**Informed Consent Guidance**

Informed consent forms must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative to understand the reasons why one might or might not want to participate in the research.

NOTE: For some projects, if your consent form is brief and well-organized, the entire form can be considered a concise and focused presentation of key information.

**Informed Consent Checklists**

These checklists do not need to be submitted with your protocol. They are included to help you prepare informed consent documents. When they are ready, we will post sample informed consent forms.

|  |  |
| --- | --- |
| Met | Required Element |
|  | Written in non expert’s language understandable to the people who are being asked to participate (informed consent forms should be translated into the participants’ preferred language). Participants should have an opportunity to discuss the information and ask any questions before they sign the form. |
|  | A statement that the study involves research, who is doing the research, and if the research is sponsored by any particular organization. |
|  | An explanation of the purpose of the research. A statement that describes how the participant was selected and approximately how many people will be included in the study.  |
|  | An estimate of the expected duration of the participant's participation. |
|  | A description of what exactly the research participant will do. For example, saying “classroom observation” is not descriptive enough to define the participant’s involvement in the setting. Include a brief description of the activities the participant will engage in, how the participation will be recorded, the questions they will be asked, documents they will fill out or provide, etc.  |
|  | A description of any foreseeable risks or potential costs associated with participation. ~~(~~For example, some researchers write that the discomfort associated with answering any questions is no more than what people might experience in a typical day).  |
|  | A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. This should include information about how you will maintain the privacy and confidentiality of data collected over the internet.  |
|  | A statement of whom to contact for answers to questions about the research, including concerns or complaints associated with the study. |
|  | A statement of whom to contact for answers to questions about research participants' rights as a human subject.  |
|  | A statement that participation is voluntary. |
|  | A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. |
|  | A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. |
|  | Confirm participants are at least 18 years old (otherwise additional consent is required). |
|  | Make sure that you do not include any language that could lead the participant or legally authorized representative to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the researcher, the sponsor, the institution, or its agents from liability for negligence. |
|  | Informed Consent documents, flyers, and advertising materials need to include contact information for participants to call SSU’s IRB office with questions about their rights as a human subject. The statement below should be bolded: **If you have a question about your rights as a human subject contact irb@sonoma.edu or phone 707.664.2066.**  |

 **Additional Consent Elements, if Appropriate**

|  |  |  |
| --- | --- | --- |
| Met | N/A | Additional Item |
|  |  | If you include physical activity, a statement of whom to contact in the event of a research-related injury to the participant. |
|  |  | If you plan to make video or audio recordings, include a statement about * where and how long you will keep the recordings
* in what form recordings will be kept (e.g., codes in an excel spreadsheet, original recording, transcripts)
* who will have access to the recordings (this includes clips shown to public or professional audiences)
 |
|  |  | Place for participant to indicate explicit consent to be recorded.  |
|  |  | Place for participant to indicate explicit consent for recordings to be presented to the public.  |
|  |  | Place for participant to indicate explicit consent that they recognize that video (or audio) recordings will not keep their personal information confidential or anonymous. |
|  |  | Statement that participant has the right to refuse to answer individual questions. |
|  |  | Statements regarding reporting requirements for drug, child abuse and suicide. |
|  |  | Statement of individual benefits or compensation. If you plan to offer participants compensation, specify the terms and amount of compensation in the informed consent form. Compensation cannot constitute {or appear to constitute} undue pressure or influence on the perspective research participants to volunteer for, or to continue to participate in, the research study.For monetary forms of compensation (including gift cards), indicate how much, how many participants are eligible, and how compensation will be distributed. For example, if you plan a participant drawing, you should indicate the odds that a participant will receive a reward, and when the drawing will occur. If you offer gift cards, you should make it clear how many participants you can cover and how you will ensure that you limit the participants to the budget you have for compensation. |
|  |  | If you plan to collect information or biospecimens that can be traced back to individual participants, you must include one of the following statements:(i) A statement that identifiers will be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another researcher for future research studies without additional informed consent from the participant or the legally authorized representative, **if this might be a possibility**; or(ii) A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. |
|  |  | For blood, tissues, or other specimens, include how you plan to dispose or keep them after the research is complete.  |
|  |  | Indicate if and how you might keep or “bank” samples of tissues, cells, blood, or body fluids for future research.  |

**Documentation of Informed Consent Checklist**

Unless a waiver is granted, informed consent is documented via a written consent form signed by the participant or the participant's legally authorized representative. A copy should be given to the person signing the form. The IRB requires a clear script that researchers will follow to confirm consent if no written explanation of informed consent is given to participants. Informed consent records must be kept for at least three years after the original data are collected.

In other words, the consent form may be either of the following:

|  |  |
| --- | --- |
| Signed Consent Form | A written consent document that may be read to the participant or the participant's legally authorized representative. The researcher should give either the participant or legally authorized representative adequate opportunity to read ask questions and discuss it before it is signed. We expect researchers to keep signed copies of the informed consent separate from collected data.  |
| Request Waiver | An IRB may waive the requirement for the researcher to obtain a signed consent form for some or all participants, if the board finds:1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm that could result from a violation of the participant’s confidentiality.
2. The research presents no more than minimal risk of harm to participants, and involves no procedures, for which written consent is normally required outside of the research context.
3. The participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm.
4. In cases in which the documentation requirement is waived, investigators are required to provide participants or legally authorized representatives with a written statement regarding the research.
5. Researchers should include a copy of any script that they will use to ask for consent, and a plan for how they will record that the participant agreed.
 |