

Departmental Institutional Review Procedures
Department of Sociology & Anthropology
Muhlenberg College

STEP ONE: Determine the level of review needed for research.

There are four levels of institutional review: 1) Exempt; 2) Limited Review; 3) Expedited Review; and, 4) Full Committee Review.

1. Exempt from Review: research that involves no risk to subjects. At least one member of the Department IRB will review exemption requests.
2. Limited Review: research that involves minimal or no risk to subjects. At least one member of the Department IRB will review limited review proposals.
3. Expedited Review: research that involves minimal harm risk to subjects and for minimal changes to approved research. Two members of the Department IRB will review expedited review proposals.
4. Full Committee Review: research that involves a substantial risk to subjects, raises potential risk, or involves a protected group. These proposals will be sent to the College IRB.

Research projects that can be exempt from review and that requiring limited or expedited review should follow Sociology & Anthropology Departmental Review Procedures. Projects requiring full committee review should submit a proposal for Full Committee Review in consultation with the Departmental IRB Coordinators.

Detailed descriptions of the four levels of review are available on the Departmental IRB webpage and the Muhlenberg College Policies and Procedures Regarding Research with Human Subjects

http://www.muhlenberg.edu/mgt/provost/committees/irb/Muhlenberb_IRB_Policy_1994.pdf)

STEP TWO: Submit required material to Department Review Committee

Exemption from Further Review: Departmental Review Procedures

1. Read the Muhlenberg College Policies and Procedures Regarding Research with Human Subjects
http://www.muhlenberg.edu/mgt/provost/committees/irb/Muhlenberb_IRB_Policy_1994.pdf).
2. Complete the **Departmental IRB Request for Exemption** form and short description of research, available at the department website.
3. Submit **2 copies** of the application materials to Ms. Tracy Kline in the Department of Sociology & Anthropology.
4. All Departmental IRB requests will be reviewed within 2 weeks. At that time, the applicant will receive notification of approval or the need for additional information. Revised applications (those reflecting the requested changes and/or additional

information) also will be reviewed within 2 weeks. If your research project requires review by the College IRB, you should allow 2 weeks for full approval. In rare cases, the process may take longer.

5. The Departmental IRB Coordinator(s) will contact the researcher regarding the decision. The Coordinator(s) will also indicate whether any changes to the research design are necessary for approval, or if the proposal needs to be resubmitted for a different category of review (e.g., Full Committee Review).

No proposal may be considered approved until the applicant has received an IRB approval form signed by a committee member.

No funding proposal requiring IRB approval may be submitted without this signed IRB approval form.

Limited or Expedited: Departmental Review Procedures

1. Read the Muhlenberg College Policies and Procedures Regarding Research with Human Subjects (http://www.muhlenberg.edu/mgt/provost/committees/irb/Muhlenberb_IRB_Policy_1994.pdf).
2. Complete the **Departmental IRB Request for Approval**, available at the department website.
3. Enclosed with your application any and all recruitment materials (e.g., flyers, email text) and instruments (e.g., surveys, questionnaires, interview questions) that will be used in your interactions with research subjects.
4. Submit **2 copies** of all application materials to Ms. Tracy Kline in the Department of Sociology & Anthropology.
5. All Departmental IRB requests will be reviewed within 2 weeks. At that time, the applicant will receive notification of approval or the need for additional information. Revised applications (those reflecting the requested changes and/or additional information) also will be reviewed within 2 weeks. If your research project requires review by the College IRB, you should allow 2 weeks for full approval. In rare cases, the process may take longer.
6. The Departmental IRB Coordinator(s) will contact the researcher regarding the decision. The Coordinator(s) will also indicate whether any changes to the research design are necessary for approval, or if the proposal needs to be resubmitted for a different category of review (e.g., Full Committee Review).

No proposal may be considered approved until the applicant has received an IRB approval form signed by a committee member.

No funding proposal requiring IRB approval may be submitted without this signed IRB approval form.

Human Subjects Review Application Guidelines
Department of Sociology & Anthropology
Muhlenberg College

Categories of Research Review*

Exempt:

Research...

- in which there is *no risk* to the subjects of the research.
- done for a class project when the results will not be disseminated beyond the scope of the class is exempt
- conducted for the purpose of internal (Muhlenberg) information or required data collection, except in instances where the information deals with sensitive aspects of the individual's behavior

IRB Procedure:

- Researcher must apply to the departmental Human Subjects Committee for exempt status.
- Exemption from Review form and short description of research and why it is exempt from Human Subjects Review.

