Policy and Procedure Regarding Research with Human Subjects
Muhlenberg College

(adopted April 22, 1994)

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POLICY ON RESEARCH WITH HUMAN SUBJECTS

All research and experimental activities in which human beings participate as subjects must be approved by Muhlenberg College's Institutional Review Board (IRB) or by an authorized Departmental Coordinator of Human Subjects Research prior to the involvement of the subjects and prior to the distribution to subjects of any information or written materials that require approval. This applies to all research sponsored by external funding agencies, to unsponsored research, and to continuing education and instructional projects and activities conducted by College students, staff, and faculty. This applies to all research conducted under college auspices or as a part of an investigator's professional activities as an employee of the college. It does not apply to research entirely unrelated to the college or to an employee’s professional activities (e.g., conducting research for a non-profit agency) unrelated to his or her college responsibilities, though employees may choose to submit such research for IRB review.

Muhlenberg College’s human subjects policy was developed in accordance with the Federal Policy for the Protection of Human Subjects, published in the Federal Register on June 18, 1991, as a final common rule for participating federal agencies. The policy is designed to safeguard the rights and well-being of human subjects, and to ensure that the principles of respect for persons, beneficence, and justice are met by proposed activities involving human subjects.

DEFINITIONS (as defined in the federal policy):

"Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

"Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

"Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

"Interaction" includes communication or interpersonal contact between investigator and subject.

"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information is individually identifiable when the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

PRINCIPLES

The principle of respect for persons requires that researchers recognize that each individual's judgements and choices about participation in research must be respected. For those not capable of self-determination, special protection measures must be used. To meet this principle, research subjects or their legal representative must sign an informed consent form detailing the research to be performed, the potential risks and hazards, and any feature which may influence their decision to participate. The IRB or Departmental Coordinator of Human Subjects Research reviews all protocols to insure that participation of the subjects is voluntary and the information provided to gain subject consent is adequate and appropriate.

Beneficence refers to the research project's resulting benefit to the participant and society. All research should be designed to minimize risks. The IRB or Departmental Coordinator of Human Subjects Research will review all proposed research to determine if the risks to the subject are so outweighed by the potential benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks.

The benefits and the burdens of participation in research must be distributed fairly among all populations to ensure justice. Researchers must take care not to select already burdened or vulnerable groups who might be more easily coerced to participate. These include prisoners, children, residents or clients of institutions for the mentally ill and mentally retarded, and persons subject to military discipline. The IRB or Departmental Coordinator of Human Subjects Research will assure that subjects are selected fairly within a specific project and among all
College research projects so that no unjust patterns emerge. When research participation is a course requirement or opportunity for extra credit, the prospective participant is given the choice of equitable alternative activities.¹

The College's policy places the primary responsibility for the protection of the welfare, and the right of privacy, of the individual subject on the principal investigator. The responsibility is shared by the College as an institution; by the sponsoring agency where outside support is provided; and by the faculty advisor in the case of student-conducted research.

OVERVIEW

It is the responsibility of the investigator to bring any proposed research projects involving the use of human subjects to the attention of the IRB or Departmental Coordinator of Human Subjects Research. At any stage of the review process, the application may be referred to the initiating investigator for clarification or for alteration and resubmission. In accordance with federal regulations, approval of a proposed investigation is granted for a period of one year starting with the anticipated beginning date of the investigation.

It is the responsibility of the principal investigator to initiate an annual review if the activity is a continuing one. If at any time there are substantive changes in the plan of research, the principal investigator must resubmit the project to the IRB or Departmental Coordinator of Human Subjects Research for review and further action.

Different types of research require different types of review, as described below. Instructional activities that do not constitute research, as defined above, do not fall within the purview of this policy. Institutional or internal research requires no review except when involving sensitive aspects of behavior or otherwise involving more than minimal risk to human subjects. All funded research and certain other classes of research (see below) require IRB approval. Course-related, student-generated, and non-funded faculty research may require approval by the IRB or an IRB-approved Departmental Coordinator.

