# USU IRB Protecting Participants Training Series:

# Assessing Cognitive Capacity


UtahStateUniversity

February 21, 2024

Dr. Ronald Gillam & Ms. Nicole Vouvalis

# Welcome & Housekeeping

**Welcome to the USU Institutional Review Board Spring 2024 Training Series!**

**Upcoming Training Dates:**
March 27, 2024: Avoiding and Managing Bots & Fraudulent Respondents
April 8, 2024: Collecting Data on Children in Schools

**Let us know what training topics you want to see addressed in Fall 2024!**
**https://research.usu.edu/irb/feedback**

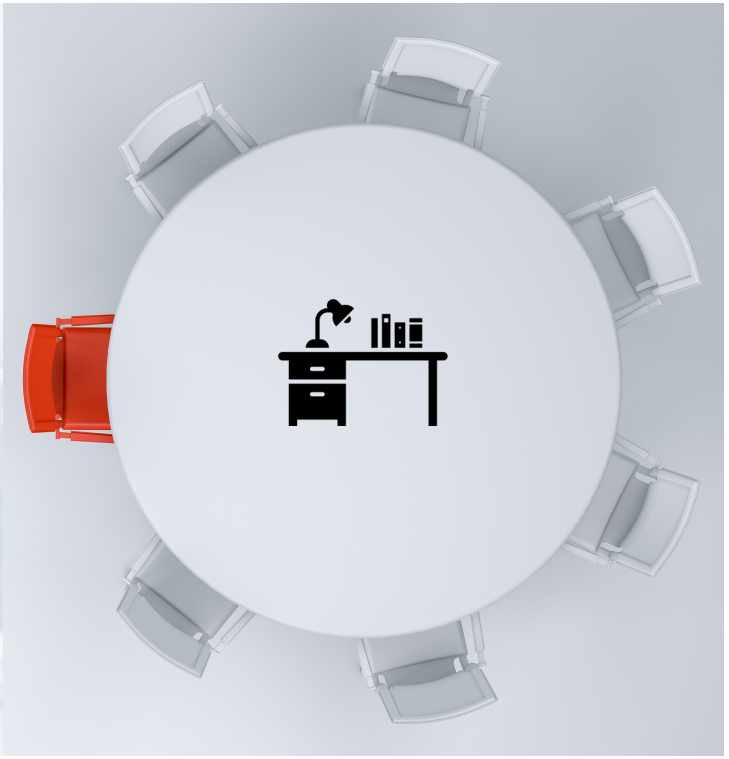
# Welcome & Housekeeping

To ask a question, please use the chat if you are attending virtually. Because of the interactive nature of this session, we are unable to take anonymous questions.


All sessions will be recorded, and the recordings and/or slides from the presentation will be posted to the IRB's website, which can be accessed at irb.usu.edu.

This session will be a listening session as much as a training session. We will use Poll Everywhere, and hope to follow those instances up with discussion among the attendees.

# The Institutional Review Board



# The Human Research Protection Program

## VP for Research

Responsible for overseeing all aspects of USU's Human Subjects Research portfolio & ensuring appropriate access to resources for a well-functioning Human Research Protection Program (HRPP)

### Human Research Protections Office

Manages the day-to-day aspects of implementing and overseeing the HRPP, including:

- Researcher training
- Coordination with COI, IBC, ICOI, SPO processes
- Receiving complaints, concerns, and questions from research participants

### The IRB

Reviews all proposed human subjects research at Utah State University according to:

- Established ethical standards,
- Policies & procedures, and
- Best practices

### Researchers

Responsible for carrying out and overseeing research with human participants in a manner that:

- Complies with the terms of IRB's review,
- Ensures adequate resources and training for the safe conduct of the research, and
- Takes proactive steps to ensure the health, safety, and well-being of research participants

# Assessing Cognitive Capacity

**Dr. Ronald Gillam**
IRB Chair
Raymond & Eloise Lillywhite Professor in Speech Language Pathology

**Nicole Vouvalis**
Executive Director, Human Research Protections

NIH National Institute on Aging

NIH Policy on Inclusion Across the Lifespan mandates the inclusion of individuals regardless of age unless there is a **scientific** or **ethical** reason for their exclusion.

