

Appendix A: Guidelines regarding Demographic Information

Researchers often collect demographic information regarding participants. If you wish to collect demographic information as part of your study, you will need to identify this information in your IRB application and explain why it is relevant to your study.

When you write your demographic survey, you should use standardized wording that is in harmony with current best practices. It is always wise to include options for “Other” and for “Prefer Not to Respond”. You should also think carefully about the characteristics of your population when designing your survey to make sure that the listed options are appropriate for your participants.

Gender, race/ethnicity, and religion are sensitive topics and wording should be carefully chosen. Some samples are provided here to assist you when designing your survey.

What is your gender?

- Female
- Male
- Other: _____
- Prefer Not to Respond

What race or ethnicity do you consider yourself?

- American Indian or Alaska Native
- Asian
- Black or African American
- Hispanic/Latino
- Native Hawaiian or other Pacific Islander
- White
- Multi-racial
- Other: _____
- Prefer Not to Respond

What is your religious preference?

- Seventh-day Adventist
- Other Protestant Christian
- Catholic
- Atheist
- Agnostic
- Buddhist
- Jewish
- Muslim
- Other: _____
- Prefer Not to Respond

Appendix B

Understanding Risks and Benefits

When designing a study that utilizes human participants, it is crucial to evaluate the risks and benefits of the study. One of the key functions of the IRB is to review these risks and benefits to protect the rights of the participants. Additionally, the IRB must ensure that the benefits outweigh the risks for any given study. This document outlines some basic definitions and concepts that will be helpful for designing your study and completing your IRB paperwork.

Risks

In this context, risk is defined as *the probability of harm or injury (physical, psychological, social, or economic) occurring because of participation in a research study*. Both the probability and magnitude of possible harm may vary from minimal to significant.

The following research activities create risk:

- Collecting and maintaining personally identifying information about research participants.
- Asking questions about the participant's psychological or social state in surveys or interviews.
- Probing for personal or sensitive information in surveys or interviews.
- Using deceptive techniques to mislead participants during the research.
- Manipulating the participant's psychological or social state in a research setting; and
- Accessing private records (such as educational or medical records).

This is not an exhaustive list- there are many other activities that can create risk. But this is a good starting point for thinking about your study and the ways in which participation might create risk.

When working with human participants, there is almost always some level of risk. If you claim that there are no risks associated with your study, the IRB will almost certainly send your application back for revision. The IRB does not expect you to eliminate risk. Instead, the IRB expects you to identify the risks associated with the research and to describe the steps you have taken to minimize the risks. As you design your study, you will need to:

- Make sure your experimental design is in line with current best practices in your field.
- Ensure that the projected sample size is sufficient for the study.
- Design procedures for informing participants about the risks associated with the study.
- Obtain the voluntary consent of participants before they participate in the study.
- Identify trained personnel who can assist participants in the event of an adverse response.
- Plan an appropriate response if a participant wishes to withdraw from the study; and
- Develop procedures to protect the security and confidentiality of the collected data.

Benefits

When evaluating research proposals, the IRB must determine if the risks to individual participants are reasonable in relation to the anticipated benefits of the study.

Benefits fall into two broad categories: 1) The overall benefit that the study will have by producing knowledge; and 2) The specific benefits for individual participants. You will need to address both of these categories in your IRB application and in your Informed Consent paperwork.

First, research studies are conducted in order to benefit society by expanding knowledge in a particular area. Reasonable risk is tolerated in light of this broader goal. As the IRB reviews your application, they will look for evidence that your study will make a meaningful contribution to the body of knowledge in your research area.

Second, the IRB will need to understand the benefits that you are offering to individual participants, including monetary compensation (cash, gift cards, etc.) or other incentives (free food, extra credit in a class, etc.). These benefits can motivate subjects to participate in the study. With that said, participants must be able to make an informed choice and must not be coerced to participate. Therefore the IRB needs to carefully evaluate any compensation or incentives offered to participants.

