

# Institutional Review Board (IRB)

## Section B: Description

Section B is perhaps the most important part of the entire set of IRB forms because it is here that you should explain your study. If, after reading your IRB submission the committee still has questions about your methodology, you may be asked to make changes or add to your information in Section B.

These instructions will take you through Section B. Each item is listed below with a link to helpful information and instructions.

### SECTION B

Respond to each of the following items or questions in the order listed. Provide enough detail so the reviewers will be able to judge how well your study protects human subjects.

Your responses must be typed and each response should be numbered to correspond to each question. If any item is NOT APPLICABLE for your study, type N/A beside the item number. Normally, your response to Section B will not exceed five double space pages.

[Note: typed, double spaced, number responses, generally 5 pages or less for this Section](#)

#### **1. Provide a brief description of the proposed study (i.e., purpose, problem to be investigated - about 100 words).**

Briefly state the purpose of your study.

- What question(s) are you trying to answer?
- Are you testing a previously developed theory?

#### **2. What are the potential benefits to the individual subjects and/or society as a result of the proposed research?**

One of the decisions the IRB will make regarding your research is whether the potential benefits will outweigh the risks involved in the research. According to the Federal Register, V56, June 18, 1991, p. 28015, part of the criteria for IRB approval is that the risks to subjects are reasonable in relation to the **anticipated benefits**, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. ([See Integrity in Research](#))

Can you explain how this research will benefit any or all of the following:

- Human subjects involved in the research
- Members of society (at large or a special group)
- Professionals in your field
- Practitioners in your field

**3. Describe the methodology of your study. Please include the setting, subjects and how they will be recruited, data collection methods, and any other details which may have an effect on human subjects. Be as concise as possible. Attach a copy of any data instrument to be used (questionnaire, survey, interview questions, etc.)**

Item 3 is one of the most important parts of the IRB packet. It is also likely to be the lengthiest item of the 8 items in Section B. The IRB is greatly concerned with the protection of human subjects, and we need to understand exactly what the participant will experience in your study.

**Copy of the Data Instrument(s)**

You **must** include a copy of all questionnaires, survey items, interview questions, instructions, descriptions of tasks -- anything the participants will be asked to read or any action they will be asked to take. You can attach these to the back of the IRB packet.

**Setting**

Where and when will data collection take place?

**Subjects/Participants**

Be as specific as possible when describing your participants. Give the age, gender, and any other specific information (i.e., college students, members of the Bloomsburg YMCA, clients seen in the Wellness Clinic).

**Note: Students as Subjects**

The fact that a person is a student can affect that person's ability to make a voluntary and uncoerced decision about participating as a subject of research. If prospective subjects are students the consent form must state that class standing or grades or status on an athletic team will not be affected by refusal to participate or by withdrawal from the study. If students are to receive class credit for participation as subjects in a research project, other opportunities must be available to earn equivalent credit, and the consent form must so indicate. All research, using students as subjects, by university faculty, staff, or students must be reviewed by the IRB or an HSRC (for exempt studies). Researchers not affiliated with Bloomsburg University who wish to use Bloomsburg University students as subjects should contact the Office of Research and Sponsored Programs. A review by the IRB is mandatory in these cases.

**Recruitment of Participants**

Describe the way participants will be recruited. Is the method of recruitment equitable? Is it random or convenient? Will the participants be offered anything for participation, such as extra credit or money? When and how will they receive this payment.

**Note: Assent**

Minors and others who cannot give legal consent must be given the opportunity to give assent (in addition to the legal consent of their parent or legal guardian). Except in therapeutic studies, a minor who does not give assent may not be enrolled in the study.

**Data Collection**

Explain, in detail, how you will collect data. From the moment a participant enters the research space until the time that person leaves -- what, exactly, will he or she experience.

**Electrical Equipment**

If any type of electrical equipment is used that will be connected to subjects then you must provide the name and qualifications of the individual who will check for electrical safety and attach a signed letter.

## Reminder: Criteria for IRB Approval of Research

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied: (Federal Register, V56, June 18, 1991, p. 28015)

- **Risks to subjects are minimized:** (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- **Risks to subjects are reasonable** in relation to the anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participants in the research).
- **Selection of subjects is equitable.** In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- **Informed consent will be sought** from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Section C.
- **Informed consent will be appropriately documented**, in accordance with, and to the extent required by Section C.
- When appropriate, the research plan makes adequate provision for **monitoring the data collected** to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the **confidentiality of the data**.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

#### 4. If deception must be employed, explain why it must be employed, how you will debrief the subjects, and the actual information which will be provided to the subject in the debriefing process.

If you are not using deception in any part of your research, then you can respond "Not Applicable" to this item.

If you are employing deception, notice that Item 4 asks for three things:

- Explain why deception **must** be employed
- **How** you will debrief the subjects
- Give/Attach the **actual information** provided to the subjects in debriefing

Make sure you address each of these in your Item 4 response. If you are using deception you should detail this appropriately in your methodology (item 3, Section B) and your discussion of risks (items 5, 6, and 7 of Section B).

