Section 1: About Informed Consent in Human Subjects Research

Learn more about informed consent at:
<https://oprs.research.illinois.edu/education-training/instructions-informed-consent>

Informed consent is the process by which potential participants are provided important information about the research study. Human subjects can only be involved in your study if they voluntarily agree to participate after having been adequately informed about the research. If the human subjects in your study are part of a vulnerable population (children, students, prisoners), special protections may also be required.

Section 2: Who Needs to Submit this Form

If you selected “Yes” in the New Study Application form under Section 8.9.1) Informed Consent, you need to complete this form as part of your application process.

If participants will have a choice to participate in your study, and you did not select “Yes” in the New Study Application, please be sure update the information in that form, and then complete this form.

Please make sure all consent documents, parental permission forms, assent forms, information sheets, questionnaire cover letters, etc. are included with the application using the templates from the OPRS website.

Section 3: Protocol Information:

Please complete the information below.

1) Principal Investigator:

Please enter the names of the PI’s.

2) Protocol Number:

Please enter the Protocol number. (If this is a new study application, the protocol number will be assigned and completed by OPRS once the application is submitted.)

3) Project Title:

Please enter the Project Title.

Section 4: Questions – Informed Consent

1) List by name, role, and affiliation (e.g. UIUC) anyone who will be obtaining consent.

Detail below:

Click or tap here to enter text.

2) Describe the location(s) where consent will be obtained.

Detail Below:

Click or tap here to enter text.

3) Describe the consent process(es), including the timing of consent. Also describe whether there is a waiting period between the consent process and obtaining consent from the subject (i.e. any time between informing subjects and actually obtaining consent).

Detail below:

Click or tap here to enter text.

4) Describe what measures will be taken to minimize the possibility of coercion or undue influence.

Detail below:

Click or tap here to enter text.

5) Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and subject.

Detail below:

Click or tap here to enter text.

6) Will a legally authorized representative (LAR) be used?

Answer Yes or No below:

[ ]  Yes [ ]  No

If “yes” (a legally authorized representative will be used), describe when the use of an LAR might arise in this study population and what the frequency of an LAR will be during the enrollment period:

Click or tap here to enter text.

7) Will a language other than English be used to obtain consent?

Answer Yes or No below:

[ ]  Yes [ ]  No

8) If a language other than English will be used, please indicate which form will be used.

Check one of the options below, if applicable:

[ ]  A translated short form with an English long form

[ ]  Fully translated consent form

If you selected “translated short form” above, please provide a justification for why a full, translated consent form will not be used:

Click or tap here to enter text.

9) If a language other than English will be used, please describe:

 a) whether a translation service will be used for the consent process, and

 b) how will the consent process will be conducted?

Detail below (if applicable):

Click or tap here to enter text.

10) Are you requesting that documentation of informed consent be waived by the IRB?

For example: a consent process is in place, but there will be no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.

Select Yes or No below:

[ ]  Yes [ ]  No

11) If you are requesting that documentation of informed consent be waived by the IRB (and answered “yes” in question 10), please complete the following questions.

11.1) Explain why the waiver of consent documentation is being requested.

Detail below:

Click or tap here to enter text.

11.2) Justification for the waiver

Select one of the following:

[ ]  The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research and the participant's wishes will govern.

[ ]  Participant in this study are members of a distinct cultural group or community in which signing forms is not the norm. The research presents no more than minimal risk of harm to subjects and the study team has an alternative mechanism for documenting that informed consent was obtained.

[ ]  The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

12) Documentation

Please make sure all consent documents, parental permission forms, assent forms, information sheets, questionnaire cover letters, etc. are included with the application using the templates from the OPRS website.