INSTITUTIONAL RESEARCH

Institutional research or internal research is the gathering of data from or about Muhlenberg students, faculty, or staff members by college offices or organizations, with the intent of using the data solely for internal informational purposes or for required data-collection purposes. Examples would include surveys or other data-collection instruments designed to: improve college services or procedures; ascertain the opinions, experiences, or preferences of the college community; or provide necessary information to characterize the college community. This kind of data collection does not require review by the IRB except in instances where the information deals with sensitive aspects of the subject's own behavior, with the result that any disclosure of the response outside the context of the research could place the subject at risk of criminal or civil liability or be damaging to the subject's reputation, employability, or financial standing. Examples would include information on subjects' drug use, alcohol use, sexual behavior, or illegal conduct. Research involving such sensitive information must receive IRB approval.

REVIEW OPTIONS

Research may be reviewed in one of two ways: Option A (Departmental Review) or Option B (IRB Review). The options are described below.

Each department in the college conducting non-funded research with human subjects must choose either Option A or Option B. It will be assumed that departments have chosen Option B unless the IRB has been notified that a department has chosen Option A.

All research funded or to be funded outside of the college must be submitted to the IRB.

In some instances, duly selected Departmental Coordinators may review research which receives no funding from sources outside the college. Only proposals that fit the criteria for limited or expedited research (see below) may be processed at the departmental level.

Student research and training activities involving human subjects may range from activities taking place entirely within the classroom to independent research and honors projects. The instructor or advisor is ultimately responsible for the protection of human subjects, for the training and supervision of student investigators, and for seeing that student-related projects have been reviewed by the IRB, if required, and meet any departmental review or approval requirements.

¹ The last sentence in this paragraph is a quotation from the American Psychological Association's (1992) Ethical Principles of Psychologists and Code of Conduct, Ethical Standard 6.11(d).
**Note:** The informal collection of information by students from respondents -- for example, informally interviewing friends or relatives for purposes of class discussion or assignments -- does not require IRB review. IRB or departmental review is required only where there is the intent to undertake a systematic investigation, produce a design or protocol for the research, a sampling of a population, reportable findings, etc.

**Option A Departmental Review**

The department elects one faculty member to serve as a Departmental Coordinator of Human Subjects Research. Until the proposed faculty member has been selected, all human subject research proposals from the department must be submitted to the College IRB.

The Departmental Coordinator must be a faculty member familiar with the criteria for reviewing research with human subjects. The Departmental Coordinator for a given department need not be a member of that department.

The Coordinator is trained by and accountable to the IRB, to whom the IRB delegates its review power in some circumstances. The Coordinator must employ forms substantially similar to those included in this document and must follow the record keeping requirements outlined below. The Departmental Coordinator or any researcher may, for any reason, request that the IRB review a research proposal. In the event that the Coordinator submits a proposal, another faculty member must be appointed to evaluate the proposal. The alternate must not be affiliated with the project in any way. Any other internal procedures may be established by the department, including review of proposals by one or more additional department members.

Each Departmental Coordinator will review his or her activities with the IRB Chair on a quarterly basis.

**Option B IRB Review**

All research proposals requiring review that are not reviewed by a Departmental Coordinator are reviewed by the IRB.

**INSTITUTIONAL REVIEW BOARD (IRB)**

**Scope of Authority**

The IRB shall review and have authority to approve, require modification in (to secure approval), or disapprove all research activities covered by this policy. The IRB shall have authority to observe or have a third party observe the informed consent process and the research.

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action and shall be reported promptly to the investigator, appropriate institutional officials, and (where applicable) to the appropriate granting agency official.

The IRB may delegate this authority to Departmental Coordinators in the ways specified below.

**Membership**

The IRB shall have members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The IRB is comprised of five standing members: three representatives from the College (two faculty members and one representative who may be either a faculty or staff member), one student member, and one community member. Each College representative is elected by the faculty for a three-year term and may be
reelected for an additional term. The student member is appointed by the president of the student body. The community member is appointed by the dean of the college, after consultation with the IRB. This person is not otherwise affiliated with the institution and is not part of the immediate family of a person who is affiliated with the institution. Associate members drawn from the faculty, staff, students, and the community who have agreed to serve are selected on an as-needed basis to review those projects and activities which fall within their areas of expertise and/or interest. Although the make-up of the IRB will change, there must always be one community member (a person not associated with the College) on the committee. In addition, there will at least one member whose primary concerns are in scientific areas and one member whose primary interests are in the nonscientific areas. The IRB will not be composed entirely of men, women, or members of one profession.

