

Preparing an Informed Consent Document

The description of the informed consent process and the Informed Consent Form is one of the most important portions of the application for approval to use human subjects in research.

The Informed Consent should be both complete, but concise; typically it would be 1-2 pages long. Subjects should have a clear understanding of what their participation will entail. The goal is to allow the subject to make a reasonable, intelligent, and informed decision, free of explicit or perceived coercion.

Informed Consent documents should contain the following elements:

- 1. Explanation of procedure and how subject was selected**

The Informed Consent says explicitly that the study involves research, and that the purpose of the form is to give the potential subject information to decide whether or not to participate. It explains, briefly and simply, why/how the subject is eligible or how the researcher recruited the subject, what the researcher will ask subjects to do and for how long. If the researcher cannot fully reveal the purpose of the research to subjects, he/she must describe (in the Application Form) exactly what subjects will be told, why it is necessary to deceive or mislead the subjects, and how the researcher will debrief subjects after their participation.

- 2. Identification of risks**

The Informed Consent explains any foreseeable risks and/or discomforts (both physical and mental) that could reasonably be anticipated. This includes any potential financial risks or burden that could ensue such as who has responsibility for any costs or expenses that might arise from the study. The Informed Consent form also describes what procedures the researcher will take to minimize the potential risks. (It is possible that the research may produce psychological difficulties for a subject; therefore, it may be necessary to make arrangements for those difficulties to be dealt with by a professional. For example, in one study of people with chronic illness, the Investigator provided all subjects with a list of mutual-help organizations in the local area.)

- 3. Identification of benefits**

The Informed Consent explains any foreseeable benefits that are anticipated. In most research, expected results are tenuous, at best. If no direct benefits due to participation are foreseen, it is appropriate to state this. If there is no direct benefit to the subject, the document should explain what the study hopes to discover and why. Remember that compensation, either tangible or via course credit, is not a benefit. However, the researcher should describe any compensation the subject

will receive, and conditions under which no payment/credit or partial payment/credit will be made.

4. **Statement of confidentiality**

The Informed Consent describes how the researcher will protect the subjects' identity. The researcher should describe how records will be kept confidential (e.g. locked cabinet, erasing of tapes, etc.). If the researcher uses audiotapes or videotapes, indicate who will hear/see the tapes, where they will be stored, and how and when they will be disposed. In the event of audio or videotaping, the Informed Consent should include a separate signature line to allow subjects to accept or decline to be recorded.

5. **Freedom to withdraw**

The Informed Consent explicitly notes that participation is voluntary, and the subject can refuse to participate without any penalty or loss of benefits. The form further notes that the subject can skip questions or withdraw at any time. If the subject is to receive compensation, the researcher should state that they will receive a pro-rated portion of that compensation.

6. **Statement of consent**

The Informed Consent form includes an explicit statement that the subject declares himself/herself fully informed and agrees to participate on a purely voluntary basis.

7. **Signatures**

The Informed Consent has a line for the subject's and researcher's signatures and the date of consent.

8. **Contact information for the Principal Investigator**

The Informed Consent includes an explanation of how to reach the researcher if the subject has questions or concerns about the project or the subject's rights. This should include the researcher's name, phone number, and email address. In the case of student investigators, this will also include the information noted above for the faculty advisor supervising the research.

9. **Contact information for the IRB Chair**

The Informed Consent also tells subjects that they may also contact the IRB Chair with questions or concerns.

Other issues in preparing an Informed Consent form:

- The Informed Consent must be written in a language subjects can understand. This means that for normal English-speaking adults, the language should be at an 8th-grade reading level. Keep the language simple and the sentences short, and avoid abstract, academic words and phrases.

- Use large print and wide margins for readability. Internal subheadings will always make the form more readable.
- In some cases the document may need to be translated into another language. If these materials are written in a foreign language, submit both the forms to be used and their English translations.
- If the prospective subject uses a language that the investigator does not speak, it might be necessary to have a translator present who will go over the document point-by-point with the subject.
- If the prospective subject speaks English but does not read it, the investigator may be the one to go over the document orally with the subject.
- Informed Consent forms must not contain exculpatory language. Researchers cannot ask subjects to waive (or appear to waive) any of their legal rights, nor may researchers ask subjects to release the investigator, any funding organization, or Cornell College from liability for negligence. By signing the consent document, the subject is not "signing away" any rights. Their signature merely indicates that the subject has read the document or has had it read to him/her, has had a chance to discuss it with the investigator, and understands it.
- Researchers must give subjects adequate time to read the form thoroughly, and are encouraged to read the form out loud to subjects.
- The researcher will give a copy of the Consent Form to the subject and retain the signed form for their records.