Appendix C

Informed Consent Guidelines and Sample Forms

Informed Consent is a crucial component for conducting an ethical research study with human participants. Your Informed Consent needs to cover specific areas, including the following:

- **Purpose:** Describe the purpose of the study.
- **Involvement:** Describe what the participant will do in the study, including the study procedures and the duration of time.
- **Risks:** Describe the risks to the participant. Identify the resources that are available if a participant experiences an adverse response.
- **Overall Benefits:** Describe the overall benefits associated with this study. State how participants may obtain a copy of the results if desired.
- **Individual Benefits:** Describe any compensation or incentives that will be offered to participants.
- **Right to Decline:** Explain that the individual has the right to decline participation in this study.
- **Right to Withdraw:** Explain that the individual has the right to withdraw from the study at any time without negative consequences.
- **Confidentiality:** Indicate the extent of confidentiality or anonymity that will be maintained and explain the methods that will be used to accomplish this goal.
- **Contact:** Provide contact information (for the student researcher and for the supervising teacher) in the case that the participant has questions about the study. Additionally, include contact information for the chair of the IRB. This individual serves as an impartial third party and can answer questions about the rights of participants.
- **Right to Ask Questions:** Explain that the individual has the right to ask questions before consenting.
- **Authorization:** Obtain a dated signature that authorizes participation in the study.

The Informed Consent form should be written in clear, accessible language. Jargon or confusing words should be avoided, and any necessary technical terms should be defined for the reader.

A copy of the informed consent document must be provided to each participant for their own records.

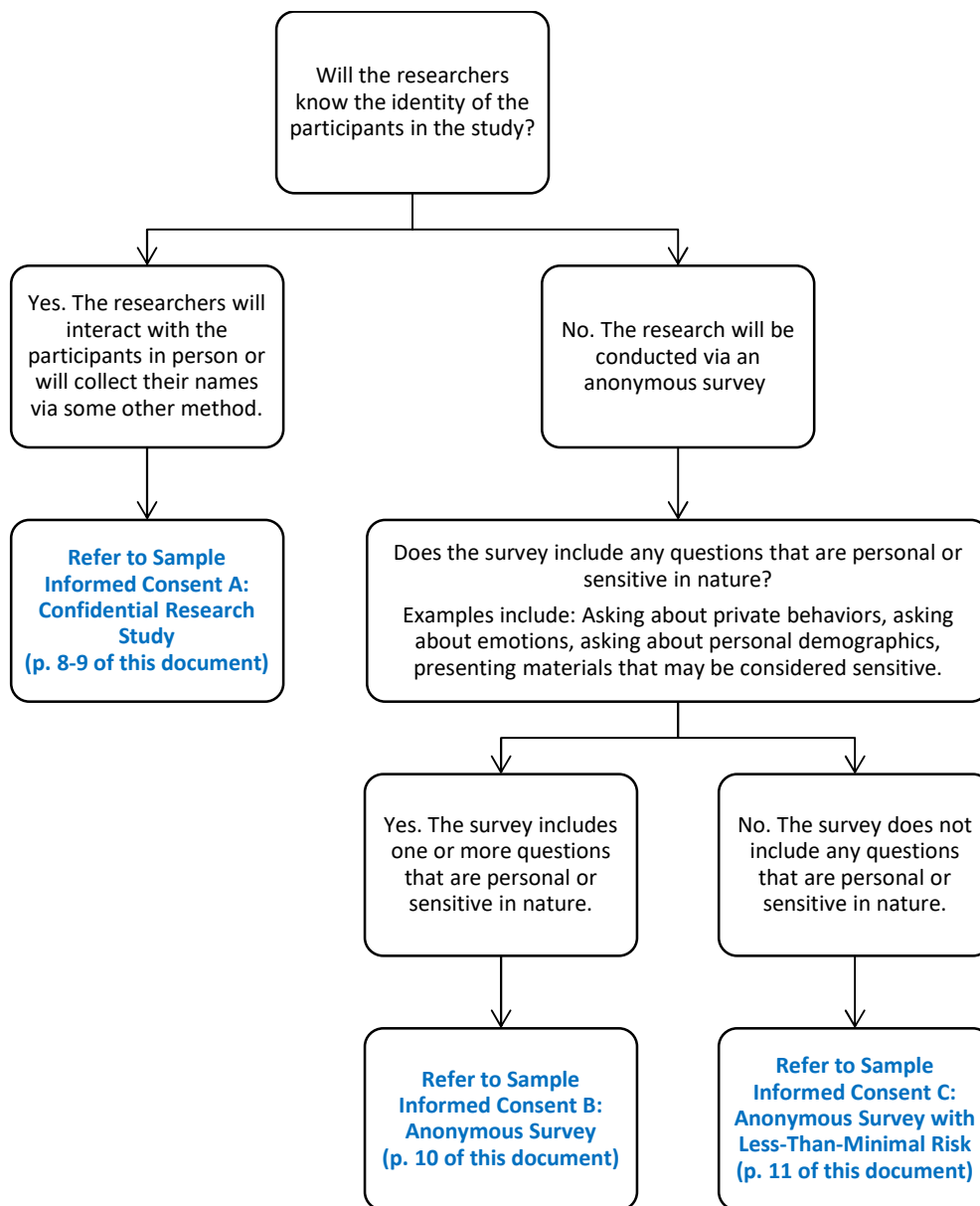
Situations that may not require Informed Consent

