Consent for Participants in Research Projects Involving Human Subjects

Checklist to Assess Completeness of the Document

Use this checklist to ensure that all of the required elements are included in your study’s consent form. This checklist is not exhaustive. Provide additional information as necessary. This checklist is for your own use; do not submit this checklist to the IRB.

☐ Study Title has been included.

☐ Investigator(s) are listed, and her/his affiliation with Virginia Tech is described.

I. Purpose of this Research Project (does the consent document include):
   ☐ A clear statement that the study involves research
   ☐ Nature of the study
   ☐ Purpose for conducting the research
   ☐ Total number of subjects involved
   ☐ Brief description of the subject pool

II. Procedures (does the consent document include):
   ☐ Step-by-step explanation of what will be expected from study participants
   ☐ Length and frequency of each study procedure and total time commitment for the subject
   ☐ Location of the research
   ☐ The instruments / documents that will be used and conditions involved (include an explanation of the instruments in appropriate language)

III. Risks (does the consent document include a description of):
   ☐ All potential risks described (mental, social, financial, legal, dignity, or physical). [Note the use of survey questions of a sensitive nature may pose emotional distress caused by remembering unpleasant experiences]
   ☐ Safeguards that are to be employed to reduce or minimize risks
   ☐ If subjects must seek medical or counseling services as a result of their participation, there should be a statement that neither the PI nor the University have funds to pay for such services, and that the costs of such services must be paid by the participants

IV. Benefits (does the consent document include):
   ☐ All direct or indirect benefits
   ☐ If no benefits accrue to the subjects, the larger societal benefits
   ☐ Statement “No promise or guarantee of benefits have been made to encourage you to participate”
   ☐ Optional: Checkbox for subjects to indicate whether they would like a summary of the research results when available [if subjects are children, the parent/guardian must make the request]
   ☐ Note, Compensation is not included/described in this section
Virginia Polytechnic Institute and State University - IRB
Consent for Participants in Research Projects Involving Human Subjects
Checklist to Assess Completeness of the Document

V. Extent of Anonymity and Confidentiality (does the consent document include):
- ✔ Extent to which subjects will be identifiable
- ✔ Explanation of how the study will provide the utmost confidentiality or anonymity [confidentiality = individual can be identified directly or through identifiers, but the researchers promise not to divulge that information; anonymity = individuals cannot be identified by anyone, including researchers]
- ✔ Explanation of the use of study ID/codes, if applicable
- ✔ Optional: Statement “At no time will the researchers release the results of the study to anyone other than individuals working on the project without your written consent.
- ✔ Explanation of who will have access to the data
- ✔ Statement, “It is possible that the Institutional Review Board (IRB) may view this study’s collected data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research.”
- ✔ Description of when data will be destroyed

VI. Compensation (does the consent document include):
- ✔ Subjects informed whether compensated or not
- ✔ Amount of compensation (including extra credit, if applicable)
- ✔ If extra credit is offered, what comparable alternative means of obtaining extra credit will be offered to those who decline to participate in the study

VII. Freedom to Withdraw (does the consent document include):
- ✔ Statement that subjects are free to withdraw from the study at any time without penalty
- ✔ If study involves compensation, statement that subjects will be compensated for the portion of their time spent in the study (if applicable) or fully compensated if they choose to withdraw
- ✔ Statement that subjects are free not to answer any questions or respond to experimental situations that they choose without penalty.
- ✔ Optional: Statement describing that there may be circumstances under which the investigator may determine that a subject should not continue as a subject. The subject must be compensated for the portion of the project completed

VIII. Subject’s Responsibilities (does the consent document include):
- ✔ Statement, “I voluntarily agree to participate in this study. I have the following responsibilities:”
- ✔ List of subject’s responsibilities

IX. Subject’s Permission (does the consent document include):
- ✔ Statement, “I have read the Consent Form and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:
- ✔ Signature line for subject
- ✔ Optional: Signature line for witness (use for certain classes of subjects)
- ✔ Contact information of investigators
- ✔ Contact information of IRB Chair listed as follows:
  If I should have any questions about the protection of human research participants regarding this study, I may contact Dr. David Moore, Chair Virginia Tech Institutional Review Board for the
Structure of Consent Document

☐ Language of the consent form is directed toward the individual signing the form (avoiding use of jargon, scientific terms, and concepts not readily comprehended by the non-scientist public)
☐ The text and readability of consent form is appropriate for the age, mental capacity and maturity of the individual signing the form
☐ The consent form does not contain any exculpatory language in which the subject is made to waive or appear to waive any of the subject’s rights
☐ The final draft of the consent document has been reviewed for grammatical and typographical errors