Surveys and IRBs
What You Don't Know Can Hurt You

Enid Karr
Science Librarian
Clark University
IRB.... What's an IRB...?

- Institutional Review Board
- Review research proposals to insure protection from:
  - Harm - Including psychological
  - Violation of privacy or dignity
- Research on human subjects only
- Required for Universities with gov’t funding for research
A Little History

- What led to formation of IRBs
  - Lack of oversight
  - Tuskegee experiment etc.

- Research Act of 1974
  - Biomedical only

- After 1981
  - Any research on human subjects
But Igor, I Don't Experiment on Human Subjects!

Photo credit "Scott Beale / Laughing Squid"
Oh, I **DO** Experiment on Human Subjects

---

**Home Delivery Satisfaction Survey**

Thank you for participating in WorldCat Direct, a pilot program being tested by your library. Your feedback on this pilot program is critical. Please take a few minutes to complete this questionnaire and return it in the prepaid postage envelope. If you have already completed a survey with respect to the home delivery of library materials, we encourage you to complete it again based on your experience with each delivery. Or, if you prefer, you may fill out the survey online at: www.surveymonkey.com/worldcatdirect

Please rate your level of satisfaction with the following on a scale from 1 to 5, where 1 = Very Satisfied and 5 = Very Dissatisfied. (Circle one rating for each of the following.)

<table>
<thead>
<tr>
<th></th>
<th>Very Satisfied</th>
<th>Very Dissatisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall home delivery service</td>
<td>1 2 3</td>
<td>4 5</td>
</tr>
<tr>
<td>Speed of the delivery of materials</td>
<td>1 2 3</td>
<td>4 5</td>
</tr>
<tr>
<td>Options for returning the materials</td>
<td>1 2 3</td>
<td>4 5</td>
</tr>
</tbody>
</table>

Please provide comments, if any, about the above ratings.

---

Photo credit: Jen-the-Librarian
IRBs and Your Institution

- IRB is required, but they have a lot of discretion at each institution
- Do they publicize?
- How to find out
  - By accident - NOT recommended!
  - Search web site
  - Talk to other who have undertaken "research"
IRBs.... The Board

Who is on the IRB
- At least 5 members
- At least one non-university member
- Scientists and non-scientists
- Men and women
- You could be on the IRB....
Things to keep in mind

- Get started with the IRB before you send out survey
  - Leave sufficient time!
- Anonymize if possible
  - Other speakers will mention some great ways to do this online
- Don’t forget consent
IRBs… The Process

- Devise your study
- Take (online) Human Subjects Training Course if required by your institution
- Submit your forms
- Review
- Outcome
  - Approval
  - Ask for revisions
  - Denial
    - Appeals
Levels of IRB Review

- Exempt
- Expedited
- Full
About “Exempt” Status

- Anonymized Library surveys often qualify
- *Still* requires submitting forms
“Exempt research is free from continued oversight by the IRB although the institution (either a designated IRB representative, the entire committee, or some other institutional authority), not the researcher, must determine that the project is exempt in the first place. Usually this is accomplished through a brief review process. “

Possible Shortcuts

- May Work at Some Institutions
  - “Blanket” Approval for Library Surveys
  - Casual discussion with IRB
Sample Forms for IRB Exempt Status
Please fill out the following form. You cannot save data typed into this form. Please print your completed form if you would like a copy for your records.

PLEASE FORWARD ORIGINAL COPY TO THE GRANTS OFFICE
IRB Form B-1
Bryn Mawr College Institutional Review Board for Protection of Human Subject:
Research Review Status: Self-Report

Project Title: ____________________________ New _________ Renewal ________
Anticipated Dates for Data Collection: Start: _________ End: ____________
Primary Investigator: ____________________________
Address: ______________________________________
E-Mail: __________________ Phone: ________________
PI Status: BMC Faculty BMC Staff BMC Student
Haverford Student Swarthmore Student Other
If Other, please explain: __________________________
Name of external funding agency (if any) and proposal title (if different from above): ______________
Review Status (to be completed by the Primary Investigator):
In my judgment, the above named research project (check one and attach all required supporting
documents; see Instructions):
Is exempt from expedited or full Committee review ______
Qualifies for expedited committee review ______
Requires full Committee review ______
I certify that the statements herein are accurate and complete. I agree to protect the rights and welfare of
the human subjects participating in my research, to abide by College guidelines for securing informed
consent, to safeguard the confidentiality of my research data, and to inform the chair of the IRB should
any changes in the research protocol or human subject issues arise during the course of this research.

