
(Enter the category number that applies to this study):
 ▼

Section 2: Likelihood of impaired consent capacity.
Rate the likelihood of impaired consent capacity for the target population for this study
using the categories listed below.
 ▼

Section 3: Likelihood of changes in consent capacity over the duration of the study.
Rate the likelihood of changes in consent capacity (positively or negatively) for the target population for this
study using the categories listed below.
 ▼

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Your composite score is: 1 B i

IRB recommended protections for this composite score are:
For projects with any research level 1, do an informal participant assessment during routine interview
procedures to determine consent capacity and change over time if indicated. No other special
procedures must be considered.

[Back to IRB Form](#)

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Investigation of 2 weeks of radiation therapy for a patient with newly diagnosed lymphoma and no significant comorbidities

1st Dimension

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, because
- **Category 4.** The study does not fall under Category 1, 2, or 3, listed above.

2nd Dimension

Risk 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 risk of impaired consent capacity
- **Category B.** The target population for the study has a minimal risk of impaired consent capacity
- **Category C.** The target population for the study has a moderate risk of impaired consent capacity
- **Category D.** The target population for the study has a high risk of impaired consent capacity related to:

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3rd Dimension

- **Category i.** The target population for the study has a low to no risk of changes in consent capacity over the duration of the study.
- **Category ii.** The target population for the study has a minimal risk of changes in consent capacity over the duration of the study.
- **Category iii.** The target population for the study has a *moderate risk of changes in consent capacity* over the duration of the study.
- **Category iv.** The target population for the study has a high risk of changes in consent capacity over the duration of the study.

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Section 1: Research risk level.
Rate the overall risk level posed by this study according to the categories listed below.
(Enter the category number that applies to this study):
This study presents greater than minimal risk and prospect of direct benefit to the participants. ▾

Section 2: Likelihood of impaired consent capacity.
Rate the likelihood of impaired consent capacity for the target population for this study
using the categories listed below.
The target population for this study has a minimal risk of impaired consent capacity ▾

Section 3: Likelihood of changes in consent capacity over the duration of the study.
Rate the likelihood of changes in consent capacity (positively or negatively) for the target population for this
study using the categories listed below.
Minimal risk of changes in consent capacity (positively or negatively) over the duration of this study. ▾

Calculate Composite Rating Score

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Your composite score is: 2 B ii

IRB recommended protections for this composite score are:
Do an informal participant assessment and document all of the following: 1) participant understanding;
2) participant understanding of the study; 3) participant choice to participate; and 4) participant's
evidence of reasoning.

[Go to your plan.](#)

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Investigation of bat venom as an acute treatment for ischemic stroke

1st Dimension

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, because
- **Category 4.** The study does not fall under Category 1, 2, or 3, listed above.

2nd Dimension

Risk 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 risk of impaired consent capacity
- **Category B.** The target population for the study has a minimal risk of impaired consent capacity
- **Category C.** The target population for the study has a moderate risk of impaired consent capacity
- **Category D.** The target population for the study has a high risk of impaired consent capacity related to:

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3rd Dimension

- **Category i.** The target population for the study has a low to no risk of changes in consent capacity over the duration of the study.
- **Category ii.** The target population for the study has a minimal risk of changes in consent capacity over the duration of the study.
- **Category iii.** The target population for the study has a *moderate risk of changes in consent capacity* over the duration of the study.
- **Category iv.** The target population for the study has a high risk of changes in consent capacity over the duration of the study.

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Section 1: Research risk level.
Rate the overall risk level posed by this study according to the categories listed below.
(Enter the category number that applies to this study):
This study presents greater than minimal risk and prospect of direct benefit to the participants. ▾

Section 2: Likelihood of impaired consent capacity.
Rate the likelihood of impaired consent capacity for the target population for this study
using the categories listed below.
The target population for this study has a high risk of impaired consent capacity. ▾

Section 3: Likelihood of changes in consent capacity over the duration of the study.
Rate the likelihood of changes in consent capacity (positively or negatively) for the target population for this
study using the categories listed below.
High risk of changes in consent capacity (positively or negatively) over the duration of this study. ▾

Calculate Composite Rating Score

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Your composite score is: 2 C iii

IRB recommended protections for this composite score are:
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

[Go to your plan.](#)

[Back to IRB Form](#)

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Investigation of renal biopsy to identify pathogenic mechanisms in endstage renal disease patients on dialysis

1st Dimension

Research Risk:

- **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, because
- **Category 4.** The study does not fall under Category 1, 2, or 3, listed above.

2nd Dimension

Risk 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 risk of impaired consent capacity
- **Category B.** The target population for the study has a minimal risk of impaired consent capacity
- **Category C.** The target population for the study has a moderate risk of impaired consent
- **Category D.** The target population for the study has a high risk of impaired consent capacity

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3rd Dimension

- **Category i.** The target population for the study has a low to no risk of changes in consent capacity over the duration of the study.
- **Category ii.** The target population for the study has a minimal risk of changes in consent capacity over the duration of the study.
- **Category iii.** The target population for the study has a *moderate risk of changes in consent capacity* over the duration of the study.
- **Category iv.** The target population for the study has a high risk of changes in consent capacity over the duration of the study.

