Instructions for Preparing a Comprehensive Informed Consent Form

Use age-appropriate language for children and language appropriate for disabled participants to understand and freely consent/ assent to participate. Obtain assent/ consent from parents/ guardians for children and mentally or other disabled adult subjects.

1. **Purpose:** Describe the purpose/ goal of the study—be specific. Learners should identify themselves as researchers and include in this section a statement that the research study will be conducted as part of a specific degree program at Union Institute & University in [insert location]. Include all potential uses of the study data—dissertation, thesis, final document, culminating study, future journal article, professional presentation.

2. **Procedures:** Using bullets, list activities that subjects will do;
   - Identify experimental procedures, if any, under a separate Experimental Procedures heading.
   - Include a statement about audio and video recordings (digital recordings are ok), photographs, or other media to be used.
   - Include a statement about participants’ review of transcripts for accuracy and/or clarification.
   - State whether you will ask participants for examples of their art projects, journals, or other personal items and whether they will be returned.
   - State that you will request access to academic records (indicate grades, attendance, test scores) from school administrations, if research protocol requires such records.
     - Add another participant signature line for the release or use of specific information, “I consent to the release/use of my (indicate grade(s), scores, attendance records, direct quotes, videotape usage).” Detail specific information to be requested for release in the procedures and signature sections. For students under the age of 18 (or age of majority), parents must also consent to the release of their child’s school records.

3. **Time:** Provide an approximate amount of time that participants will be involved; include follow-up questions and transcript review in this time estimate.

4. **Risks/ Benefits:** Carefully consider all possible or reasonably anticipated risks and benefits to subjects. Use bullets to list risks to subjects and benefits of study to subjects and to community at large. Use “may” instead of “will” when listing potential benefits—no guarantee that subjects or community will derive any benefit from the study.
   - Avoid stating that study involves no risk; some risk is associated with most studies.
   - If minimal risk, may indicate, “The risk associated with this study is no greater than is experienced in everyday life.”
   - Include psychological risk, mental stress, embarrassment, and loss of confidentiality as potential risks when applicable.
   - If appropriate, disclose alternative procedures or courses of treatment and the alternative’s advantages to subjects.
   - If no benefits to participants, may indicate, “Although you may not benefit directly from your participation in this study, your comments and opinions are valuable and may help others (specify) in the future.”

5. **Compensation/ Payments:** Use a heading, Compensation/ Costs. List any costs and compensation provided (e.g., mileage reimbursement, parking, bus fare, etc.); if reimburse travel expenses, state basis for reimbursement—receipts; include whether extra credit will be granted if working with students. If grant extra credit for participating, must provide an equal opportunity for earning extra credit to students who do not participate. If giving monetary gifts or gift cards, include a statement about them and any conditions on receiving them such as must complete the study or complete most of the study. Can prorate monetary gifts based on length of time in the study.
6. **Confidentiality and Privacy Protections**: Describe procedures used to maintain and protect the confidentiality of research data and participants’ privacy. One definition of privacy is “being secluded from the presence or view of others, concealed, or secret.” Confidentiality pertains to the treatment of information or data that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Ensuring privacy of participants is different from assuring confidentiality of data. Indicate any conditions under which confidentiality will be broken; e.g., criminal activity, child neglect, child/elder abuse, or a clear, serious, and direct harm to self or others. Indicate to whom necessary information would be reported (i.e., the police, child protective services, school counselor, parent, or appropriate professional).

   **Sample wording in studies involving children**: No one will know what you tell me during this study, but if I see signs of or hear about abuse, I am required by law to report it to [insert whom to report]. Also, if I hear that you intend to harm yourself or others, I may need to report it.

   a. Describe use of number codes or pseudonyms for identifying data or subjects.

   b. Describe length of time that study records will be retained before destruction—a minimum of three years. Follow study records retention requirements in ethical guidelines for researcher’s professional association.

   c. Include a statement of confidentiality protection for e-mails: If we communicate by e-mail during this study, please be aware that e-mail is not a secure form of communication. However, my computer has security software, and I am the only person who has access to my e-mail account. No one else will read our communications.

   **Studies with audio or video recordings**, participants must be told:

   (a) interviews or sessions will be audio- or videotaped; digital audio recordings may be stored on flash drives

   (b) tapes will be coded so that no personally identifying information is visible on them;

   (c) tapes/ flash drives/ digital recordings will be kept in a secure location (e.g., a locked file cabinet in a secure location);

   (d) tapes/ flash drive files/ digital recordings will be heard or viewed only for research purposes by the researcher and his/her associates that may include faculty advisor, dissertation chair/ committee, and the IRB;

   (e) tapes/ flash drives/ digital recordings will be stored, with all other study data, in a secure location for a minimum of three years. If you wish to keep the tapes/ digital recordings for additional analysis in the future, state: The researcher will keep the recordings for possible future analysis.

   • If you wish to present the recordings at a conference or use them for other educational purposes, you should get permission by adding the following statement after the signature lines on the consent form:

     I may wish to present some tapes from this study at a professional conference or as demonstrations in classrooms. Please sign below if you are willing to allow me to use your tape for these purposes. **Add another signature line prefaced by**: I hereby give permission for the video (audio) tape made for this research study to also be used for educational purposes.

   • If you plan to post any part of the results or anything else about the study online on a website or social media site, you must include clear statements about your intentions and obtain permission from all participants before posting anything online.
7. **Studies involving greater than minimal risk – subject to full IRB review**: Use a heading, Treatment for Adverse Effects. Insert the following statement for studies requiring full review, not for expedited or exempt studies:

   If you are injured as a direct result of taking part in this research study, emergency care will be provided by [name] medical staff or by transporting you to your personal doctor or medical center. Neither the [researcher’s name] nor Union Institute & University will provide you with long-term medical treatment or financial compensation except as may be provided through your employer’s insurance programs or through whatever remedies are normally available by law.

8. **Interview, survey, questionnaire questions that pose more than minimal risk**: Include a statement in the Risks/ Benefits section regarding potential for emotional upset during interview/ survey/ questionnaire or while thinking about a current or past event and what researcher will do for participants. Offer to discontinue the interview and to refer the participant to an affordable counselor at participant’s expense if necessary.

9. **Termination of study**: Describe circumstances under which the study may be terminated without prior consent or notice to participants; e.g., failure to meet for an interview or to set up a time for an interview after two attempts. Include reasons that researcher may need to terminate the study such as illness, inclement weather, loss of funding, etc.

10. **Subject and Researcher Authorization**: (add signature and date lines)

    Insert the legal statement that applies to specific participants – adults, children, or parent/ guardian/ legal rep.

    Adults:
    I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable federal, state, or local laws.

    Children:
    I have read and understand this consent form, and I understand that I will receive a copy of this form. I voluntarily choose to participate in this research study.

    Parent/ Guardian/ Legal Representative:
    I have read and understand this consent form, and I voluntarily consent to my child’s participation in this research study. I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable federal, state, or local laws.

11. **Witness Statement**: Use when participants are non-English speakers, elderly, or have a physical or mental disability that may affect their ability to understand and freely consent to participate. Add signature and date lines.

    My signature attests that I was present during the informed consent discussion of this research for the above named participant and that the information in the consent form and any other written information was accurately explained to, and apparently understood by the prospective participant, or his/her representative, and that the informed consent decision was made freely by the participant or the participant’s representative.
12. **Other individuals assisting the consent process:** Add signature lines when more than one person assists in obtaining assent/consent.

13. **Resources for questions:** Add information about whom to contact for questions, rights as a research participant, and study-related emergencies. (See Comprehensive Consent Form template for suggested wording.)