Template for the Study Information Page to Gain Informed Consent in Minimal Risk, Human Subjects Experiments

Researchers can use the wording shown below for a Study Information Page, presented either electronically or in paper form, for a minimal risk study. In either case, the participants must read and understand the Study Information Page and be given the chance to ask any questions before the experiment continues.

The text below should be modified and can be personalized by the researcher(s) to fit the needs of their specific experiment. The superscripts and footnotes should be deleted when used by a researcher, but they are included here only to describe the PURPOSE of each part of the document and show how it satisfies the informed consent elements required by federal regulations.

[Insert Title of Study]

Thank you for participating in my/our research project[1]. In this study, I/we am/are trying to [*insert hypothesis or purpose of your study*] [2]. You will be asked to [*insert experimental procedure*] [3]. The entire experiment will take approximately [*insert time commitment*] [4]. During this experiment [*list the possible risks, if applicable*] [5]. If at any time you feel [*describe possible negative reaction*] or do not want to participate anymore, you may choose to leave the experiment[6]. Your name will not be collected in this study, and all data and identifiers will be kept confidential. No identifying information about you will appear in any published results.[7] Participants in this study will receive [*describe compensation, if applicable*] [8].

If you have any questions or concerns about this study or any of these procedures, please contact [*name of the researcher(s)*] at this time or contact them later at [*email or phone number(s) of researcher(s)*]. If you have questions or concerns about the rights and welfare of research participants, please contact the John Carroll University Institutional Review Board Administrator at (216) 397-1527.[9]

Your participation is voluntary. You may quit the experiment (or skip any question) at any time without penalty.[10]

By continuing with this experiment you confirm that you have read and understand the information above and you willingly give your consent to participate in this research study.[11] You also confirm that you are at least 18 years of age [12] [*insert other inclusion/exclusion criteria, if applicable*].

Footnotes: THE ELEMENTS of INFORMED CONSENT from 45 CFR 46, §46.116

Your informed consent document must contain the following:

1. A statement that the study involves research
2. An explanation of the purposes of the research
3. A description of the procedures to be followed and identification of any procedures which are experimental (examples: take a survey, answer some questions, watch videos, listen to music, perform a task, etc.)
4. The expected duration of the subject's participation
5. A description of any reasonably foreseeable risks or discomforts to the subject, if applicable. (examples: you may become upset, you may recall disturbing memories, experience eye strain, get lightheaded, etc.)
6. A disclosure of appropriate alternative procedures or courses of treatment, if applicable, that might be advantageous to the subject.
7. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
8. An explanation of any compensation, if applicable. (Examples: receive 0.5 research credit from the Psychological Science Department, be entered into a drawing for a gift card, receive pizza and soda, etc.)
9. Research, Rights or Injury: An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
10. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.
11. The requirement for a written and signed consent form may be waived if the research presents no more than minimal risk of harm to subjects, and involves no procedures, for which written consent is normally required. (This is true for the majority of SONA studies at JCU.)
12. Only a legal adult, 18 years of age or older, can give informed consent for themselves. Minors would require Parental Consent from a parent or legal guardian.

    See http://sites.jcu.edu/research/pages/irb/informed-consent/ for more information.

    Please feel free to contact the IRB Administrator, Carole Krus, (ckrus@jcu.edu, x1527, AD250) with any questions.