# Regulatory & Accreditation Requirements

- 45 CFR 46.111(a)(3): “The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as… individuals with impaired decision-making capacity.”
- 45 CFR 46.111(a)(4): “Informed consent will be sought from each prospective subject or the subject’s legally authorized representative.”
- 45 CFR 46.111(b): “When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, **individuals with impaired decision-making capacity**, or economically or educationally disadvantaged persons, additional safeguards [must be] included in the study to protect the rights and welfare of these subjects.”

# Regulatory & Accreditation Requirements

**Association for the Accreditation of Human Research Protection Programs:**

“Research, unlike medical treatment, is intended to generate new or generalizable knowledge. Subjecting unimpaired participants to risks associated with IRB-approved research is ethically permissible when the participants decide that doing so is in their interests, or in line with their values, and provide consent. However, some participants with conditions leading to diminished functional abilities might be less likely to understand the purpose or voluntary nature of research, or to anticipate reasons against their participation. This can make it difficult for them to determine whether participation in a given study is in line with their interests and values. For this reason, it might be ethically appropriate to limit risks to such participants to a level below that which is permissible for unimpaired participants.

## Log in to Poll Everywhere

To present live activities, please log in to your Poll Everywhere account in a separate window.

Launch log-in window

# Utah State University IRB Review Standards

**Utah State University's Institutional Review Board conducts its reviews according to two prevailing ethical standards:**

**Belmont Report**

- Respect for Persons
- Justice
- Beneficence

**45 C.F.R. 46 (The Common Rule)**

- Subpart A: General Review standards
- Subparts C, D: Vulnerable Population Requirements

# USU IRB Standard Operating Procedure 503

I. Definitions & Scope

**Assent**: A positive indication of willingness to participate in a study.

**Capacity to consent**: The ability to provide legally effective consent to enroll in a research study.

**Diminished or fluctuating functional abilities**: Substantial impairment of cognitive functions (such as attention, comprehension, memory and intellect), communication abilities or other abilities that affect capacity to make and express a decision regarding participation in a study that may be temporary, permanent, or change over time.

**Dissent**: Any expression of unwillingness to participate in a study or component of a study, including refusal to undergo a procedure involved in the study.

**Legally Authorized Representative**: (LAR) an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

**Minimal Risk**: Defined, based on DHHS regulations, as studies for which, "the probability and magnitude of 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 examinations or tests."

# USU IRB Standard Operating Procedure 503

## I. Definitions & Scope

When feasible, researchers should make efforts to support or enhance prospective participants' ability to consent. Some individuals who are not capable of consenting under routine consenting procedures might be capable when special measures are adopted. Such methods include:

1. designing a stepwise consent process, which involves a waiting period between each phase of the process: capacity assessment, initial presentation of information, and obtaining consent;
2. enhanced presentation of consent information during initial presentation and/or immediately prior to obtaining consent, including:
    1. repetition of information (especially misunderstood information),
    2. both oral and written presentation of information,
    3. multi-media presentation of information,
    4. interactive questioning, and
    5. written study summaries;
3. continuous dissemination of consent information throughout the course of the study; and
4. conducting the consent process in an environment in which the participant is comfortable.

