

Instructions: Print out and complete this form. Submit it and all necessary attachments to Dean Jacks by campus mail or to his office in 218 Science Center. Email questions to jacks@hanover.edu

Notes: Attachments to this form should include a reference to the item they address (e.g., II.A.2). Although the guidelines below can be used to classify research as exempt from review or qualifying for expedited review, the IRB reserves the right to reclassify research if, in its evaluation, the research requires more stringent review.

I. DESCRIPTION OF THE RESEARCH. In a separate document, answer the following questions.

- A. Provide the following information for each of the researchers: First name, middle initial, last name, email address
- B. If the researchers are all students, provide the name, email address, and department of the faculty sponsor.
- C. Expected start and end dates of data collection
- D. Title of research project
- E. Describe the purpose of your research and your procedures and measures in lay terms. What will the typical participant in your project experience or, if your study involves naturalistic observation or archival research, how and where will you collect data? How much time will be required of each participant? Be as brief as possible, but provide enough information for a non-specialist to understand your research.
- F. What is the expected size of your sample, and how will you recruit people to be in your study (e.g., ask friends, post signup sheet, students will receive extra credit in classes)?
- G. Attach copies of the following, or justifications for their omission from your procedure:
 - 1. Informed consent form (see federal guidelines at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>)
 - 2. Surveys or questionnaires that participants will receive
 - 3. Any stimulus materials to be presented to participants (video clips, images, text passages, etc.). If these are available on a website, you can include the web address of that website.
 - 4. Any recruitment letters or advertisements to be used
 - 5. Written debriefing form, or debriefing script

II. DETERMINATION OF “EXEMPT FROM REVIEW”

Your research may qualify as EXEMPT FROM REVIEW, in which case your application will be evaluated by only one member of the Institutional Review Board to confirm that it qualifies as exempt. You may not begin your research until you receive this confirmation.

- A. Please circle Y or N to whether your study involves any of the following. If your answer to any of these questions is yes, your study cannot be exempt from review. *For each question to which you answer “yes”, you should attach an explanation of how your study meets the criterion and the steps you will take to protect participants.*

Y	N	1. More than minimal risk (Does the study involve a risk of harm or discomfort that is beyond what is encountered in daily life or during the performance of routine physical or psychological tests?)
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Y	N	2. Deception (Will you be deliberately misleading participants about the topic of your study or about the procedures they will be performing? This includes the use of actors posing as participants.)
Y	N	3. Sensitive questions (Questions are considered <i>sensitive</i> if participants are likely to feel some discomfort in disclosing the information in a face-to-face setting. Example topics include criminal actions, disease or disorders, sexual behavior, or racism.)
Y	N	4. Objectionable material (Will participants be exposed to material that they might find offensive, threatening, or degrading, such as pornography, intense scenes of violence or horror, or racist statements?)
Y	N	5. Private information (Are you collecting <i>personally identifiable</i> information in a context where participants can reasonably expect no observation to take place? Has the information you are collecting been provided with the expectation that it will not be made public, such as with a medical record, and is it also personally identifiable?)
Y	N	6. Vulnerable populations (Are you studying groups for which informed consent is unclear or for whom special protection is required, such as <u>children under age 18</u> , <u>prisoners</u> , <u>pregnant women</u> , <u>mentally disabled persons</u> , or <u>economically or educationally disadvantaged persons</u> ?) If Yes, please describe any special steps you are taking to protect the rights and welfare of your subjects.

B. Please answer Y or N to each of the following questions. If your answer to all of the questions above in part I.A. was “no” and your answer to any of the questions below is “yes,” then your research should qualify as exempt from review.