**Criteria for Approval of Research**

In order to approve research covered by this policy the IRB or Departmental Coordinator shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized:
   a. by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   b. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB or Departmental Coordinator should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB or Departmental Coordinator should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB or Departmental Coordinator should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with the policy outlined below.

5. Informed consent will be appropriately documented, in accordance with the policy outlined below.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
CATEGORIES OF RESEARCH REVIEW

There are three categories of review: limited, expedited, and full committee review. Research proposals requesting funding from Health and Human Services agencies are required by the agencies to receive full committee review if they are not eligible for expedited review.

A. Limited Review

Certain research may be reviewed through limited review procedures. The chair of the IRB or Departmental Coordinator (if available) determines whether a research project will undergo a limited review. As necessary, the chair will consult with other IRB members (or the Coordinator with other department members) when making this decision. Proposals are exempt from more detailed review if the research described poses minimal risks to subjects and proper procedures are used to implement ethical principles for the protection of human subjects. The following types of research may fall into the limited review category:

1. 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.

2. 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 the 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. Examples include sensitive aspects of subjects' behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

   Note: Research involving children under 18 is not eligible for expedited review under this category. Please see Special Considerations: Children as Subjects in Research.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph (2) of this section if:
   (i) the human subjects are elected or appointed public officials or candidates for public office; or
   (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

5. Sponsored research and demonstration projects which are conducted by or subject to the approval of federal 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;
   (iv) possible changes in methods or levels of payment for benefits or services under those programs.

   (6) 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.

B. Expedited Review

Expedited review procedures may be used for certain types of research involving no more than minimal risk and for minor changes in approved research. The review may be carried out by the IRB chair, by one or more experienced reviewers designated by the chair from among members of the IRB, or by the Departmental Coordinator (if available). In reviewing the research, the reviewers may exercise all of the authorities of the IRB
except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth below. Reviewers may refer the proposal to full committee. The principal investigator will be informed in writing whether the proposed research has been approved or referred for full committee review. All members of the IRB will receive written notification from the chair of research activities that have been approved by limited review.

Limited review can be used for minor changes in previously approved research, during the period for which approval has been authorized, and for the following categories of research:

1. Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, X-rays, microwaves).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6. Voice recordings made for research purposes such as investigations of speech defects.

7. Moderate exercise by healthy volunteers.

8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

C. Full Committee Review

Any research not covered under the limited or expedited review categories is referred to the IRB for full committee review. The investigator may be invited to attend the review. The research is approved, approved pending modifications which must be verified by committee members, or not approved. Investigators will be notified in writing about the committee's decision.
D. Certification by Another Institution's IRB

If a Muhlenberg student, faculty member, or staff member is conducting research in another institutional setting, Muhlenberg's requirement for research ethics review will be met by a certification, signed by the principal investigator of the other institution, verifying that the research project has been reviewed and approved. That certification and a copy of the letter notifying the Principal Investigator that the research has received institutional approval must be submitted to the IRB Chair or Departmental Coordinator. Review of research funded by or conducted at Muhlenberg, or for which a member of the Muhlenberg academic community has primary responsibility, must follow the procedures outlined in other sections of this document.

SPECIAL CONSIDERATIONS

A. Children as Subjects in Research

The range of activities that may be approved by limited review is reduced when children are involved as subjects in research. Specifically, research involving survey or interview procedures and research involving the observation of public behavior where the investigator is a participant in the activities being observed may not receive limited review when these research activities involve persons under the age of 18 (hereinafter, "child" or "children").