### **Informed Consent**

When introducing deception into the methodology the researcher complicates a subject's right to make an informed decision as to whether to participate in a study. According to the Federal Register, V56, June 18, 1991, p. 28015, the IRB should ensure that Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [Section C \(Informed Consent\)](#). Informed consent will be appropriately documented, in accordance with, and to the extent required by [Section C](#).

### **5. What are the potential risks to the subject, and what is the likelihood and seriousness of these risks (i.e., risks could be physical, psychological, social, legal, etc. and may result from your experimental procedures, or your method of obtaining, handling or reporting data)?**

Item 5 is part of a sequence of items on potential risks in the research. Notice the sequence:

- Item 5, What are the potential risks?
- Item 6, What other methods were considered?
- Item 7, How will you minimize the risks?

Item 5 is asking you to do three things: (1) give the potential risks, (2) the likelihood of the risks, and (3) the seriousness of the risks.

There are many factors that can introduce risk into a research procedure. Here are some items to consider when assessing potential risk.

### **Vulnerable Participants**

If your participants include children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, you should consider potential risks which are unique to your participant sample.

### **Physical Risk**

If there is any physical component to your research you should think this through carefully. What if the subject panics? jerks? faints? has an allergic reaction? pushes himself/herself too hard? What if the equipment malfunctions?

### **Electrical Equipment**

If any type of electrical equipment is used that will be connected to subjects then you must provide the name and qualifications of individual who will check for electrical safety and attach a signed letter.

### **Psychological Risk**

Are you asking the subject to reveal anything sensitive? Embarrassing? Highly confidential or highly personal? Have you designed a group experience in which a subject could feel embarrassed, humiliated, or insulted? If you are using deception, will the subject experience adverse emotions upon learning the 'real' focus of the research?

### **Social Risk**

Will any of the factors mentioned above in Psychological Risk become known to others? If you are collecting sensitive data you need to consider if there is any chance that the data could found by someone other than the researcher(s)?

### **Legal Risk**

Is there any way a subject could face legal repercussions based on data given in your study? Is there any risk that a subject could bring legal action against the researchers based on participation in this study?

### **Safeguarding the Data**

Could the data fall into the hands of someone outside the study at any point in the procedure?  
Could the participants' names be easily associated with individual responses?

The areas of risk are often unique to each particular investigation. The IRB will most concerned with the following: (Federal Register, V56, June 18, 1991, p. 28015)

- **Risks to subjects are minimized:** (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- **Risks to subjects are reasonable** in relation to the anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participants in the research).
- When some or all of the **subjects are likely to be vulnerable** to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

### **6. As applicable, for each risk identified in item 5, describe other methods that were considered that would reduce or eliminate these risks, and explain why they will not be used.**

Your response to Item 6 depends on your response to Item 5. For each risk identified in Item 5 you need to do two things:

- describe other methods that were considered that would reduce or eliminate these risks
- explain why they will not be used

### **7. As applicable, describe how you will minimize or protect against potential risks to subjects throughout the study. (Describe emergency procedures, confidentiality safeguards, debriefing procedures, security measures for storing data, and how to obtain informed assent for minors or others who cannot give legal consent but can give assent.)**

No matter how you responded to Items 4 (deception) and 5 (risks) you should have additional information to add to Item 7. Your response to Item 7 should **not** be N/A.

Notice that Item 7 is asking for numerous pieces of information. You should address each one as applicable.

### **Emergency procedures**

When any physical risks are involved, which includes all biomedical procedures, emergency procedures should be specified. For example, when performing a biomedical procedure on a participant on the Bloomsburg University campus, you should:

- Have someone who knows CPR present
- Contact (written form) to BU police informing them of the study, exercise times, and procedure
- State that participants will be taken to Bloomsburg Hospital if problems arise
- Have a written health screening form from each participant (there is a standard form available)

### **Confidentiality Safeguards**

What safeguards have you put into place to ensure that any data collected will remain confidential? If you are collecting data in a group setting how will you make sure that each participant's privacy is respected? Will you use code numbers on any information sheets rather than participants' names?

### **Debriefing Procedures**

If you will use deception in your study, is there anything you need to add to your response in Item 4?

### **Security Measures for Storing Data**

Where will your data be stored? Will it be locked in a file cabinet and/or in an office? Will you store any information with participants' names in a separate place from the data? How long will you keep the data? When and how will you destroy the data?

### **Assent**

If your study involves minors and/or others who cannot give legal consent, you should have a way to allow those participants to give assent. This is in addition to legal consent from the appropriate parent or guardian.

If the participant is not able to read and sign a form then the investigator will ask for verbal assent. If you intend to do this you must explain why in this section of Item 7.

If the participant is able to read and sign a form then a separate Assent Form should be provided. Here is sample text from an example of an assent form:

*I agree to answer the questionnaire given to me. I understand that you are only interested in what I think, and that there are no right or wrong answers. I understand that my name will not be put on my answers so that no one will know what I have said. I know that I can stop at any time without any negative consequences. I also know that my parent(s) or guardian(s) said that I can take part in the study. If I have any concerns I know I may ask the person conducting the study.*

*I understand what I have been asked to do and agree to participate in the study.*

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Signature

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Date

**8. Identify all personnel involved in the study, their role, their qualifications and their access to data.**

Item 8 is very straightforward. For each person involved in the study you should give 3 pieces of information: Role, Qualifications, Access.