Bryant University

Seven Questions to Consider

Before starting any project involving human subjects, faculty should reflect on the following questions. The same questions are considered by the IRB in reviewing a protocol.

1. Are the risks reasonable in relation to the benefits?

This question is intended to ensure that the generally accepted canons of good scientific research are fulfilled and that there is scientific propriety. What are the risks, and what are the benefits? Faculty should consider the entire protocol from the participant's point of view and decide if the information gained is of sufficient benefit to society or to the advancement of knowledge to outweigh any risks to the participants. Contact any member of the IRB if there is any uncertainty about this question.

2. Are the risks minimized?

Faculty should take every possible precaution to minimize pain, discomfort, or harm to the subjects. Are there adequate safeguards for the participants against anticipated risks? For example, have steps been taken to ensure that the participants remain anonymous in the way the data are reported?

3. Is the selection of participants equitable considering the goals of the experiment?

Care should be taken to avoid discrimination or the over-selection of vulnerable participants who are not required for the purposes of the experiment. For example, children should not be used as subjects unless the research specifically pertains to children. Who are the participants, do they come from a specific population, and is proper randomization being used? Selection of particularly vulnerable participants requires specific consideration of the protection of those participants.

4. What is informed consent, and has it been obtained?

"Informed consent" means that the participant has agreed to volunteer for the project after receiving a full disclosure of the procedures involved, any risks of these procedures, and the confidentiality of the information that will be collected. The circumstances of being a participant must be understood by a competent individual, either the participant or the legal guardian of the participant. The decision to

participate must be free of coercion. Even a simple survey should describe the purposes and uses of the study and should reassure the participants of its confidentiality.

Incomplete disclosure of the purposes of the research prior to the experiment is justified only when all three of the following conditions are met: 1) complete disclosure would invalidate the research, 2) risks to subjects are minimal, and 3) debriefing and complete disclosure are eventually carried out.

5. Is the selection of participants equitable considering the goals of the experiment?

Participants should be informed that they have the right to refuse to participate and the right to withdraw from the procedures at any time without being penalized. Surveys should include a statement that participation is voluntary and confidential. For studies involving risk, faculty are encouraged to obtain informed consent using a form similar to the example given (see the document **Model for Consent Form**). It is recommended that faculty retain the filled-out forms for three years, or five years if the subjects are minors or adolescents.

6. Are the privacy and confidentiality of the participant protected?

The reporting of data obtained from a participant must be handled so that the individual's identity is not revealed, and the information is not traceable to that person by anyone who is not a researcher on the project. Researchers and research assistants who have access to the information should be specified. The privacy of the subjects and their capacity to control their way of life must be respected.

7. Are the data monitored and the risk assessment re-evaluated during the course of the study?

The investigator should have in mind the preceding questions not only while designing experiments, but also while data collection is proceeding. The results should be assessed for effectiveness - is the information sought being obtained? Is the information worth the risk (if any) to the participants? In the event of any unexpected negative consequences to participants (e.g., unforeseen discomforts or harmful repercussions for the subjects), the investigator should notify the IRB. See the document **Responsibilities of the Investigator**.