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.