

Reed College
Human Subjects Research Committee (IRB)
Submission Form 2005-2006

NOTE: Please download to your computer and use Word to supply requested info.

COVER PAGE

Project Title:

Submission Date:

Name of Primary Investigator:

On-Campus Address:

Department:

Faculty Advisor (if applicable):



Signature of Faculty Advisor: (signature indicates that the proposal has been read and approved.)

Please indicate your agreement to the following stipulation:

I will promptly report changes in the proposed study and any unanticipated problems involving risks to participants, including adverse reactions, to the Human Subjects Research Committee.



Signature of Primary Investigator

If your submission is **similar to** a submission that has been approved previously (within the past two academic years, 2003-2005), please identify that proposal by Project Name and Primary Investigator.

A. BASIC PROTOCOL INFORMATION:

1. Is this study being performed at sites other than the Reed College campus?

YES NO

If YES, list other sites:

2. Is this study being funded by the federal government or by some other agency that requires certification of review by the Reed College HSRC?

YES NO

If YES, list funding information (including agency and protocol number) and append a copy of the funding application.

3. Does the research require approval from one or more non-Reed organization(s) or IRB(s)?

YES NO

If YES, does the other organization/IRB require review by Reed's HSRC (IRB)?

YES NO

Attach application to other organization and, if approval has been granted, documentation of the approval.

NOTE: If the study is not federally funded and will be run at an off-campus site, AND if the research has been approved by an appropriate off-campus IRB, STOP HERE. Submit only the Cover Page, this page of the application, and the approved application to the off-campus IRB.

4. Although the IRB ultimately determines which type of review your protocol will receive, please consult the guidelines in the document entitled "Categories of Review" and then check the category of review you believe applies.

Exempt

Expedited

Full

5. Please indicate whether the primary focus of your research will be on one or more of the following populations:

Children (individuals <18 years) **COMPLETE APPENDIX A**

Individuals who are or may be decisionally impaired

Prisoners

Individuals who live outside the US **COMPLETE APPENDIX B**

Non-English speakers **COMPLETE LANGUAGE SECTION, APPENDIX B**

Elected or appointed public officials or candidates for public office

B. SUMMARY (all categories of review, 3-5 sentences)

1. Provide a brief summary of the purpose of the research.

C. BACKGROUND (only if your proposal requires Full Review)

1. Provide a brief summary of prior, relevant research findings and the importance of the knowledge you expect to gain.

D. PARTICIPANTS (all categories of review)

1. Does your research involve only accessing an existing database(s)?
 YES NO

If **YES**, list the database(s) and then **SKIP TO** Section G, and fill out items 2-4.

2. Describe the participant population.

NOTE at D.2.: If your study involves only...

- the observation of public behavior of elected or appointed public officials or candidates for office
- research on normal educational practices in accepted educational settings, in which any presentation or publication of the data will not identify individual participants

...STOP HERE you do not need to submit the remaining pages of this form. (Note that some professional journals Do require IRB review of educational research.)

3. Identify all criteria for inclusion and exclusion of participants. Provide rationales where these may not be obvious.

a. Inclusion:

b. Exclusion:

4. Recruitment

NOTE at D.4.: If your study involves only the observation of public behavior, check here and **SKIP TO** Sections G and H.

- a. How will potential participants be identified?

NOTE at D.4.a.: Attach recruitment ads and/or letters if appropriate.

If it is not obvious from the recruitment ad or letter:

- b. How will potential participants be screened for inclusion and exclusion criteria?

- c. What will they be told about the purposes of the research before being asked for consent to participate?

E. PROCEDURES (all categories of review EXCEPT as indicated in Section D)

1. Provide the following information:
 - a. Expected duration of individual participation:
 - b. Study location(s):
 - c. Type or amount of compensation to participant, if any:
2. Provide a specific description of what each participant will be asked to experience or to do.

NOTES at E.2.:

- a. For studies structured by an experimental design, please specify the design as part of this description.

- b. Append all questionnaires and surveys, and include sample items from computerized tasks, unless these have been approved as a “research protocol” by the HSRC. Approved research protocols may be listed by name.

- c. For structured interviews, provide interview protocol. For unstructured interviews, describe the goals of the interview and any topics to be avoided.

F. RISK/BENEFIT ASSESSMENT (all categories of review EXCEPT as indicated in Section D)

1. Benefits

Describe the potential direct and indirect benefits, if any, to participants.

NOTE at F.1.: Incentives for participation should not be included here.

2. Risks

a. Indicate whether the research involves any of the following by checking in front of applicable items:

- Deception of participants
- Procedures that may result in mental or emotional stress, such as induction of negative mood, damage to self-esteem, manipulation of attitudes, exposure to aversive stimuli
- Procedures that may involve physical harm to participants, such as ingestion of any substance, physical exercise, invasive physiological measurements
- Presentation of materials and/or behaviors commonly regarded as socially unacceptable within the setting of the research
- Observations or questions that might be regarded as invading privacy, especially if these might lead to disclosure of information that could be harmful to participant (e.g., criminal behavior, immigration status, information that might affect academic or employment status, information that could affect the participant's reputation or be considered stigmatizing)

b. For each of the items checked above:

- i. Describe why each is necessary. If possible, provide at least one previous reference upon which your way(s) of proceeding is(are) based, indicating and justifying any changes you have made. Please do so using non-specialist terms, keeping in mind that the review committee is comprised of members from various disciplines.

ii. Describe how you will minimize each risk posed.

G. CONFIDENTIALITY ISSUES

1. Will you be audio/video taping or photographing participants?

- YES NO

If YES:

Provide a rationale for taping/photographing. Describe confidentiality procedures, including what will become of records after use (e.g. shown at scientific meetings, erased), the final disposition of the records (e.g. destruction, archiving), and a reasonable timeline for this disposition.

NOTE at G.1.: Be sure to include a specific section for permission to tape or photograph in the informed consent process. Where written consent is waived by the IRB, participants should be asked to confirm their consent as part of the recorded material.

2. Will you be collecting any obvious identifiers (names, social security numbers, detailed physical descriptions, genealogies, addresses, etc.?)

YES NO

3. Will you be collecting data that, when considered in light of the potential participant pool, could lead to the identification of an individual participant? Examples include autobiographical accounts or identifiable patterns of demographic information.

YES NO

If YES to either of these questions (2. or 3.):

- a. Specify to the extent possible what information will be collected and why.
- b. Specify the procedures for coding and/or storing the data so that confidentiality of individual participants' data is protected.

4. If data are identified by a code, will you retain a master list linking codes and direct identifiers? YES NO

If YES, explain why this is necessary, how and where you will secure the master list, and how long it will be kept.

5. Please provide the following information about confidentiality of data:

- a. Will information that could identify the participant be shared in any way?
 YES NO

If YES, explain.

- b. Describe your plan for presentation and/or publication, as well as data retention and future use of records.

H. INFORMED CONSENT (all categories of review EXCEPT as indicated in Section D)

1. Please note whether written informed consent will be sought from all participants.

Written informed consent will be sought from all participants.

Waiver of written informed consent is being requested. **COMPLETE APPENDIX C.**

NOTE: APPEND ALL WRITTEN CONSENT DOCUMENTS AND/OR ORAL CONSENT SCRIPTS.

2. Describe the context in which consent (either written or otherwise) will be sought, when consent will be sought, how often consent will be sought (if appropriate), as well as who will be responsible for seeking consent from participants.