

# Best Practices for IRB Applications

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Here are some suggestions for facilitating a smooth (and timely) IRB approval process.

First, follow the form closely. Here are some clarifications that help. The numbering system follows the Form B application – but the information also applies to Form A's.

## **I. Identification of Project**

1. Provide full contact information for each PI, Co-PI, or Advisor (as relevant). It helps to include email addresses, as that is usually a faster way to contact you. If there are multiple people listed, you will need to provide signature lines (and collect signatures) from each person.

5. Estimated completion date – this refers to the whole research project, not just data collection. Going for a longer time creates no problems with approvals, and may save you from having to file for an extension. I urge people to give themselves plenty of time here. If the application is for a class project that you may want to later expand on for a conference paper or publication, be sure to go beyond the end of the term for the completion date.

## **II. Project Objectives**

This should be relatively short, with a focus on what information is to be gathered, and what benefits may result from what you learn. The benefits may be practical, or furthering knowledge in the field. If your research poses risks, it is important to be more specific about potential benefits, and argue that the benefits outweigh the risks.

## **III Description and Source of Research Participants**

This should describe the target population for the study, and how you will recruit participants. Be detailed about the process, outline the steps involved.

Any screening for inclusion or exclusion criteria should be clearly stated, and you should indicate why you are using those criteria.

If you are using any recruiting materials (signs, letters, emails, script to read), you need to provide a copy as an attachment (drafts are ok).

If you are recruiting from off-campus groups, you may need to provide a letter of support from those groups/organizations before final approval.

Provide an estimate of the anticipated sample size (this is not binding – rather just to provide a rough guideline to the number of people affected)

If your research involves children (under 18), you will need to provide additional details about gaining parental consent/assent. **If not, state explicitly in this section that all subjects will be 18 or older.**

If your research involves other protected populations, or where the recruitment might seem coercive (i.e. a professor or coach asking their students to volunteer), you may need to provide additional information and protections to assure informed consent.

If your research involves an international sample, or non-English speakers, you may need to provide additional information about local laws, or provide translations of informed consent.

#### **IV Methods and Procedures**

This section should describe what happens after subjects are recruited. It is important to describe what information will be collected and how (interview guides or draft questionnaires should be provided). If you are asking them to engage in any activities (such as engaging in Web search activities, participate in group decision-making, etc.) those should be described.

You should provide estimates of time involved, or any other costs for participants.

You should be clear in this section about what promises you are making with respect to anonymity or confidentiality. To be clear, anonymity refers to the situation where no one, not even the researcher, knows what information came from which respondent. Focus groups, in person or telephone interviews, any recording, or when separate data collections are linked are by definition not anonymous. Confidentiality refers to the researcher promise not to provide to others any individual responses which might be identifiable. This can apply to anonymous data in the sense of not reporting any individual responses. For data collected where the researcher knows who supplied the data, the issue is what steps the researcher takes to limit linking data with identification.

This section should discuss how your procedure helps to preserve anonymity and/or confidentiality. What we will look for is what steps you take to limit access to identifiable data. At minimum, that may mean keeping such information in a secure location, and limiting access to it.

If your procedures involve activities which could be recorded (but aren't), such as using a webcam in an experiment, you should explicitly indicate that no recordings will be made.

You can conduct research without promising either anonymity or confidentiality, but in such cases you must use a Form B, and the informed consent must be clear that you may identify specific responses. It helps if you also give them the option of withdrawing their consent (at least for identifying them) later.

## V. Specific Risks and Protection Measures

There is no such thing as “no risk.” Or at least you should never put that on the application. At best, where data collection is anonymous and does not address sensitive issues, there may be “no foreseeable risk.” Another way to phrase it, if you can think of a possible source of risk, but little negative impact, is to indicate that there are “minimal foreseeable risks.”

If data collection is from identifiable individuals, there is always the risk that confidentiality may be breached – that someone may learn who gave what responses. In focus groups, for instance, individual responses are heard not only by the researcher(s), but by other participants. Tapes are presumed to allow identification, and so there is concern over who has access to them, and to what uses are they put.

