

HUMAN SUBJECTS REVIEW for SENIOR RESEARCH PROJECTS in WOMEN'S STUDIES Barnard College / October 2004

If the project you are undertaking for your senior thesis involves human subjects you should review the Human Subjects Research guidelines set out on the Barnard website:

<http://www.barnard.edu/grants/humansubjects.html>

We recommend that you should work through the tutorials offered on the Columbia Institutional Review website, RASCAL (see: the "Testing Center," under Compliance/Human Subjects; also useful is the page offering "Helpful IRB Information"): <https://www.rascal.columbia.edu/>

The following guidelines are excerpted from these webpages.

Does your project require IRB/human subjects review?

The section "Students as Researchers" on the RASCAL website specifies that:

Research...conducted by graduate and undergraduate students...is subject to federal regulations which require that all research protocols involving human subjects be reviewed by an Institutional Review Board for the protection of Human Subjects in Research (IRB). However, these regulations allow certain types of course-related studies to be conducted without IRB review.

The one exception to the requirement for human subjects review is research conducted as a "classroom exercise" (e.g., in the context of a research or clinical practicum): "course-related research or evaluation projects and/or directed studies that are designed to provide students an opportunity to practice various research methods." Student research constitutes a "classroom exercise" in this sense if:

- it is limited in scope; it does not lead to generalizable knowledge and is not undertaken with this goal in mind;
- it does not put subjects at more than minimal risk (e.g., data should be recorded anonymously, and is not used in such a way that subjects can be linked to the data collected).

In such cases the instructor is ultimately responsible for the protection of subjects. However, IRB/human subjects review may be required for the course itself: "if it involves training in research methods and class assignments that require research with human subjects, even if the class exercise does not seem to qualify as 'true research'" (e.g., when the results are not intended for publication, will not advance work in another area, or will not contribute to generalizable knowledge).

The bottom line: "any research conducted by students, graduate or undergraduate, that does not fall under the definition of a research or clinical practicum, which uses human subjects, and which is intended to contribute to generalizable knowledge, must be reviewed and approved by the IRB. This includes, but is not limited to, all independent undergraduate research projects and honors theses, masters' theses, and dissertations."

What do you do if your project needs IRB/human subjects review?

1. Determine whether your project meets the requirements for **exempt** status (see below), or will require **expedited** or **full IRB review**.
2. If your project meets the requirements for **exempt status**, develop a protocol describing your project and documenting this status following the guidelines that follow. Submit this protocol to your instructor who will arrange for human subjects review. Your instructor will convene a review committee of two Women's Studies faculty who are not involved in supervising or advising on your project. This committee will assess your protocol following standard guidelines for IRB review (they function as a proxy for the Barnard IRB). When your project is approved you will receive a letter documenting this, and your protocol will be kept on file in Women's Studies for two years.
3. If your project requires **expedited** or **full IRB review**, follow the guidelines set out on the Barnard webpage for Human Subjects Review: <http://www.barnard.edu/grants/humansubjects.html>.

EXEMPT DECLARATION

excerpted from the RASCAL IRB guidelines: <https://www.rascal.columbia.edu/>

Your study will not require expedited or full Institutional Review Board review if it meets the criteria that define “exempt” status, as specified by federal regulations. You will be required, however, to document the exempt status of your project; you must submit a research protocol in which you explain how your study meets the criteria associated with one of the following **categories of exempt research**:

Educational Practices Research

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Educational Testing Research

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

Survey or Observational Research

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not otherwise exempt as “educational testing research” if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) the confidentiality of personally identifiable information will be maintained throughout the research and thereafter (this federal statutes require the confidentiality be maintained without exception).

Research on Existing Data

Research involving the collection or study of existing data, documents, records, or specimens, if these sources are publicly available or the information is recorded by the researcher in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

Public Benefit Research

Research and demonstration projects, which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

NOTE: Research is not exempt if it involves deception or subjects drawn from the following populations:

- prisoners; fetuses; pregnant women; human in vitro fertilization;
- students, if the investigator is their instructor;
- university employees, if the investigator is their supervisor;
- children involved in Educational Testing Research, unless the research involves observations of public behavior and the researcher does not participate in the activities observed;
- other vulnerable populations (i.e., those likely to be vulnerable to coercion or undue influence), such as mentally disable persons or, economically or educationally disadvantaged persons.