If your research uses the following methodology, you may not be required to obtain informed consent.

- Data collected from secondary sources in the public domain.
- Data collected via observation in the natural environment and in a public area.

Choosing a Sample Informed Consent Form

Each study is unique, and the Informed Consent Form must be tailored to match the design of the study. The samples included in this appendix can provide a helpful starting point. Three samples are provided- use the following decision tree to determine which sample is most appropriate for you.



Sample Informed Consent A: Confidential Research Study

1. Introduction

You are being asked to be a voluntary participant in the research project described below. Before agreeing to take part in this research study, it is important that you read this consent form so that you can make an informed decision. Please ask the study researcher or staff to explain any words or information that you do not clearly understand.

2. Why is this study being done?

The study is designed to help us understand {TOPIC}. Approximately {#} participants will be enrolling in this study at Pacific Union College, sponsored by the {DEPARTMENT NAME} under the supervision of Professor {PROFESSOR NAME}. If you decide to enroll in this study, your involvement will last about {#} minutes. You must be at least 18 years of age to participate in this study.

3. What is involved in the study?

If you agree to take part in this study, you will {GENERAL OUTLINE OF STUDY ACTIVITIES}.

4. What are the risks and discomforts of the study?

{USE ONE OR BOTH OF THE FOLLOWING STATEMENTS, AS APPROPRIATE. PLEASE NOTE THAT EVERY STUDY HAS SOME LEVEL OF RISK, SO IRB WILL EXPECT YOU TO IDENTIFY AND ACKNOWLEDGE THE RISK THAT ARE INHERENT IN YOUR STUDY}

There is minimal physical risk in this study. In this study, participants will be asked to {BRIEFLY DESCRIBE PROCEDURE THAT CONTAINS PHYSICAL RISK}. This has the possibility of causing soreness or unpleasant physical symptoms. If you experience unpleasant physical symptoms, resources are available at PUC Health Services: 707-965-6339.

There is minimal emotional risk in this study. In this study, participants will be asked to {BRIEFLY DESCRIBE PROCEDURE THAT CONTAINS EMOTIONAL RISK}. This may bring up some unpleasant emotions. If you experience distressing emotions, resources are available at the PUC Counseling Center: 707-965-7080.

5. What are the benefits of this study?

By participating in this study, you will help us find out more about {TOPIC}. If you are interested in the results of this study, please let us know. As a participant, you are entitled to receive a copy of the results upon request.

6. Will I be paid to participate or get any direct benefits for being in this study?

{DESCRIBE ANY DIRECT BENEFITS TO THE PARTICIPANT, IF RELEVANT}

7. What other options are there?

You have the option not to take part in this study. There will be no penalties involved if you choose not to take part in this study.