You should provide details in this section as to what steps you will take to minimize the risk of identification – removing identifiers, keeping contact and linking information separate, limiting access to recordings, etc. With recordings, we also look for a specific statement as to how long they will be kept, and the specific location where they will be kept (give the address – preferably on campus).

The informed consent should outline those protections (but not provide specific details such as addresses).

If data collection involves sensitive information or topics (anything that might cause distress or harm), that needs to be identified, and we will look for what steps you will take to minimize the risk, or to mitigate the harm. Sensitive information includes questions about health status, sexual activities, drug use, physical abuse, or other illegal activities. It can also include procedures that might evoke negative psychological responses (for example, viewing websites from hate groups, or images of sexual violence). If the information is such that it requires the researcher to notify others, that needs to be spelled out. We will look for what steps you take to minimize the risk, or to help mitigate negative reactions.

In general CCI research does not pose risk of physical harm, but if so, that also needs to be addressed.

We also look to see that prospective research participants are warned about the potential sensitive topics, at least in the informed consent, and the informed consent explicitly indicates that they are free to not answer any question they are uncomfortable with. If there is the potential for risk, they must be notified of that, and given the option to not participate or to withdraw.

You can undertake research that is risky, but we will look carefully at what steps you take to minimize that risk, and that the prospective subjects are adequately notified of that risk. We will also consider whether the potential benefits outweigh the risk. These applications are also likely to require full Form B review, so can take more time for approvals.

## **VI. Benefits**

This section should outline any specific benefits for research participants (extra credit for classes, gifts, prizes, food and drink at focus groups, etc.). This is an issue in gaining approval only if the promised benefits are so high that they might seem coercive (Say offering \$100 for a ten minute survey)..

This section should also indicate what benefits might be gained from the research project. If it's only an increase in knowledge or understanding, put that down; but if you can think of any other benefits, put those down as well.

## **VII. Methods for obtaining Informed Consent**

Obtaining informed consent is required for all human subjects research.

In the case of anonymous research, or research with minimal risk, this can be done by an informed consent statement read or presented prior to data collection. See the “Basic Elements of Informed Consent” document<sup>1</sup> for what is expected to be in the statement. We also look to see an indication of the general topics/purpose of the research, an outline of what you expect from the participant (the time involved, etc.), and some affirmative action on the part of the respondent to continue participating. It is also helpful (but not required) if the consent statement is provided in such a way that the respondent can keep a copy if they so desire.

If the research uses certain procedures, has elements of risk, or does not promise anonymity or confidentiality, it may be necessary to use a more formal informed consent form. If you use a formal informed consent form and collect signatures, then Federal rules require that the be kept in a secure location for a minimum of three years. Give the specific location in this section.

If the population or the procedures are such that it is difficult or inappropriate to collect signed consent forms, other ways of ensuring that informed consent is provided may be approved. These will need to be adequately described in this section (for example, if recording a telephone interview, one could read the form and get verbal agreement on tape before starting the interview).

If your subjects are minors, be sure to specify procedures for collecting both parental/guardian consent as well as minor assent.

If respondents speak other languages, you may need to provide copies of informed consent translated into those languages.

Samples of informed consent are available at the Office of Research Compliance website.

## **VII. Qualifications**

You should indicate in this section what background or experience you have that would be helpful. It may be just indicating that you've had a methods class, or will be supervised by someone with more experience. This is more a concern if your research may have risks; in that case we will look for more specific qualifications to deal with the risk.

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<sup>1</sup> A copy of this form with some comments specific to CCI research is attached as an addendum to this document.

## **IX. Facilities and equipment**

If you are using any specific facilities or equipment (computer lab with specialized software, videoconferencing equipment) you should indicate so. If the facilities or equipment are provided from outside the University, you may need to provide additional information or letters of support.

## **XI. Signatures**

A separate signature line is required for anyone listed as PI, coPI, or Advisor. An original hard copy of the application with original signatures is required before approval can be given. You may submit drafts in hardcopy or by email for initial review, but we'll need the one with signatures eventually.