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Section 1: Research risk level.
Rate the overall risk level posed by this study according to the categories listed below.
(Enter the category number that applies to this study):
This study presents greater than minimal risk and no prospect of direct benefit to the subjects. ▾

Section 2: Likelihood of impaired consent capacity.
Rate the likelihood of impaired consent capacity for the target population for this study
using the categories listed below.
The target population for this study has a moderate risk of impaired consent capacity. ▾

Section 3: Likelihood of changes in consent capacity over the duration of the study.
Rate the likelihood of changes in consent capacity (positively or negatively) for the target population for this
study using the categories listed below.
Moderate risk of changes in consent capacity (positively or negatively) over the duration of this study. ▾

Calculate Composite Rating Score

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Your composite score is: 3 C iii

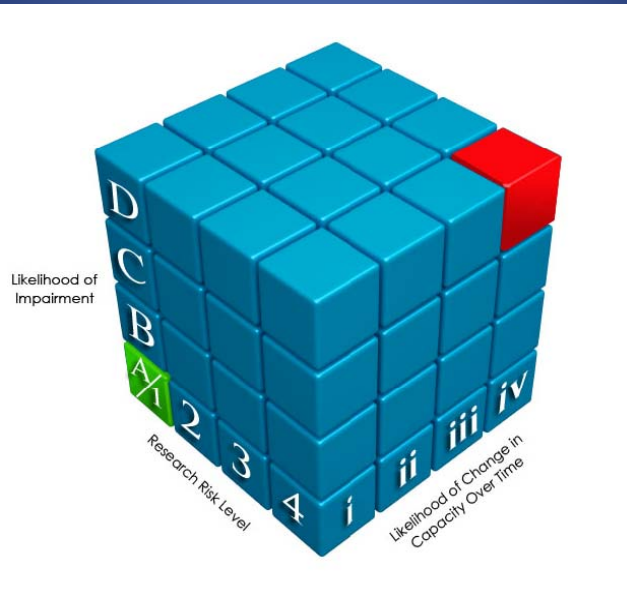
IRB recommended protections for this composite score are:
Use independent assessment by MD, psychologist or social worker with experience in consent
capacity assessment OR MacArthur Competence Assessment Tool and repeat at appropriate
intervals– every 6 months recommended

[Go to your plan.](#)

[Back to IRB Form](#)

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Multidimensional Model for Participants with Impaired Consent Capacity



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Additional considerations...

- LAR
- Simplifying the consent process with study summaries
- Assessing assent/dissent

The new "Form T" recommendations...

Automated Tool Display of Results

Based on your composite score and IRB recommended protections for that score the IRB requests additional information about your proposed plans. Please identify your plans below.

Do you plan to use an independent assessment of decisional capacity by an MD, psychologist or social worker with experience in consent capacity assessment or the MCAT or other tool?

Yes
 No, the plan is to use (describe tools and persons who will assess consent capacity).....

Rationale: _____

Do you plan to re-assess capacity every 6 months?

Yes (explain how) _____
 No, the plan is to _____

Rationale: _____

Investigator response on Form T

Based on your composite score and IRB recommended protections for that score the IRB requests additional information about your proposed plans. Please identify your plans below.

Do you plan to use an independent assessment of decisional capacity by an MD, psychologist or social worker with experience in consent capacity assessment or the MCAT or other tool?

Yes
 No, the plan is to use (describe tools and persons who will assess consent capacity).....

Rationale: _____

Do you plan to re-assess capacity every 6 months?

Yes (explain how) _____
 No, the plan is to _____

Rationale: _____

Investigator variation from IRB recommendation

Based on your composite score and IRB recommended protections for that score the IRB requests additional information about your proposed plans. Please identify your plans below.

Do you plan to use an independent assessment of decisional capacity by an MD, psychologist or social worker with experience in consent capacity assessment or the MCAT or other tool?

Yes

No, the plan is to use (describe tools and persons who will assess consent capacity)

Every potential subject in this study already has current complete neuropsychological testing that will address consent capacity

Rationale: The subject pop for this study has been thoroughly assessed as to competence and consent capacity prior to the study

Do you plan to re-assess capacity every 6 months?


Yes (explain how) brief clinical assessment by professional not associated with the study

No, the plan is to _____

Rationale: _____

For those with impaired consent capacity

- Legally authorized representatives should be considered.
- ORI has new pamphlets to help educate LARs about their role in consenting on behalf of subjects.
- One pamphlet is for medical studies another is for non-medical studies.
- They are optional tools if investigators want to use them.





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If you have questions about your rights as a legally authorized representative of a UK research study volunteer, you may call the University of Kentucky Office of Research Integrity at (859) 257-9428 or toll free at 1-866-400-9428.

Advice to Legally Authorized Representatives of Adult Participants
University of Kentucky Institutional Review Board



see blue.
in everything we do.

