Informed Consent Guidance
Exempt Research

There is no required consent template for exempt research; however, the following elements of informed consent should be included in consent forms or scripts as applicable. Consent forms or scripts may not be applicable in certain types of research; e.g., observation, quality improvement, normal educational activities, and so forth.

- **Subject rights:** State that the activity involves research, participation is voluntary, and that participants may withdraw at any time without penalty or loss of benefits.

- **Purpose of the study:** Provide a brief non-technical explanation of the purpose(s) of the research. Explain why the subject is being asked to participate in the study (e.g., *You are being asked to participate in this research study because…*).

- **Study tasks or procedures:** Provide a complete description of procedures (including the order in which they take place). Identify and distinguish procedures that are being performed solely for research purposes from any activities that would otherwise occur. Include information about audio- or videotaping and/or any records that may be accessed (e.g., educational records).

- **Duration of subject’s participation:** Provide expected duration of the subject’s participation (e.g., time required to complete surveys). Ensure that the proposed time period is realistic for the procedures to be performed.

- **Confidentiality:** Include a statement describing the extent, if any, to which confidentiality of the data/records will be maintained. Discuss the retention or disposition of participants’ data/records following conclusion of the research. *Note: Do not interchange the terms “confidential” (i.e., maintained in a way that prevents inadvertent or inappropriate disclosure of participants’ identifiable information) and “anonymous” (i.e., identifiers were not collected or have been permanently removed).*

- **Contacts and Questions:** Provide the name and contact information of the Principal Investigator for questions, concerns, or complaints about the study. Include contact information for research staff, as applicable. The person(s) listed should be knowledgeable about the research. Include area code or international dialing codes for phone and fax numbers.

- Provide Institutional Review Board (IRB) contact information for questions about subject rights and as a contact who is not part of the study team for participant concerns or complaints about the research: *For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Donna Bryden in the Center for Research at 734-432-5666.*