# USU IRB Standard Operating Procedure 503

II. Incapacity Due to Age

1. Children

   Legally speaking, children -- or those who have not yet reached the age of 18 in most jurisdictions in the U.S. -- are “incompetent” to enter into contracts and give legally effective informed consent. For this reason, informed consent from a legal guardian (often a parent) is required for the involvement of children in a research study, absent a waiver consistent with the provisions articulated in SOP 502. Children should still be given an opportunity to assent to the research, even where a waiver is applied, where their age, maturity, and comprehension skills would permit them to understand the nature of the research and what it is they might be agreeing to. Generally speaking, a seven year old neurotypical child is considered capable of assenting to most research procedures. In school settings especially, it is very common for researchers to request an “opt-out” informed consent process. This requires a waiver of informed consent in most cases. Children who reach the age of majority while they are still human subjects in the research should be given an opportunity to give their own legally effective informed consent to continue on with the study. Researchers who are working with children likely to reach the age of majority during the conduct of the study must articulate a plan for obtaining the informed consent of these individuals, or must obtain a waiver of informed consent for their continued inclusion in the study.

# USU IRB Standard Operating Procedure 503

## II. Incapacity Due to Age

1. The Elderly
   Being elderly does not mean that an individual does not have the capacity to render legally effective informed consent. Age, on its own, is not an acceptable justification for seeking informed consent from someone other than the participant themselves. However, participant age is one factor that researchers should consider when developing a plan to ensure that the party they are seeking informed consent from is the party legally able to give it. The primary focus should be on capacity: attention, intellect, comprehension, memory, and ability to communicate. Advanced age might be an indicator that the research team should carefully consider issues of capacity.

# USU IRB Standard Operating Procedure 503

## III. Individuals with Limited Capacity

Functional abilities exist along a continuum, and prospective adult participants can have greater or lesser ability because of various physical and psychological conditions. The extent and nature of impairment may vary based on the nature of the condition and on factors specific to individual participants. However, **prospective adult participants with limited (not complete) impairments to functional abilities are presumed to be capable of providing consent to enroll and participate in a research study unless there is substantial evidence that they are not capable**. Researchers should not consider the mere presence of a condition that leads to diminished functional abilities as indicative of a lack of capacity to consent.

When the recruitment plan includes individuals who are likely to have impairment to their functional abilities, the capacity of such prospective participants to consent to enroll in the study in question should be assessed on an individual basis prior to their enrollment. Research with these populations should target individuals with the least amount of impairment necessary to achieve the aims of the study.

# USU IRB Standard Operating Procedure 503

## III. Individuals with Limited Capacity

Various approaches to assessing prospective participants' capacity to consent to enroll in a study are appropriate, depending on the nature of the research. The assessment methodology should increase in rigor as the degree of risk associated with participation and extent of likely impairment to prospective participants' functional abilities increase. One or more individuals with relevant expertise should be identified to evaluate prospective participants' capacity to consent and make an objective determination regarding the capacity to consent of each participant. In most instances, this will be a member of the research team, but for studies involving a high degree of risk to participants it might be necessary to engage an independent evaluator. Methods to assist with evaluators' determinations include:

1. conducting clinical interviews with prospective participants and asking them to describe aspects of the study;
2. using standard psychological and neuropsychological screening tests; and
3. utilizing a formal instrument for assessing capacity to consent in clinical research.

Cognitive tests and competence assessment instruments alone cannot provide the basis of the evaluator's determination regarding a participant's capacity to consent, and should at most supplement or support the evaluator's expert judgment.

## Log in to Poll Everywhere

To present live activities, please log in to your Poll Everywhere account in a separate window.

Launch log-in window

When poll is active respond at **PollEv.com /irbcog**

Send **irbcog** and your message to **22333**

## What *tools* come to mind for assessing cognitive capacity?

Nobody has responded yet.

Hang tight! Responses are coming in.

When poll is active respond at **PollEv.com/irbcog**

## What are some barriers to adoption of these tools in USU-based research?

Nobody has responded yet.

Hang tight! Responses are coming in.

