

Haverford College
INSTITUTIONAL REVIEW BOARD (IRB) FOR HUMAN SUBJECTS RESEARCH
PROPOSAL APPLICATION FORM (form rev. Oct. 2007)

Review Requested: Expedited <input type="checkbox"/> Full <input type="checkbox"/> Date of Request	Review Assigned: Expedited <input type="checkbox"/> Full <input type="checkbox"/> Proposer is (check one): Faculty <input type="checkbox"/> Staff <input type="checkbox"/>
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Part I. RESEARCH AND INVESTIGATOR INFORMATION

PROPOSER (FACULTY/STAFF INVESTIGATOR OR SPONSOR)

Name: _____ Department: _____
 Tel. _____ e-mail: _____

STUDENT or CO-INVESTIGATORS

Names, and if other than Haverford College students, affiliations and contact information:

TRAINING IN RESPONSIBLE HUMAN SUBJECT RESEARCH

Name of Investigators (for students, please include graduation class)	Senior Thesis Project for this investigator?		Description and approximate date of training in responsible conduct of research with human subjects (for example: "Hum. part. prot. course at cme.nci.nih.gov , 5/2005")
	Yes	No	
PROPOSER (named above)	---	---	
	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	
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	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	

Project Title:

Grant Title if different from Project Title:

Project start date: _____ **Anticipated end date:** _____

Note: IRB approval is always for one year (or less). If you need more time, you will need to submit a request for continuation of approval.

Is this research funded by (or an application to) an external funding agency? Yes No

If yes, complete the following:

Funding Source:

Date of Award (or proposed date):

Study Location:

If another IRB reviews this proposal, a copy of that IRB's letter of approval must be provided with this application or submitted to the IRB as soon as it becomes available.

HUMAN SUBJECT INFORMATION

Number of subjects expected to participate:

Briefly describe any foreseeable risks or discomforts and discuss attempts to minimize such risk to subjects:

How and where will recruitment of subjects take place?

Does the project preserve subject confidentiality? Yes: No:
Describe procedures used to maintain confidentiality of responses:

Are data analysis and storage anonymous? Yes: No:
Describe procedures used to protect anonymity of data:

Are any vulnerable populations to be recruited for this project? (Check all that apply.)
 Children Prisoners Pregnant Women Elderly others
If "others", please explain:

How will subjects be compensated?

Will informed consent be obtained? Yes: No:

Is Investigator requesting waiver of documentation of informed consent? Yes: No:
If yes, explain:

Is Investigator requesting waiver of any of the elements of informed consent (please fill in check list on following page) Yes: No:

- If yes, check appropriate boxes for waiver requested
- (#4) Because this investigation does not involve treatment, there are no "alternative procdures or courses of treatments" to disclose.
- (#6) This proposal does NOT involve more than minimal risk, so basic element #6 (see next page) does not apply.
- (#7, second half) Because there is no conceivable chance of a research-related injury, a waiver is requested from the requirement that the consent form specify a contact person "in the event of a research-related injury"
- Other waiver requested (explained below). Federal regulations allow such waivers only when there is no more than minimal risk AND the research would be negatively impacted if carried out without such a waiver
Explain and justify:

Is Investigator requesting authorization for use and disclosure of Protected Health Information (PHI) Yes: No:

If yes, is Investigator requesting waiver of authorization for use and disclosure of PHI? Yes: No:

CONSENT FORM CHECKLIST

Check boxes on the left to certify that each element of informed consent is contained in the consent form (or oral consent briefing, if a waiver of documentation is requested). The text in the right column (except that in brackets) comes directly from the federal regulations (45CFR46.116(a) and (b)). **If you do not check all boxes in section a (basic elements), you must request (on page 2) a waiver of informed consent element.**

(a) Basic elements of informed consent. (Please check items that are provided.)

<input type="checkbox"/>	(1) A statement that the study involves research,
<input type="checkbox"/>	an explanation of the purposes of the research and
<input type="checkbox"/>	the expected duration of the subject's participation,
<input type="checkbox"/>	a description of the procedures to be followed, and
<input type="checkbox"/>	identification of any procedures which are experimental;
<input type="checkbox"/>	(2) A description of any reasonably foreseeable risks or discomforts to the subject;
<input type="checkbox"/>	(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
<input type="checkbox"/> *	(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
<input type="checkbox"/>	(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
<input type="checkbox"/> *	(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
<input type="checkbox"/>	(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, [Suggested text: <i>If you have further questions about the research or your rights as a research participant, please contact (your name and contact information). You may also address any concerns to _____, chairperson of Haverford College's IRB (a committee with oversight over human subject research).</i>]
<input type="checkbox"/> *	and whom to contact in the event of a research-related injury to the subject; and
<input type="checkbox"/>	(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject. (Please check items that are provided.)

<input type="checkbox"/>	(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
<input type="checkbox"/>	(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
<input type="checkbox"/>	(3) Any additional costs to the subject that may result from participation in the research;
<input type="checkbox"/>	(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
<input type="checkbox"/>	(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and...
<input type="checkbox"/>	(6) The approximate number of subjects involved in the study.

* - If any of these boxes are left unchecked, please check the appropriate box on page 2 to request a waiver.

Part II. DESCRIPTION OF PROJECT: Briefly describe the project (in language understandable to the lay reader) and the procedures to be used in the research. Indicate whether any of these procedures have been approved by Haverford College's IRB in the past. If the project is being carried out in the context of a course, briefly describe the educational objective of the research exercise. Attach any questionnaires, consent forms or other relevant materials used in the study to this application form.

1. PROBLEM ABSTRACT: Briefly state the rationale and research questions.

2. RESEARCH DESIGN and METHODS: Describe procedures to be used in the current study.

3. HUMAN SUBJECT SELECTION CRITERIA AND EXCLUSIONS. Please describe how human subjects will be recruited and selected for this study. Indicate if you will be applying selection criteria in choosing or advertising for participants, and justify any exclusions of sub-groups. For instance, if you will be selecting only right-handed women, this should be stated and justified. **THIS IS A NEW AND REQUIRED SECTION – ADDED OCTOBER 2007.**

Part III. ASSURANCES

List all collaborating agencies.

If the research involves a cooperating agency, institution, school district, etc., a letter of agreement to participate in the research (on letterhead) is required. If the cooperating agency has an IRB, a copy of that agency's IRB approval is required

List all independent investigators.

Researchers collaborating with independent investigators that are not employees of this Institution or of another institution with a Federalwide Assurance (FWA) must sign a formal written agreement of commitment to follow the human subject protection policies of this Institution.

**Haverford College
ASSURANCE STATEMENT**

I CERTIFY as follows concerning the above named research proposal

The rights and welfare of the subjects will be adequately protected.

Risks or discomfort (if any) to subject(s) have been clearly indicated and it has been shown how they are outweighed by potential benefits to the subject or by the importance of the knowledge to be gained.

The informed consent of subjects will be obtained by appropriate methods that meet the requirements of the College's general assurance procedures.

Any proposed changes in research activity that would introduce additional risk will be reported to the IRB. Those changes may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazard to the subjects.

Any unanticipated problems involving risks to human subjects or others will be reported to the IRB immediately.

Signature: _____ date: _____
Faculty/Staff Investigator or Sponsor

Signature: _____ date: _____
Co-investigator (if applicable)

Signature: _____ date: _____
Student Investigator