SAMPLE Informed Consent Form

Cornell College

IRB # _____

Title of Project [List title of project]

Researcher's Name(s) and Contact Information

You are invited to participate in a study conducted by [student name, department, contact information]. The purpose of this form is to give you information to help you decide whether or not to participate in this study. The faculty advisor for this project is [name, department, contact information].

Purpose

The purpose of this study [explain purpose or objectives of the study].

Participants

The participants in this research project are [describe target population and how the participant was identified].

[Explain if there is a condition or circumstance that makes the person eligible for this study and specify the information].

Procedures

If you agree to participate in this study, you will be asked to do the following: [Explain tasks and procedures: subjects should be told about video or audio taping, assignment to study groups, where the study will be conducted, length of time for participation, frequency of participation, etc.]

Voluntary Nature of the Study

Participation in this research is completely voluntary. There will be no consequences and your current or future relationship with [school] will not be affected if you refuse to participate. You can withdraw from the study or refuse to answer any question at any time without penalty or loss of benefits.

Contact [student's name and contact information] should you decide to withdraw from the research.

Add the following statement for student participants recruited in a class:

If you decide not to participate or withdraw from this research, there will be no effect on your academic status or grade in this or other classes.

Risks of Participation

There are risks associated with participating in this study. [For each real/potential risk, provide subjects an estimate of its magnitude (e.g., mild, moderate, severe). Investigators should give an adequate and honest description of the magnitude of the risks without unrealistic minimization of

risks. If the research involves any procedures which could cause possible physical, social, legal, economic, and other harm, describe the risks in lay terms and any ramifications that could result should an unanticipated problem or adverse event occur].

If research involves minimal risk to human subject, include the following statement: To the best of the researcher's knowledge, there will be no more risk of harm than you would normally experience in daily life. The anticipated risks associated with participation in this research will be minimal.

If the research involves any procedures which could cause possible emotional or mental harm, include the following statement: You may find some questions that are asked (or some procedures you are asked to do) to be upsetting or stressful. If so, you can contact the following people or agencies to help you with these feelings. In addition to the risks listed above, you may experience a previously unknown risk or side effect. [list of contacts]

Benefits of Participation

There are benefits associated with participating in this study. [For each real/potential benefit, investigators should provide subjects an estimate of its magnitude (e.g., few, moderate, substantial). Investigators should give an adequate and honest description of the magnitude of the benefits without unrealistic exaggeration of the benefit.] However, there is no guarantee you will receive any benefit.

Cost and Compensation of Participation

There are [list itemized costs associated with study OR no costs] to you as a result of participating in this project.

You [will OR will not] receive any compensation for your time. [If a dollar amount will be paid for participation, specify amount, when the compensation will occur, and address matter of proration if participant withdraws or if the study is terminated by researcher. If subjects receive class points or some other token, include that information here.]

Privacy

Data collected in this study will be kept private and confidential. Specifically, the researcher will ... [explain how you will keep their names and data secure and who will have access to the data (e.g., members of the research staff, advisor, teacher). If there is a master list that includes the participant's name and a code linking the name to the data, the master list must be kept secure and separately from the collected data.]. [If tape recordings or videotapes are made, explain who will have access, and when they will be erased.] [Explain when the consent forms and any other identifiable data will be destroyed.]

Questions, Suggestions, Concerns, or Complaints

Before you decide whether to accept the invitation to participate in this project, you can ask any questions about the study. If you have any questions, suggestions, concerns, or complaints about this project, you can contact [student's name and contact information] and/or [faculty advisor and contact information].

If you have questions about your rights as a participant, you may contact the [school IRB, contact information]

Statement of Consent

By my signature, I am affirming that I have read this information, asked questions and received answers, am at least 18 years old and consent to participate in this study. I also affirm that I have been given a copy of this information for my records.

Signature of participant

Date

Printed name of participant

Person Obtaining Consent:

I have explained to the participant above the nature, purpose, risks and benefits of participating in this research project. I have answered any questions that may have been raised and I will provide the participant with a copy of this consent form.

Name of [authorized]
person obtaining informed consent

Date