Consent Form

Any researcher who intends to work with human subjects should seek legally effective "informed consent from each prospective subject or the subject's legally authorized representative." Under federal regulations, this is mandatory rather than an optional matter because informed consent is "one of the primary ethical requirements underpinning research with human subjects," reflecting the principle of respect for persons.

It is our experience that **90% of delays** in the processing of IRB applications result from **inadequate or missing Consent Forms**. We urge all applicants to submit a consent form.

Below you will find details on how to prepare an informed consent form. Once you have completed it, you will submit it along with your application and any other required documents via our online application.

Preparing an Informed Consent Document

In reviewing your application, the IRB reader will look for an informed consent document and will check to make sure that it contains all of the following information:

1. The document describes, briefly and simply, **what the research is about**.
2. It tells the subjects **what they will be asked** to do and for how long.
3. It explains any **risks and benefits**. If there is no direct benefit to the subject, the document should explain what the study hopes to discover and why.
4. If you promise to **protect your subjects' identity**, you must describe how you will do this. If it is impossible for you or anyone else to link the data you collect to a specific person, then you may promise to guarantee your subjects' anonymity. However, in most cases it will be possible to use your records to identify a subject. In that case, the most you can promise is to keep the subjects' personal information private to the extent allowed by law.
5. The document describes any **compensation** the subject will receive and conditions under which no payment or partial payment will be made.
6. The document makes it clear that **participation is voluntary**.
7. It tells subjects that they may skip questions or withdraw from the study at any point **without penalty**.
8. It gives the subjects the names, addresses, and telephone numbers or e-mail addresses of **persons to contact** if they have questions or concerns about the study. The IRB asks that name, address, and telephone number or e-mail address be included for the investigator and his or her faculty advisor (if the investigator is a student).
9. It tells subjects that if they have questions or concerns, they may also **contact the IRB chair**, c/o the Office of the Associate Dean of the college (see examples below).
10. It does not contain **"exculpatory language."** Subjects must not be asked to waive (or appear to waive) any of their legal rights, nor may they be asked to release the investigator, any funding organization, or Carleton 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.

Information in the consent document should be presented to prospective subjects **"in a language they can understand."** The reading level of the consent form should match the reading level and background of the subjects. In some cases the document may need to be translated into another language. It is best to use simple declarative sentences and avoid abstract, academic words and phrases. It is best to construct the consent form **using "you"** rather than "I" because it may be unclear whether "I" refers to the investigator or to the subject. Use large print and wide margins for readability. Internal subheadings will always make the form more readable.

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.

The federal regulations emphasize that an investigator should get **signed consent**. If a subject is a *minor* (a person under age 18 in Pennsylvania, or below the age of majority in the state or country where he/she lives), the signed consent of a parent or legal guardian is required. Ordinarily the investigator should give one (signed) copy of the consent form for the subject to keep, and retain another (signed) copy with the project records.

In unusual circumstances, the IRB may waive some points that are usually covered in the consent document. In some cases the IRB may determine that your research is "exempt" under Federal Guidelines, which may mean that you will not need to employ a consent form. But it is in your interest to submit a consent form anyway to avoid unnecessary delays in reviewing your application.

An Informed Consent Form Example

The following template is adapted from a form posted at the website of the IRB at the University of Minnesota. You may alter it to your own needs.

My name is (blank) and I am a student in the American Studies Program at Thiel College in Greenville, Pennsylvania. I am doing research about rodeos in the American West. I would like to interview you. You were selected as a possible participant because [explain how subject was identified.] We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The interview would take about half an hour of your time, and I would like to tape-record it with your permission. You will be asked to talk about [describe some questions so that they will know generally what they'll be doing]. Your contribution will be valuable in teaching others about life in the west today. If you provide your address, I'll send you copies of my paper. There are no particular risks to participating in this study as the questions are non-controversial and not personal.

I plan to use the interview information in conducting my senior research at Thiel. I will keep your identity confidential and use a pseudonym when referring to you, unless you give explicit permission below to use your name. We will keep all facts about you private. We will keep your records private to the extent

allowed by law. Your name and other facts that might point to you will not appear when we present this study or publish the results.

Your participation is voluntary and no compensation will be offered. Please share only what you are comfortable with sharing. You may decline to participate, or you may choose not to answer any particular question that I ask. If you change your mind about participating, you may stop the interview at any time. Please feel free to contact me or my advisor if you have any questions, concerns or comments about the project.
Thank you!
Joe College
[local address and telephone]
[Thiel address and telephone]
Faculty advisor:
Professor Jane American
[Thel address and telephone]

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), contact the Institutional Review Board for Research with Human Subjects at Thiel College, c/o Office of the Dean of the College, Thiel College, 75 College Avenue, Greenville, PA, 16125; telephone (724) 589-2200.

Statement of consent (Please initial only the items you agree to):
_____ I have read the above information. I have asked questions and have received answers. I consent to be interviewed in Joe College's study of rodeos.
_____ I give permission for the interview to be tape recorded.
_____ I give permission to be photographed and allow the photos to be used in the photo exhibit described above.
_____ I give permission to use my name in the photo exhibit.
_____ I give permission to use my name in your senior essay.

Signature: _____
Print name: _____
Date: _____
Address: _____

[**Only** if minors are involved]
Signature of parent or guardian: _____
Date: _____
Signature of Investigator: _____
Date: _____