UNI IRB Informed Consent Checklist

Directions: Please use language that lay people can read and understand, and include all elements of consent that pertain to your study. The format and ordering of items can be of your choosing, and the form need not be long and involved, but it must include the following basic information, as applicable.

Consent Form Layout
- Presented on letterhead or must state in the first paragraph that the project is being conducted by persons affiliated with the University of Northern Iowa
- For written consent, a statement that participants will be offered a copy of the consent form (near the signature line)

Study description
- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the person's participation
- A description of the procedures to be followed
- Identification of any experimental procedures or medical treatments
- The location where the procedures will be done

When participants will be drawn from a classroom or special program:
- A statement about whether or not the procedure is part of the regular curriculum of a class or program
- A statement about whether or not the participant will miss any regularly scheduled work/class and if so, a statement about whether or not s/he will be allowed to make up this work
- A statement as to whether participation or non-participation will affect the participant's grade or status in a program
- An explanation of what non-participants will do while the research is taking place

Risks
- A description of any reasonably foreseeable risks or discomforts -- a study may have "minimal risk" or "risks no greater than those of day-to-day life" but that it would be extremely rare for them to have "no risk"

For Research Involving More than Minimal Risk
- An explanation as to whether any compensation is available if injury occurs
- An explanation as to whether medical or psychological treatment is available if injury occurs, what it would consist of, and where further information may be obtained
Benefits

☐ A description of possible benefits to the participant, which may reasonably be expected from the research, or a statement that individual participants may not benefit from participation, but that there may be benefits to general knowledge or to society

☐ An explanation of any compensation and, if appropriate, procedures to prorate compensation for participants who withdraw prior to completion of the study.

Also, in some cases, researchers are required to inform the UNI Business Office about compensation provided to research participants, for tax purposes. (See UNI subject compensation policy.) If this will be a requirement in your study, your consent information must include: a) a statement that names and contact information of compensation recipients will be provided to the UNI business office; b) that actual data from the study will not be provided nor even the title of the study; and c) that participants may decline the compensation if they wish.

Alternatives

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant (4)

Confidentiality

☐ A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained

☐ If study is online, please add the following statement to the consent form. “Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.”

☐ In studies that elicit information that could lead to a disclosure about abuse, neglect, or harm to self or others, a statement must be included in the consent regarding any exceptions to confidentiality. (If you are not a mandatory reporter, you must decide for yourself which exceptions to confidentiality, if any, you will make.)

Right to refuse or withdraw

☐ A statement that participation is voluntary

☐ A statement indicating that the participant may refuse to participate or may discontinue participation at any time during the project without penalty or loss of benefits to which the participant is otherwise entitled

☐ No language through which the participant is made to waive any of her or his legal rights, including any release of the university or its agents from liability or negligence

Whom to Contact

☐ The name(s), title(s), and telephone number(s) (or email addresses, if appropriate) of the person(s) to contact for answers to questions about the research (PI and Faculty Advisor), and the name, title, and telephone number of the responsible project investigator, if different

☐ The telephone number of the person to contact for answers to questions about research participants' rights. (This should be Anita Gordon, UNI IRB Administrator, 319-273-6148, anita.gordon@uni.edu.)

☐ The name, title, and telephone number of the person to contact in the event of a research-related injury, if different from above.