

# Institutional Review Board (IRB) Basics for GW Researchers

---

## PURPOSE

The IRB supports and helps researchers protect the rights and welfare of human subjects in research.

The IRB performs *prior* review of every research project at GW that uses human subjects – even unfunded research and pilot research. This means that the IRB must review your plan to conduct research with human subjects to make sure that specific ethical criteria are met *before* you begin any research with human subjects. This document is meant to help you understand and navigate IRB review.

---

## HELPFUL HINTS

### **The IRB Submission is Your Research Blueprint**

What the IRB approves is what you are expected to do. Any research activities that deviate from the IRB approved submission are not approved and will be considered noncompliant. For this reason, it's important for researchers to provide full details about their research along with specific, practical information on how procedures will be carried out, confidentiality protected, etc. All study activities and components must be described in the IRB form.

### **Be Succinct, Descriptive, & Consistent about Study Procedures and Specific Methodologies**

The IRB reviews specific methodology and needs detailed information about how the study will be carried out. It is in the details of a study that risks are found. Therefore, make sure to fully describe all study activities that involve human subjects or identifiable data. The IRB must be confident that it fully understands what your research entails and what your human subjects will experience before it can make any review determinations.

### **Answer All Application Questions and Carefully Review the Information You Provide**

The IRB has no prior knowledge of your research and therefore relies on the information you provide in the IRB submission. The *Study Application* is where you will describe, in detail, your research procedures. *Study Documents* are meant to reinforce and supplement the information in the *Study Application*. If information is inconsistent, unclear, or incomplete, IRB review of your research will be delayed.

### **Submit All Relevant Study Materials/Documents**

The IRB must see all study materials from recruitment materials (ads, letters, emails, flyers, etc.) through thank you letters/debriefing. The IRB must have a clear and complete understanding of what human subjects will experience throughout the course of the research.

### **Modifications to Your Study Must Be Approved by the IRB Before Implementation**

Any changes made after initial IRB approval must be reported to the IRB and approved prior to implementing them.

### **IRB Review is Required Before Contacting Any Potential Participants and/or Receiving Identifiable, Private Data for Research**

#### **Confidentiality of Data**

When the IRB asks about confidentiality of data, it is referring to the collection, analysis, and storage of data - not just the reporting of results. Information to the IRB should include descriptions of how confidentiality will be protected in all phases of the research.

**Anonymity** means that there is absolutely no way for anyone (not even the researcher) to trace a subjects' identity from the data.

#### **The IRB Review is a Collaborative Process**

Consider the IRB staff and board members a resource for navigating difficulties when planning and conducting your research. The IRB review of your research is likely to be a collaborative process involving communication between the IRB and you about your research. You are the expert of your research, and your involvement during IRB review is important.

---

## CRITERIA FOR IRB APPROVAL

The following numbered points are criteria that the IRB has to find in order to approve research:

### 1. *Risks to Subjects are Minimized*

- ◆ Risks to subjects are minimized by using research procedures which are sound science, but do not unnecessarily expose subjects to risk
- ◆ Risk in social and behavioral research is primarily risk of *loss of confidentiality*.

This means that someone besides the researcher could find out:

- a) that a person is involved in a study, and
- b) the data collected about an individual in a certain study.

Either scenario could have a harmful effect on a subject, depending on the study. For example, if someone is discovered to be participating in a study entitled, "Psychological Causes of Impotence," just knowledge of participation is embarrassing. If an employer finds out a certain employee's answers in a management study, "How satisfied are you with your job?" there could be professional repercussions for that employee.

- ◆ Other risks from social and behavioral research include: *psychological risk, embarrassment, discomfort, loss of social or professional standing, and legal or civil prosecution*.

The IRB considers intended as well as unintended consequences of the information.

Risks from research fall under 5 categories:

1. Physical
2. Emotional
3. Legal
4. Social
5. Fiscal/Professional

- ◆ Primary considerations for social and behavioral research should be:
  - What sort of information is covered in the study?
  - How could it possibly be discovered by someone outside of the study?
  - How could it embarrass, harm, or cause discomfort to the subject?

The IRB considers "worst case scenarios," such as an investigator leaving behind a briefcase full of research notes, or the theft of a computer containing data. Also, keep in mind that research records can be subpoenaed.

- ◆ Sometimes, the survey questions themselves could cause harm to subjects. For example, questions about experiences with sexual assault or other violence could trigger memories in a subject who had experienced assault. If research activities contain any questions that may be potentially upsetting to subjects, that must be planned for in the research procedures.