8. What if I want to withdraw, or am asked to withdraw from this study?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, there will be no penalty. If you choose to take part, you have the right to stop at any time. However, we encourage you to talk to a member of the research group so that they know why you are leaving the study. The researchers may decide to stop your participation without your permission, if they think that being in the study may cause you harm, or if your behavior during the study is judged to be disruptive.

9. What about confidentiality?

Your part in this study is confidential. None of the records collected for this study will identify you by name, except this Informed Consent Form, which will be kept separate from all other records and linked only using a code number.

10. Who do I call if I have questions or problems?

You may ask any questions you have now. If you have questions later, you may email {STUDENT NAME} at {STUDENT EMAIL ADDRESS}.

If you have questions or concerns about your participation as a research subject, please contact {PROFESSOR NAME}, the PUC faculty member supervising this research, at {PROFESSOR EMAIL}. You may also contact Aimee Wyrick-Brownworth, Chair of the PUC Institutional Review Board at 707-965-6636 or irb@puc.edu.

11. Authorization Statement

I have read each page of this paper about the study (or it was read to me). I know that being in this study is voluntary. I certify that I am at least 18 years of age and I choose to be in this study. I know I can stop being in this study without penalty. I know that I can get a copy of this consent form now upon request to the research staff, and I can get information on the results of the study later if I wish. My signature below indicates my consent to participation.

Name (Please Print)

Signature

Date

Sample Informed Consent B: Anonymous Survey

Introduction

You are being asked to be a voluntary participant in the research project described below. Before agreeing to take part in this research study, it is important that you read this information so that you can make an informed decision.

Purpose. The study is designed to help us understand {TOPIC}. Approximately {#} participants will be enrolling in this study at Pacific Union College, sponsored by the {DEPARTMENT NAME} under the supervision of Professor {PROFESSOR NAME}. If you decide to enroll in this study, you will complete a survey that takes about {#} minutes. You must be at least 18 years of age to participate in this study.

Risks & Benefits. There is minimal emotional risk in this study. In this study, participants will be asked questions regarding {BRIEFLY DESCRIBE QUESTIONS THAT CONTAINS EMOTIONAL RISK}. This may bring up some unpleasant thoughts or emotions. If you experience distressing thoughts or emotions, you may discontinue the survey at any time.

All responses and participants will be anonymous; none of the records collected for this study will identify you by name.

There are no direct benefits for participation in this study. However, you will contribute to the general body of knowledge by helping us find out more about {TOPIC}.

Voluntary Participation. Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, there will be no penalty. If you choose to take part, you have the right to stop at any time.

Contact Information. If you have questions later, you may email {STUDENT NAME} at {STUDENT EMAIL ADDRESS}. You may also email this address to request a copy of the study results.

If you have questions or concerns about your participation as a research subject, please contact {PROFESSOR NAME}, the PUC faculty member supervising this research, at {PROFESSOR EMAIL}.

You may also contact Aimee Wyrick-Brownworth, Chair of the PUC Institutional Review Board at 707-965-6636 or irb@puc.edu.

Consent

- I have read this information. I certify that I am at least 18 years of age and I agree to participate in this study. I understand that I can stop the survey at any time.
- I do not agree to participate in this study.

Sample Informed Consent C: Anonymous Survey with Less-Than-Minimal Risk

We are students in {CLASS} and we are gathering information for a class project regarding {TOPIC}. We would like to have your opinion on this topic. The survey has some basic questions regarding your opinions on {TOPIC} and participation will take about {#} minutes of your time. The questions are not personal or sensitive in nature and your responses will be anonymous. There are no benefits being offered for participation in this study. Participation is voluntary and you can choose to stop the survey at any time.

If you have questions about this project, you can email {STUDENT NAME} at {STUDENT EMAIL ADDRESS}.

- I have read this information and I agree to participate in this study. I understand that I can stop the survey at any time.
- I do not agree to participate in this study.