You are what is called a “legally authorized representative” of a patient who is or might become a participant in a research study.

This means that the participant whom you represent does not have the capacity to make an independent decision about treatment or about participating in research. Therefore, you have been asked to make decisions on behalf of the patient.

Research Risk

Basically, you are being asked to weigh the risks and benefits of participating in clinical research. “Risk” means the chance of harm that might happen. There could be risks from medication side effects or risks from certain medical procedures. Sometimes doctors will tell you about these risks as “very rare” or “common” or sometimes they will give you information to help you understand the level of risk. For example, they might tell you that a side effect has happened to 10% of research subjects in the past.



Research Benefit

Likewise, you are asked to evaluate the benefits to the patient for participating. A benefit might be that the new experimental drug would actually help treat the patient’s medical problem. Doctors call this kind of benefit a “direct” benefit to the individual. There is

another kind of benefit that is indirect. In this case, the benefit might be that a lot can be learned about promising medications or procedures. Also, other patients might benefit from the knowledge gained from this study.

Risk and Benefit

You have to weigh the risks against the benefits. That is, “this much risk for that much benefit.” The benefits should outweigh or offset the risks.

Two Approaches

When you are asked to make this risk/benefit decision, there are two ways to go about it: (1) the “substituted judgment” approach and (2) the “in the individual’s best interest” approach.

The substituted judgment approach means that you are being asked to make the decision based on how you think the participant would do it. In other words, you express exactly what you think the patient would do if he or she could still make independent medical decisions.

For example, a research treatment might have a small likelihood of benefit for the patient and may have serious side effects, but you know that the patient would want to advance science and be of possible benefit to others. In this case, you might decide to agree to the patient’s participation using the substituted judgment approach.

The individual’s best interest approach takes a very different turn. In this situation you make the decision

about a treatment or about participating in research based on what you think is best for the patient, independent of what he or she might have decided if there was no impairment in decision-making. In other words, you act almost as parent for a child where you look out for the safety and overall well-being of the patient. In using this approach, you can consider all aspects of well-being.

For example, a research treatment might hold out a promise of effectiveness, but the participant is so ill that even this improvement will make no difference in quality of life. In this case, you might decide to not agree to the research treatment if you follow the best interests of the individual approach.

Being a legally authorized representative is a serious role and the patient’s research doctor takes it seriously as well.

One other thing – sometimes choosing to participate can mean that you must spend considerable time bringing the participant to appointments and waiting for procedures to be done. Be sure to ask about how much time you or other family members will need to spend waiting during these visits.

If you are having difficulty in making this decision, ask the participant’s doctor or the research doctor for more information until you feel confident that you are making the best decision you can under the circumstances.



Study overviews: A bridge into consent

- Subjects may find it helpful to have a digest of the study elements in very simple language.
- These overviews contain the essential features of a consent but cannot be used in lieu of a consent.

STUDY OVERVIEW

Dr. XXXXX's Study

THIS IS NOT TO BE USED AS A CONSENT FORM –

You are being asked to participate in a study because you have been diagnosed with Alzheimer's disease. You are asked to have your partner or caretaker with you to look at this study.

WHAT IS THE STUDY ABOUT?

It's about a drug that might remove some of the plaque that builds up around people's nerve cells.

WHAT ARE YOU ASKED TO DO?

First, we have to see if you qualify for the study. That means completing a survey, having a physical exam, and having some blood drawn. We want to know if you are a carrier of a certain gene for a protein that may be related to Alzheimer's. If you have that gene, you're in - *if you want to be*.

Then you'll get an MRI (a scan of your brain) and other neurological tests.

WHAT NEXT?

You will go into one of two groups. Either you will get the experimental drug or a placebo (normal salt water). This is because we have to test whether the medicine does better than nothing at all. That means everybody goes through the same tests and procedures no matter which medication they get.

We will draw blood for this study and the sample will stay with the company that makes this drug. That blood sample won't have your name on it.

You'll get a drug 5 times – once every 4 weeks. The drug goes into your blood, so it takes a while for our staff to do it. We'll also check up on your health at each of these visits and we may need to check your spine fluid.

We'll do 3 MRIs over the time you're in the study. We'll test your heart and draw some blood. And we may ask you to join in with a couple of other similar studies that include more MRIs and blood and other samples.

RISKS

There isn't a lot of info on this drug yet. There have been only 14 studies.

It could cause brain swelling and if so, we take you off the drug. You might have an allergy to the drug and there are a number of other risks that Dr. XXXX will discuss with you – they are important.


BENEFITS

It is not certain, but you may not get any benefit from this drug. However, what we learn may help doctors and other patients in the future. Plus, you will get a lot of medical tests at no cost and these tests may identify some other needs for treatment.

Assent/dissent

- New assent templates have been developed for use with adult subjects.
- Also, the new Form T asks about the use of an LAR and assent.
- Form T also solicits responses about the uses of dissent (if called for) and provides a menu of possible forms of dissent to be selected for the study.

<http://www.research.uky.edu/ori/ORIForms/FormT/Scale.asp>



DISCUSSION