**Do not** get signatures for the DRC and dept. head lines. Those are for the committee and College reviewers.

### **Attachments:**

**Always** attach informed consent statements or forms. They are the critical component of the application.

Attach information about specific questions or topics if possible (draft surveys, interview or focus group question outlines, guiding questions, etc.)

If you plan to use formal recruiting documents (flyers, letters, email, etc.), attach a draft.

If you are promising confidentiality and anyone other than the listed PIs, co PIs, Advisors, or University IRB has access to identifiable information, you will need to indicate that they will sign a confidentiality pledge, and include a draft of the pledge.

If the research is done in cooperation with outside organizations, or uses their facilities or equipment, you may need a letter of support from them.

That should do it. If you have any questions, feel free to ask the College IRB representative.

## **Appendix 1 – Basic Elements of Informed Consent** (Revised 3/12/2007 for College of Communication and Information Researchers)

### **General Informed Consent Considerations**

Investigators should seek consent only under circumstances that provide the prospective participants sufficient opportunity to consider whether to participate, and that minimize the possibility of coercion or undue influence. Consent and information forms must be written in language that is understandable and clear to potential participants. The consent process may not include exculpatory statements through which participants waive or appear to waive any legal rights, or release or appear to release the investigator, sponsor, institution, or agents from liability for negligence.

### **Basic Elements of Informed Consent**

As you develop your consent form or procedure, please include the following information.

1. State that the study involves research.
2. Explain the purposes of the research and the expected duration of the participants' participation.
3. Describe the procedures that directly involve human participants, and identify of any procedures that are experimental.
4. Describe any foreseeable risks or discomforts to participants.
5. Describe any benefits to participants or to others that may reasonably be expected from the research.
6. If you plan to publish your research, include this information in your benefits statement. This does NOT give you the right to publish work that has not been approved by the IRB. However, it does alert participants that you may publish your findings (with clear protections of personal privacy in place). And IF your IRB protocol is fully approved you can include those responses in your analysis – even though the informed consent form might have been signed prior to approval. IF, however, any changes are required to protocol, THEN you may not publish any data that was collected prior to those changes in the protocol. Following is a sample statement to include in your “benefits” section:

“One potential benefit of this study is that the author plans to seek publication of findings. This can help extend the body of knowledge to other researchers and practitioners. By signing this form you acknowledge that findings may be published. Published findings will not identify you in any way.”

7. Disclose alternative procedures or courses of treatment, if any, which might be advantageous to participants.
8. Describe the extent to which confidentiality of records identifying participants will be maintained, where the records will be stored, and who will have access to the records.
9. For research involving more than minimal risk, explain whether any compensation or medical treatments are available if injury occurs. If compensation or treatments are available, they

should be described. The procedures for obtaining additional compensation/treatment information should be stated.

10. Identify the persons participants can contact for answers to pertinent questions about the research, and participants' rights.
11. State that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which participants are otherwise entitled, and also that participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.
12. For studies that involve students or any other population that might include persons less than age 18, include a statement in the informed consent document that verifies the age of the participants (unless of course, you are studying persons under age 18 – in which case see separate documents for protections for children). A good place for this statement is the section that indicates that participation is voluntary. Following is a sample paragraph including the statement about age:

“Your participation in this study is voluntary; you may decline to participate without penalty. If you are less than age 18, please notify the researcher and do not participate in the study. By signing below, you confirm that you are age 18 or older. If you decide not to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed”

### **Additional Elements of Informed Consent**

The following additional elements of informed consent may be required.

1. A statement that the particular treatment or procedure may involve risks to the participant that are unforeseeable.
2. Anticipated circumstances under which a participant's participation may be terminated by the investigator without regard to the participant's consent.
3. Any additional costs to the participant that may result from participation in the research.
4. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
5. A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant.
6. The approximate number of participants involved in the study.

### **Contacts for Further Information**

If you have any questions about preparing an informed consent form or procedure, please check with your Departmental Review Committee or the Office of Research [Compliance Officer](#) at (865) 974-3466.