COMPONENTS of a RESEARCH PROTOCOL

based on the RASCAL guidelines for developing a protocol: <https://www.rascal.columbia.edu>

These are the key components of a research protocol that documents the exempt status of your project.

Cover Page / General Information

- Title of Project / Principal Investigator / Affiliation and contact information
- Dates of the project (when it will begin and end)
- Types of research procedures to be used: e.g.: analysis of existing data; interview/survey/questionnaire; observation of public behavior
- Types of research facilities to be used: e.g.: on-campus school or department; other university; elementary/secondary school; off campus institution
- Statement of IRB category that fits your study: Exempt / Expeditable / Full review

Personnel

Specify who will be involved in the research project (the research team) and who will have access to information from or about your research subjects.

Research Description

If you are unsure what to include in any of these components of your research description, check the RASCAL website (especially useful are the ‘help’ options available on the ‘protocol builder’ and ‘consent builder’ pages).

Abstract: give a brief plain language description of the purposes and nature of the research project

Study Purpose and Rationale: outline in more detail what you hope to learn from the project, to include pertinent background and references that explain the need to do this study.

Study Design and Procedures: describe the research methodology/procedures you will use in terms that will be accessible to a reviewer not familiar with the field (so they can assess potential risks and benefits). Include a description of questionnaires or interview schedules you will use in your project and attach samples of these instruments to your protocol.

Study Subjects: identify the composition of your study population, the number of subjects who will be involved, and how they will be recruited.

Confidentiality: describe how confidentiality will be maintained (if it is to be maintained).

Potential Risks: describe any risks that might arise, including risks encountered in past studies.

Potential Benefits: describe potential benefits; as with risks, explain why they are expected given current knowledge and past experience.

Location

Indicate where the research will take place (there is no limit on the number of locations specified).

Investigational Product

Describe the form that the results of your study will take, including any reports or presentations that will be made available to subjects or to the general public.

Consent Form

If you will be using a consent form, attach it; if not, explain why.

Exempt Declaration

Indicate which category of exempt research your project fits: Educational Practices; Educational Testing; Survey or Observational Research; Research on Existing Data (see the requirements for exempt status outlined above).

CONSENT FORM

If a consent form is appropriate for your project, it should include the following elements. Consider writing this as a letter addressed to those you will be asking to participate in your project.

Identify your project: Principal Investigator
Protocol Title
Dates of project
Number of subjects involved / anticipated duration

Contact Information: specify how research subjects (and others) can contact you and/or who can answer questions about the nature of the project.

Information on Research: provide a brief, plain language description of the purposes of your research project; explain why the subject is being asked to participate; specify what procedures will be involved, and the expected duration of the subject's participation.

Risks: describe any foreseeable risks of discomfort, inconvenience, or other potential or known burdens. (For a full list of areas of potential risk see the RASCAL guidelines. They include, for example, breach of confidentiality; conflicts of interest; emotional distress; exposure to litigation, or risk of damage to economic or social status, reputation or employability).

Benefits: a simple, non-exculpatory description of any benefits that might arise from participation in the study, direct or indirect. (For sample statements see RASCAL, "Consent Builder.")

Confidentiality: describe the extent to which, and the means by which, personally identifiable information will be held in confidence. (For sample statements see RASCAL, "Consent Builder.")

Voluntary Participation: make it clear that participation in your research project is strictly voluntary: subjects are free to refuse to participate altogether, if they do participate they may choose not to participate in all aspects of the project; and they are free to withdraw at any time.

Statement of Consent: include at the end of your consent form a statement that the subject can sign, if they agree to participate, indicating that they understand the nature and purposes of the study and freely consent to participate. (For sample statements, see RASCAL, "Consent Builder.")