

IRB Guidance: Consent Guidance for Exempt Research

What information should I include in the consent materials?

For exempt research that involves interaction with subjects, there usually should be a process to ask subjects to participate and confirm their agreement. However, signed consent is not required for exempt research, and the consent process and documents can be much simpler than those required for non-exempt research.

Verbal or implied consent is usually sufficient for exempt research that involves interaction with subjects.

What information should I include in the consent materials?

Include the following information and review the exempt consent templates for sample language.

Required information:

- That the activity involves research and participation is voluntary
- A brief description of the study purpose, and activities or types of questions that will be asked
- If Category 3 (research involving benign behavioral interventions) study involves deceiving the
 subjects regarding the nature or purposes of the research, this exemption is not applicable
 unless the subject authorizes the deception though a prospective agreement (consent) to
 participate in research in circumstances in which the subject is informed that he or she will be
 unaware of or misled regarding the nature or purposes of the research.
- Subjects can stop participating at any time and, if applicable, skip survey questions
- Confidentiality of the research data will be maintained
- Name and contact information for the investigator conducting the study and whom to contact with questions (if different)
- IRB contact information
- Identification of KSU optional if evident from the context of the consent process
- Statement of financial interest, only if one exists

What changes are not allowed?

As noted in <u>IRB Policy: Exempt Research</u>, you can make some minor modifications to the study – including the consent materials – without notifying the IRB. However, certain revisions are not allowed in the consent documents:

- Do not remove any of the required consent information (see above).
- Do not add coercive language.
- Do not highlight payment by bold or larger type.

What if I'm enrolling children in my study?

If you are enrolling children in your study and it is appropriate to obtain consent, there generally should be a plan to obtain permission from the parents and the agreement of the children to participate in the study.

Reminders:

- Under the Family Educational Rights and Privacy Act (FERPA, 34 CFR Part 99), schools must have written permission from the parent or eligible student in order to release information from a student's education record.
- Children cannot be enrolled in exempt category 2 research (educational tests, surveys, interviews or observations of public behavior).

Resources:

Consent Templates
IRB Policy: Exempt Research
Investigator Manual
Verbal Consent Talking Points

Verbal Consent Talking Points

Instructions: Use the bullet points below to guide the verbal consent discussion.

- Who you are: Identify yourself and clarify that you are associated with Kennesaw State University.
- Research study: Explain that you are asking the subject to participate in a research study.
- Who's in charge: If the principal investigator is not conducting the consent discussion Give the name of the researcher in charge of the project.
- **Purpose and/or procedures:** Provide a brief description of the study purpose, and activities or types of questions that will be asked.
- Why subjects were selected: If unclear how subjects were chosen Describe how the subject was selected or why he/she is being asked to participate.
- Time commitment: Clarify how long participation will take.
- **Stop Participating:** State that the subject can stop participating at any time and, if applicable, skip survey questions.
- **Confidentiality:** Confirm that confidentiality of the research data will be maintained, and the subject's personal information will not be shared with anyone outside the research team.
- **Optional Participation:** Explain that participation is voluntary and ask if the subject wants to participate.
- Contact Info: Provide contact information for the investigator conducting the study and whom to contact with questions (if different). Also explain that the subject can contact the KSU Institutional Review Board at irb@kennesaw.edu with questions or concerns about his/her rights as a research participant.
- **Questions:** Ask if they have any questions about the research.
- Agreement: Inform the participant that by proceeding with the activity (interview, etc.) they are agreeing to participate in the research just described and that they should not proceed if they do not wish to participate.