(Signature of Primary Investigator) ____________________ (Date) ______________
Sponsor (Students/Others must have qualified BMC Faculty/Staff Sponsorship):
BMC Faculty/Staff Sponsor: ____________________________
Campus Address: ____________________________ E-Mail: __________________ Phone: ____________
I have reviewed this application and will oversee this research in its entirety.

[Signature]

http://www.brynmawr.edu/grants/FormB1.pdf
Please fill out the following form. You cannot save data typed into this form.
Please print your completed form if you would like a copy for your records.

PLEASE FORWARD ORIGINAL COPY TO THE GRANTS OFFICE

Principal Investigator: ______________________________
Name of Project: ______________________________
Date received by departmental reviewer: ______________
Date received by Grants Office: ______________

IRB Form B-2
Checklist for Research Qualifying as Exempt from IRB
Review and Guidelines for Proposal Preparation

DIRECTIONS: Submit this form to the Departmental Reviewer if you believe that your project qualifies for exempt review. Please check all applicable items in Parts A and B and provide all relevant information in Part C. Research activities will only be considered for exemption from further review when all items in Part A and at least one item in Part B applies.

Part A:
☐ The research does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.
☐ The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.
☐ The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
☐ The research does not involve subjects under the age of 18 (except as they are participating in projects that fall under categories 1, 2, 3, and 4 in Part B). Category B2 studies that include minors should be submitted for expedited review.
☐ The research does not involve deception.
☐ The procedures of this research are generally free of foreseeable risk to the subject.

Part B (Check all categories that apply to your research project):

1. ☐ The research will be conducted in an established or commonly accepted educational setting and will involve normal educational practices (e.g., research in regular and special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).
2. ☐ The research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of aptitude/behavior. Information will be recorded anonymously (i.e., so that the human subject cannot be identified, directly or through identifiers linked to the subject). [NB: Survey/interview/observational research in which deceased or appointed public officials or candidates for public office serve as subjects is exempt whether or not data collection is anonymous].
3. ☐ The research will involve the collection of data, documents, records, pathological specimens, or diagnostic specimens. These sources are either publicly available or the information will be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).
4. ☐ The research (including demonstration projects) will be conducted by or subject to the approval of federal department or agency heads, and is designed to study, evaluate, or otherwise examine:
   (i) Public benefit or service programs (e.g., social security, welfare, etc.);
Please fill out the following form. You cannot save data typed into this form.
Please print your completed form if you would like a copy for your records.
Please fill out the following form. You cannot save data typed into this form. Please print your completed form if you would like a copy for your records.

5. Indicate any benefits that are expected to accrue to subjects as a result of their participation in the research. In the event that subjects will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research.

6. Describe any relationship between researcher and subjects, such as mentor/student, supervisor/student/principal/teacher, employer/employee. If such a relationship exists, how will it affect the subject’s ability to participate voluntarily and how will the principal/investigator handle it?

July 2001
More Sample Forms for IRB
PROJECT REVIEW COVERSHEET

Statement by Principal Investigator

INSTRUCTIONS: This form must be signed if there is not sufficient space to answer questions. Please attach additional pages. Please use the TAB key to move from one block of text to another. This text check should not be filled in with underscores.

Investigator Name: ____________________________
Investigator Program: __________________________
Investigator Position: __________________________
Investigator Address: __________________________

Signature: ____________________________
Date: ____________________________

Study Name: ____________________________
Study Type: ____________________________
Study Purpose: ____________________________

Research Project Title: ____________________________

Brief Description: ____________________________

Is this project being reviewed by any other institutional review board? Yes ☐ No ☐
If yes, please provide name and location of institution.

Institutional Review Board: ____________________________
Institution Name: ____________________________
Institution Location: ____________________________

Institutional Review Board: ____________________________
Institution Name: ____________________________
Institution Location: ____________________________

Institutional Review Board: ____________________________
Institution Name: ____________________________
Institution Location: ____________________________

1. a. Please indicate with ✓ if your project involves any of the following populations:

   - Children 0-17 years of age
   - Individuals with a physical or mental disability
   - Individuals with a cognitive impairment
   - Individuals with a psychiatric condition
   - Individuals with HIV/AIDS or other communicable disease
   - Individuals with a history of substance abuse
   - Individuals with a history of sexual behavior
   - Other populations (please specify):

   b. Please indicate if your project involves any of the following populations:

   - Individuals with a head injury
   - Individuals with a spinal cord injury
   - Individuals with a learning disability
   - Individuals with a genetic disorder
   - Individuals with a mental health disorder
   - Individuals with a substance abuse disorder
   - Individuals with a history of sexual behavior
   - Other populations (please specify):

   c. Please indicate if your project involves any of the following populations:

   - Individuals with a head injury
   - Individuals with a spinal cord injury
   - Individuals with a learning disability
   - Individuals with a genetic disorder
   - Individuals with a mental health disorder
   - Individuals with a substance abuse disorder
   - Individuals with a history of sexual behavior
   - Other populations (please specify):

NOTE: If you have checked any of the above listed categories and your research study involves a least minimal risk, the proposal must include a review.
2. If you will be utilizing outside agencies to conduct your research have you appended the appropriate permissions letters to these agencies? If not, please append these letters to the consent form with your research.