Y	N	1. Is your research on educational practices (e.g., the effectiveness of a new curriculum) AND conducted in normal educational settings (e.g., a 3rd-grade classroom)?	
Y	N	2. Circle “Y” if BOTH of the following are also answered “Y”	
	Y	N	a. Involves educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, educational tests, OR observations of public behavior.
	Y	N	b. Records of participants’ responses are EITHER anonymous (they cannot be connected to participants’ identities) OR maintained in confidentiality and of only minimal risk to a participant’s reputation, liability to prosecution, employability, financial standing, or insurability.
Y	N	3. Is your research on elected or appointed public officials or candidates for public office?	
Y	N	4. Does your research involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens that are EITHER publicly available OR anonymous?	
Y	N	5. Does your research evaluate federal public benefit or service programs?	
Y	N	6. Is your research on the evaluation of food quality AND involves the consumption of food that is EITHER wholesome and without additives OR contains additives or contaminants below the level found to be safe by the relevant federal agency?	

C. Based on the criteria in II.A. and II.B., is your study exempt from review?

_____ Yes. Proceed to section IV.

_____ No. Proceed to section III.

III. DETERMINATION OF “EXPEDITED” REVIEW

Some research may be eligible for a faster review by a subset of the Institutional Review Board. These categories are described in further detail online:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.110>

- A. **Factors excluding research from consideration for expedited review.** If your answer to any of the following questions is “Yes”, your study is not eligible for expedited review and must be reviewed by the full Institutional Review Board.

Y	N	1. Does the study involve a <u>risk of harm or discomfort</u> that is beyond what is encountered in daily life or during the performance of routine physical or psychological tests? If yes, your study is not eligible for expedited review and you should proceed to section III.
Y	N	2. Will the responses you collect be <u>identifiable to particular subjects</u> AND of <u>more</u> than minimal risk to the subjects’ reputation, liability to prosecution, employability, financial standing, or insurability)? If yes, your study is not eligible for expedited review and you should proceed to section IV.

- B. **Categories of research eligible for expedited review.** Only certain categories of research may be approved for expedited review.

Y	N	1. Is your research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior)?	
Y	N	2. Does your research employ survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies?	
Y	N	3. Does the study involve drugs or medical devices? If yes, complete the form “Research involving drugs or medical devices” and attach it to this application.	
Y	N	4. Does your study involve the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture? If yes, please answer a, b, and c below.	
	Y	N	a. Will all of your participants be healthy, nonpregnant adults who weigh at least 110 pounds?
	Y	N	b. Will the amount drawn be less than 550 ml in an 8 week period and collected no more frequently than 2 times per week?
	Y	N	c. Has the person performing the collection met all state and federal training and licensing requirements for the type of blood collection he or she will perform?
Y	N	5. Will you be collecting biological specimens by <i>noninvasive</i> means? (e.g., hair or nail clippings, sweat, saliva, mucosal or skin cells collected by buccal scraping or swab, skin swab, mouth washings).	
Y	N	6. Will you be using documents, specimens, or other records of behavior that have already been collected, or will be collected, solely for nonresearch purposes (such as medical treatment or diagnosis)?	
Y	N	7. Will you be collecting data from voice, video, or image recordings made for research purposes?	

IV. RESEARCHER RESPONSIBILITIES

A. If you learn of any risks to subjects through their participation in your research, you are obligated to immediately:

1. inform the chair of the IRB
2. make any changes that are necessary to insure the safety of your subjects
3. cease all research activities unless such cessation would further endanger subjects (such as might be the case with research involving medication)

B. Any changes to your research procedures described in this document can be made ONLY AFTER THEY HAVE BEEN APPROVED BY THE IRB except when such changes are necessary to protect the safety of subjects.

Each researcher should sign and date in the space below, indicating that they accept personal responsibility for conducting the study in accordance with the above description.

Signatures of applicants

Date

For Student Projects:

As Faculty Sponsor, I certify that I have reviewed the application and approve it for submission. I further certify that the student is competent to perform the proposed research involving human subjects. I will oversee and take full responsibility for the conduct of the research.

Sponsor's name, typed

Faculty Sponsor's signature

Date