Written permission is required of both parents or the child's guardian for each child under the age of 18 who will be the subject of research. The permission of one parent is sufficient if: (a) the other parent is not reasonably available or is incompetent; (b) only one parent has legal responsibility for the care and custody of the child; or (c) the research is such that it either does not involve more than minimal risk to the child or involves more than minimal risk but also presents the prospect of direct benefit to that child. The requirement for written permission may be waived by the review committee where it is not a reasonable requirement to protect the subjects (for example, neglected or abused children).

Assent: In addition to the written permission required of parents, it is necessary to acquire the assent of children, when they are capable of providing assent. "Assent" means a child's affirmative agreement to participate in research; mere failure to object should not be construed as assent. Ordinarily for children 14 years and older, written assent is required. For children under 14, verbal assent may be obtained. The Principal Investigator must submit to the IRB the methods that will be used to obtain and document assent. The ages, maturity, and psychological state of the children should be taken into account in deciding whether assent must be obtained and how it will be documented.

Children who are wards of the state or of any other entity may be included in research involving greater than minimal risk and no prospect of direct benefit to the individual children only if the research is related to their status as wards or is conducted in schools, camps, hospitals, or other similar settings in which the majority of children involved as subjects are not wards. An individual must be appointed as advocate for the wards; the advocate may not be associated with the research, the investigators, or the guardian organization. The advocate must have the background and experience to act in the best interests of the children for the duration of their participation in the research. It is suggested that the principle investigator identify a suitable advocate and secure his or her consent to serve prior to review by the IRB. Advocates for child wards are not required for research involving no more than minimal risk or for research presenting the prospect of direct benefits to the individual children.

B. Research involving Fetuses, Pregnant Women, or Human In Vitro Fertilization

Additional protection and limitations are placed on research involving pregnant women, fetuses in utero, or fetuses ex utero. Please contact the Chair of the IRB for additional information.

C. Research Involving Prisoners

Additional protection and limitations are placed on research on prisoners. Please contact the Chair of the IRB for additional information.
D. Policy on Informing Those Tested About HIV Serostatus

The Public Health Service (PHS) requires that when HIV testing is conducted or supported by PHS, individuals whose test results can be identified must be informed of their results and provided with the opportunity to receive appropriate counseling. This applies to all intramural and extramural PHS activities, including research and service activities, domestic and foreign. Pennsylvania law also imposes specific consent and counseling requirements. Please contact the Chair of the IRB for additional information.

INFORMED CONSENT

A. General Requirements for Informed Consent

Before any research can be undertaken, the investigator must obtain the informed consent of the subject or of the subject's legally authorized representative. An informed consent is knowing consent from the individual (or representative) which has been obtained without coercion or undue influence. The information given to the subject or the representative should be in language understandable to the subject or representative. In addition, the agreement, written or verbal, entered into by the subject, should include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his/her legal rights, including any release of the College or its agents from liability for negligence. A copy of the informed consent form must be given to every subject.

The basic elements of informed consent are:

1. An explanation of the purposes of the research, and a description of the procedures to be followed (including an identification of those which are experimental) and of the expected duration of the subject's participation;
2. A description of any attendant discomfort and risks that can reasonably be expected;
3. A description of any benefits that can reasonably be expected;
4. A disclosure of any appropriate alternative procedures that might be advantageous for the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
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;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury; and
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.

When appropriate, any of the following additional elements of informed consent should be included:

1. A statement that the treatment or procedure to be used may involve risks which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
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.
6. The approximate number of subjects involved in the study.

The IRB or Departmental Coordinator may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB or Departmental Coordinator finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The IRB or departmental coordinator may consult with the college attorney about the legal requirements for informed consent, should consider doing so in complex cases and cases where substantial risk exists, and must do so in cases where physical touch (i.e., potential battery, e.g., surgery) is involved.

B. Documentation of Informed Consent

Informed consent is documented by the use of a written consent form, which is approved by the IRB or Departmental Coordinator and signed by the subject or his/her legally authorized representative. A copy is given to the person signing the form. The consent form may be either of the following:

1. a written consent document that embodies the elements of informed consent described above; or
2. a "short form" written consent document stating that the elements of informed consent described above have been presented orally to the subject or his/her representative.

