SOUTHERN ILLINOIS UNIVERSITY CARBONDALE
Institutional Review Board

Guidance Title	**Oral (Verbal) Consent Guidance**
Initial Approval	**March 21, 2025**
Last Reviewed	
Scope	**Principle investigators and all study personnel conducting human subjects research using oral/verbal consent, IRB members, and institutional officials involved in the review or oversight of such research**

Guidance Purpose

This guidance outlines the requirements and best practices for obtaining oral consent in research studies. Oral consent may be appropriate when written documentation is impractical, culturally inappropriate, or when written documentation of consent poses a risk to participants (would be the only link between the participant and their participation).

Unlike written consent which requires a signature or online survey consent, which typically requires participants to affirm their consent electronically, oral consent relies on verbal agreement without a written record. Due to the absence of a signed record, additional safeguards must be in place, such as detailed verbal explanations, participant comprehension checks, and thorough documentation by the researchers to ensure ethical compliance and participant understanding.

Guidance Definitions

Informed Consent means a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research.

Investigator means the principal investigator (PI), co-PI, faculty sponsor, and any individual listed on the key personnel table of the IRB application.

Oral (Verbal) Consent is a process by which an individual verbally agrees to participate in research after being fully informed of the relevant details, risks, benefits, and alternatives, without signing a written document.

General Procedures

Protocols requesting oral consent require review at a convened IRB meeting with a quorum present. Investigators must justify the need for oral consent and describe, within their protocol application, the procedures they will follow to ensure participant informed decision-making. When approving the use of oral consent, the IRB may require an audio recorded consent or third party (witness) record of consent.

When considering requests to alter written consent through the use oral/verbal consent, the IRB considers the following:

- Investigator Justification: Investigators must provide a clear rationale for why written consent is not feasible or appropriate.

- Proposed Oral/Verbal Consent Process: Investigators must include a detailed plan for the oral/verbal consent process. Generally, this can be included in the response to question 18 on the IRB application's Section C. The process must include providing participants with adequate information to make an informed choice to participate.

- Confidentiality & Risk Mitigation: The investigator's plan should address how participant confidentiality will be maintained and how oral/verbal consent will minimize risk and is appropriate for the proposed research.

- Documentation: Investigators must submit a detailed script of the oral consent process to the IRB for review and approval (See Appendix A).

Appendix A: Informed Consent Elements

Investigators are responsible for ensuring their research activities comply with all federal, state, and University regulations/policies related to human subjects research, including all required consent elements.

The SIUC IRB provides sample consent templates on their website and investigators are encouraged to use those templates. The consent process, whether written or verbal, must include the following components:

- Introduction: Explain who the researcher is, affiliation, and organization.

- Research statement: Statement that participation involves research.

- Study purpose: Briefly explain the purpose of the research.

- Study procedures: Describe what participation involves, including duration and activities.

- Minimum requirements to participate: List age and/or sample frame requirements.

- Voluntariness: Emphasize that participation is voluntary and that the participant may withdraw at any time without penalty, including a statement on how the participant can withdraw (i.e., verbally notify the researcher, call, email, etc.).

- Compensation: Amount of compensation offered, if any, and the identifying participant information you will need to collect to provide payment (mailing address, email address, etc.).

- Risks/Benefits: Any risks and benefits associated with participating (or a statement that there are no foreseeable risks or benefits associated with participation).

- That you are taking written notes or recording and will assign a pseudonym if quoting the participant in any published or shared material.

- Confidentiality: Explain how you will protect participant privacy, how personally identifiable information will be stored/collected, and that de-identified data may be shared with the research community at large. Do not use the term anonymous if collecting identifiable information. Instead use the term confidential.

- Contact information: Provide contact details for the investigator and the IRB for questions or concerns.

- Verbal confirmation: Request the participant's verbal consent and document their agreement in study records.