3. Will you be recording any identifiable private information about an individual subject? YES NO

If you have answered YES to Item 3 please read and sign the statement below:

I understand that I am obligated to protect and keep confidential any identifiable private information gathered about individual subjects through the conduct of my research, and I agree to keep such information confidential. I understand that it is an expectation of my participation in the research project that the information will be destroyed upon completion of the research project.

Signed

4. Will you be asking volunteers or volunteers in your research? YES NO

If you answered YES to Question 4, please provide a detailed description of what you are doing and why.

Also, what will be the disposition of the recorded tapes after completion of your research? These tapes must be destroyed by the researcher within one year of the completion of the research project. You will also need to inform the subject of your intent to record your audiotapes and/or videotapes, by including this information on the Informed Consent Form.

5. If your research involves any recognizable risk, do you personally, or if your subject includes any of these, if identified in Item 10, or any similar vulnerable group, then you have given informed written consent from your subjects and/or a legally responsible guardian or child and were exposed to any foreseeable or significant risk of any physical, psychological, or emotional harm.

6. When you have completed your contact with the research participant, will there be a follow-up session? YES NO

If your answer is YES please describe the procedure that you will follow.

ATTACHMENTS: If you will be asking questions following research, or manipulating the subject, please append copies of questionnaires, tests, interviews, protocols, or the materials that are your grant or project. If you have not yet to ask the next procedure, you will require them. Provide specific examples of the type of forms, treatments, or questions you will ask.
2. If you will be utilizing outside agencies to conduct your research have you obtained the appropriate permissions from the agency to be able to complete your research with your research? [YES] [NO]

3. Will you be recording any identifiable private information about individual subjects? [YES] [NO] 

   IF YOU HAVE ANSWERED YES TO ITEM 3 PLEASE READ AND SIGN THE STATEMENT BELOW: 

   I understand that I am obligated to protect and keep confidential any identifiable, private information gathered about individual subjects through the conduct of my research and I agree to keep such information confidential. [Signed]

   Signed

4. Will you be asking identifiers or identifiers in your research? [YES] [NO] 

   If the answer to Question 4 is YES, please provide a detailed description of what you are doing and why. Also, what will be the disposition of the recorded data after completion of your research? These data must be destroyed four (4) business days to a maximum of three (3) years from the completion of the research project. You will also need to inform the subject of your intent to record your subjects and/or identifiers, by including the following statement in the informed consent form:

   [Blank]

5. If your research involves any removable risk or discomfort to subjects, or if any subject is included any of the groups identified in item 7, or any similarly vulnerable group, then you must obtain informed written consent from your subject and/or a legally responsible guardian (the subject and/or legally responsible guardian of a developmentally disabled research subject). If the answer is applicable you must attach a signed and dated informed consent form that you will adapt? [YES] [NO]

6. When you have completed your contact with the research participant, will there be a debriefing session? [YES] [NO] If your answer is YES, please describe the procedure that you will use.

   [Blank]

ATTACHMENTS: If you will be asking questions, testing performance, or manipulating the subjects, please append copies of questionnaires, tests, interview protocols, or the manuals similar to your grant proposal. If you have not to this procedure you will be sent. This provides specific examples of the types of test items, forms, protocols, or agreements you will use.
Working With the IRB

- Be proactive
- Be polite
  - If you are thinking "this is ludicrous" - now is not the time to voice that!
- Work towards a more reasonable view of the role of library surveys as research
For More Information

- [http://www.hhs.gov/ohrp/](http://www.hhs.gov/ohrp/)
Photo and Screenshot permissions

Thanks to

Dr. Nona Smith, Office of Sponsored Research, Bryn Mawr College
Valerie Beaudrault, Office of Sponsored Programs, Simmons College
For permission to use screenshots of their IRB documents

Frankenstein photo

“This photo is licensed under a Creative Commons license. If you use this photo, please list the photo credit as "Scott Beale / Laughing Squid" and link the credit to laughingsquid.com.”

Survey Photo

Under Creative Commons License, visit http://creativecommons.org/licenses/by-nc-sa/2.0/deed.en-us for reuse terms