# Utah House Bill 197 (2024 Session)

## Supported Decision Making Agreements

- Formalizes a process wherein the principal makes their own decisions, but those decisions are supported by a trusted network or trusted individual
  - May not be the *legally* authorized representative (LAR)
  - LAR agrees to the use of supported decision making in some or all contexts
- Less restrictive than guardianships
  - But potentially more complex for research enrollment

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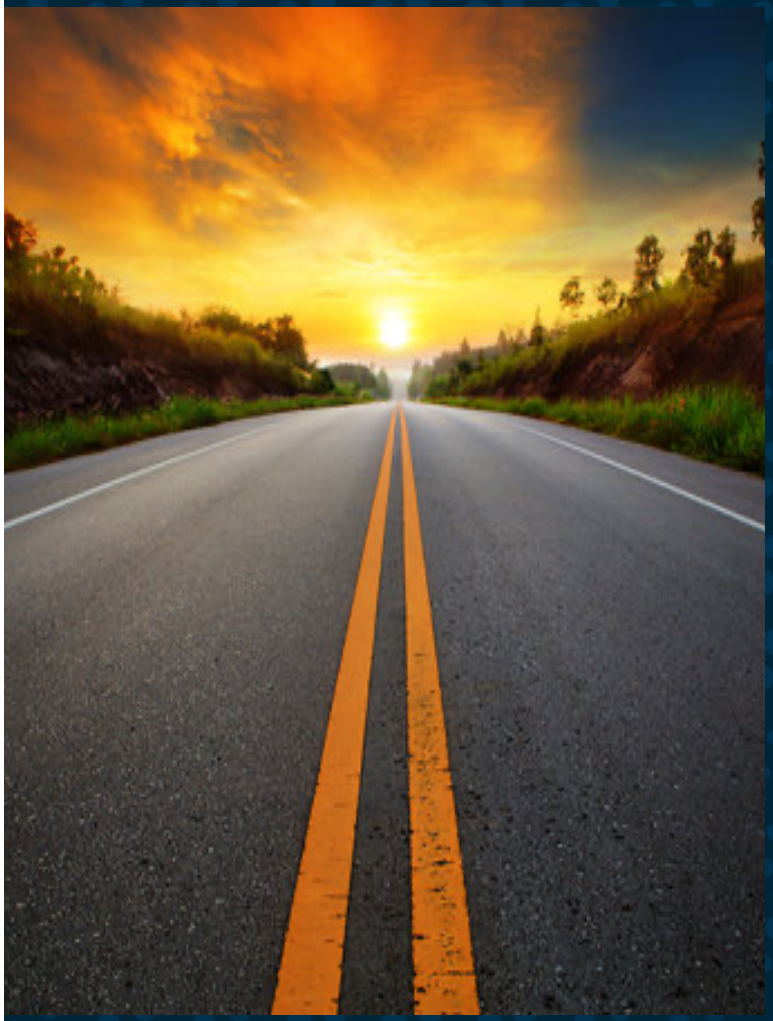
## What challenges do you anticipate in research under Supported Decision Making Agreements?

Nobody has responded yet.

Hang tight! Responses are coming in.



# Resources

- NIH Policy on Inclusion Across the Lifespan
- NIH Case Studies: Inclusion Across the Lifespan
- USU IRB Standard Operating Procedure 503: *Populations with Limited Decision Making Capacity*
- Penn Memory Center: *Overview of Supported Decision Making*
- Utah H.B. 197 (2024): Supported Decision Making
- Request a consultation with an expert at the USU Human Research Protections Office


Q&A

When poll is active respond at **PollEv.com/irbcog**

## Ask A Question Anonymously!

Nobody has responded yet.

Hang tight! Responses are coming in.

# Thank You!

**Please use the feedback link to provide ideas for future IRB training topics.**

Mark your calendars for our upcoming training topics & dates!

- March 27, 2024, 12:00 to 1:30: *Avoiding and Managing Bots & Fraudulent Respondents*
- April 8, 2024, 12:00 to 1:30: *Collecting Data on Children in Schools*