Limited:

Research...

- conducted in established or commonly accepted educational settings, involving normal educational practices
- involving the use of educational tests, survey procedures, interview procedures or observation of public behavior (see PPRRHS for specific considerations)
- involving the collection or study of publicly available existing data, documents, records, pathological specimens or diagnostic specimens
- sponsored research and demonstration projects which are conducted by or subject to the approval of federal Department or Agency heads
- taste and food quality evaluation and consumer acceptance studies
- pose no more than minimal risk to subjects

IRB Procedure:

- Researcher must apply to the departmental Human Subjects Committee for approval
- Human Subjects Review Application, including recruitment and consent materials if appropriate.

* Please see the *Policy and Procedure Regarding Research with Human Subjects* (PPRRHS) Muhlenberg College (adopted April 22, 1994) for full descriptions of each category

Expedited:

- for minor changes in previously approved research, during the period for which approval has been authorized OR

Research:

- collecting specific biomarkers, including but not limited to hair and nail clippings, excreta and external secretions, blood samples by venipuncture and supra- and subgingival dental plaque and calculus
- recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice
- collecting voice recordings made for research purposes such as investigations of speech defects
- including moderate exercise by healthy volunteer
- using existing data, documents, records, pathological specimens, or diagnostic specimens.
- examining individual or group behavior or characteristics of individuals that does not manipulate subjects' behavior
- examining drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required

IRB Procedure:

- Researcher must apply to the departmental Human Subjects Committee for approval Human Subjects Review Application, including recruitment and consent materials if appropriate.

Full Committee Review

Any research not covered under the limited or exempt review categories. This includes:

- Research proposals requesting funding from Health and Human Services agencies
- Research involving children under 18 years of age

IRB Procedure:

- Researcher must apply to the College Human Subjects Committee for approval

Human Subjects Exemption Request
Department of Sociology & Anthropology
Muhlenberg College

Please complete each section and submit 2 copies to the Department of Sociology & Anthropology

Request for Exemption from further IRB Review (please check all that apply):

- The research will involve the observation of public behavior or will involve survey or interview procedures, and, of the following conditions, numbers 1a or 1b, 2, and 3 will apply (you must check 3 boxes):
 - 1a. Data *will not* be recorded in a manner enabling the identification of participants; or
 - 1b. Data *will* be recorded in a manner enabling the identification of participants, but the participant's responses, if they were to become known outside the research, could not reasonably place the participant at risk of criminal or civil liability or be damaging to the participants' financial standing or employability.
 - 2. The research will not deal with sensitive aspects of the participant's behavior, such as illegal conduct, drug or alcohol use, sexual behavior, etc.
 - 3. The research will not deal with a vulnerable participant population, such as children, economically or educationally disadvantaged participants, mentally or physically challenged participants, prisoners, or participants who are ill.
- The research will be conducted in established or commonly accepted educational settings involving normal educational practices (e.g., research on curricular changes, teaching styles).
- The research will involve the use of educational tests, and the information taken from these sources will be recorded in such a manner that the participants cannot be identified either directly or indirectly.
- The research will involve survey or interview procedures, and the respondents are elected or public officials or candidates for public office.
- The research will involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These will be from sources that are publicly available, and the information in them will be recorded by the investigator in such a manner that participants cannot be identified directly or indirectly.

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- 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.
- Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Please provide a description of your project below (no more than one page). Describe the project's goals, design, major hypotheses or research questions, procedures, and any experimental procedures or manipulations to be used. You may also include any other information that may be helpful to the IRB in response to your request for exemption from further IRB review:

Human Subjects Review Request for Approval
Department of Sociology & Anthropology
Muhlenberg College

Please complete each section and submit 2 copies with all pertinent supporting materials to Ms. Tracy Kline in the Department of Sociology & Anthropology

Project Title

Project Start & End Date

Contact Information for Principal Investigator & names of all members of the research team

Description of Research

Description of Research Design (including data sources, number of participants, if applicable, desired outcomes)

Description of participant recruitment (including criteria for inclusion and exclusion, compensation, if any)

Descriptions of the social or theoretical significance & benefits of research

Description of the risks & benefits, if any, to research participants

Description of what type of informed consent will be obtained and the process by which it will be obtained (including consent form or oral script, if appropriate)

Description of how the confidentiality of research participants and data will be protected