### 2. *Risks to the Subject from the Research are Reasonable in Relation to Expected Benefits to Subjects, and/or the Importance of the Knowledge that May be Reasonably Expected to Result*

### 3. *When Some or All of the Subjects are Vulnerable to Undue Influence to Participate, Additional Safeguards Have Been Included in the Study to Protect the Rights and Welfare of the Subjects*

- ◆ Consider conflict of roles if you as a researcher have an existing relationship with potential participants (e.g., students in a class taught by the investigator)

#### 4. ***Selection of Subjects is Equitable***

- ◆ The setting and the purpose of the research are taken into account; including any existing relationships the researcher might have the participant population.
- ◆ Recruitment procedures should guarantee a diverse sampling, and if the study focuses on one segment of the population, there should be justification as to why.
- ◆ Amounts of compensation should not be so great as to provide undue inducement to people who are economically disadvantaged.
- ◆ Be aware of the use of, and special considerations for, vulnerable populations (i.e. minors, students, people with cognitive impairments, prisoners).

#### 5. ***Informed Consent will be Sought and Properly Documented from Either the Subject or The Subject's Legally Authorized Representative***

Basic elements of informed consent are listed on the *Consent Form Creation Guide* on the GW IRB website.

- ◆ **Informed Consent = Comprehension + Active Agreement to Participate**  
Consent must be sought under conditions that allow the subjects to learn as much as possible about the research, and to make a decision for themselves about whether or not to participate.
- ◆ Conditions should minimize undue influence, and either verbal or written assent should be obtained from minors, as well as parental permission.
- ◆ Language in the consent form should be understandable to the subject or the subject's representative. This means that consent forms should, in general, be written in eighth grade language, and should not use scientific terms.
- ◆ Consent forms may not contain any exculpatory language through which a subject waives, or appears to waive, any of his/her rights, or which release the investigator or GW of any liability
- ◆ **Waiver or Alteration of Informed Consent**  
The IRB may decide that the basic elements of consent, and consent itself, can be waived if appropriate. Waiving of some or of the elements of consent may be appropriate if,
  - The study involves no more than minimal risk to the subjects
  - A waiver or alteration of the consent process will not adversely affect the rights and welfare of the subject
  - The research could not practicably be carried out without the waiver or alteration
  - Whenever appropriate, subjects will be provided with pertinent information after participation

Waivers of some or all of the elements of consent are appropriate for a variety of social and behavioral studies, but *must be adequately justified* by the investigator. For example, obtaining informed consent may not be appropriate for studies using previously collected data, if the data was collected a long time ago and contact information for the subjects is no longer available. The IRB must approve any requests for consent waivers.

#### *Alteration of Some Elements of Consent: Studies Involving Deception/Incomplete Disclosure*

Studies that involve deception may not give subjects a complete description of study procedures in the consent form. This would be considered an alteration of some of the elements of the informed consent. If this occurs, the researcher should hand out an "information sheet" (debrief document) about the true purpose of the study after data has been collected. Subjects would then have the option of destroying their data afterwards, if they decide they don't wish to participate.

◆ **Waiver of Documentation of Consent**

The IRB may decide that written documentation of consent (a.k.a. a signature on a consent form) can also be waived, if appropriate. Usually in these instances, verbal consent is obtained, provided the IRB approves a “script” used to obtain consent that has the same elements of a consent form.

A signature on consent may be waived if;

- The only record linking the subject to the research would be the consent document, and the principal risk is a breach in confidentiality. Each subject will be asked if s/he wants documentation linking her/him with the research, and the subject’s wishes will govern.
- The study presents no more than minimal risk to subjects, and involves no procedures for which written consent is required outside of the research context.

Telephone or online survey studies may qualify for a waiver of consent documentation, since there will be no physical interaction between the investigator and subject. The IRB must approve all requests for waiver of consent documentation.

- ◆ Studies involving subjects that do not speak or read English should have appropriate provisions for obtaining consent. Appropriate provisions are either: a witnessed translator reads the consent form for the subject, followed by a short form signed by the subject and witness, or for non-English speaking subjects, a verified, translated consent form should be used.

GW Office of Human Research Institutional Review Board  
www.humanresearch.gwu.edu  
Phone: 202-994-2715  
Email: [ohrib@gwu.edu](mailto:ohrib@gwu.edu)