In addition, when the "short form" and oral presentation method is used:

1. The review committee must approve a written summary of what is to be said to the subject or to the person authorized to consent for the subject.
2. There shall be a witness to the oral presentation and the witness shall sign both the "short form" and a copy of the written summary.
3. The person obtaining consent shall sign a copy of the summary.
4. A copy of the written summary shall be given to the subject or the person authorized to consent for the subject, in addition to a copy of the "short form."

A sample informed consent form can be found in Appendix C.

C. Waiver of Signed Informed Consent

The IRB or Departmental Coordinator may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds: 1) the only record linking the subject to the research would be the consent form and the principal risk would be the potential harm resulting from a breach of confidentiality, and 2) the research poses no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

In the case of mailed questionnaires, the investigator must provide a written explanation of the study and inform subjects of their rights. This information can be provided in a cover letter which the subject can retain. In the case of telephone surveys, the investigator must provide a verbal explanation of the study and inform subjects of their rights. These explanations must be submitted to the committee for approval.

PROCEDURES FOR SUBMITTING A RESEARCH PROJECT FOR REVIEW

1. All proposals requiring IRB review should be sent to the IRB. If applicable, proposals requiring departmental review should be sent to the Departmental Coordinator. If there is any disagreement with the type of review requested, the investigator will be contacted, the reasons for the disagreement explained, and any additional material necessary to continue the review process requested.
2. The IRB meets as frequently as necessary to meet the needs of college researchers. Investigators submit all information well in advance of the anticipated start date of data collection and, in the case of sponsored research, in advance of submission of the proposal to the agency.
3. Investigators should request the type of review most appropriate for their study. Proposals are first reviewed by the IRB Chair or Departmental Coordinator. If there is any disagreement with the type of review requested, the investigator will be contacted, the reasons for the disagreement explained, and any additional material necessary to continue the review process requested.
4. The following information should be submitted to the IRB:

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<thead>
<tr>
<th>Form</th>
<th>Number of Copies Required</th>
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<tbody>
<tr>
<td></td>
<td>Expedited Review</td>
</tr>
<tr>
<td>a. Human Subjects Questionnaire</td>
<td>2</td>
</tr>
<tr>
<td>b. Informed Consent Form</td>
<td>2</td>
</tr>
<tr>
<td>c. Instruments (surveys, etc.)</td>
<td>2</td>
</tr>
<tr>
<td>d. Progress Report (if renewal)</td>
<td>2</td>
</tr>
<tr>
<td>e. Full Grant Proposal (if applicable)</td>
<td>1</td>
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</table>

The Human Subjects Questionnaire and a sample informed consent form can be obtained from the Chair of the IRB or Departmental Coordinator.

5. The committee's actions, comments, and recommendations will be sent to the investigator. If a proposal is disapproved, the principal investigator may request to attend the next committee meeting.

6. Any changes made in a proposal or consent form must be promptly reported to the IRB chair or Departmental Coordinator. In most cases these will receive a limited review.

7. All adverse reactions and unexpected side effects must be reported immediately, in writing to the IRB or Departmental Coordinator.

8. Interim progress reports should be submitted if requested by the IRB or Departmental Coordinator to insure that the rights and well-being of subjects are protected.

9. Annual renewals are mandatory. (See Human Subjects Progress Report Form, Appendix C.)

APPEALS

Investigators may request that the IRB or Departmental Coordinator reconsider the decision made. A rationale must accompany that request.

If the Departmental Coordinator sustains his or her decision, the investigator may request a review by the IRB. A rationale must accompany that request.

If the IRB sustains its decision, the investigator may appeal to the Dean of the College for Faculty. The Dean may, but need not, convene an ad hoc review panel to review all materials and make a recommendation to the dean. The dean's decision is final.

ANNUAL RENEWAL PROCEDURES

Thirty days before the anniversary of the last approval date the following should be submitted:


2. If any changes have been made, submit instruments, with any changes noted, and the consent form(s) and written explanation of study, with any changes highlighted.

Two of each of these forms should be submitted for expedited, four for limited review, and six for full review.

COMPLETION OF RESEARCH

When a project is completed, withdrawn, or past the phase involving human subjects, please inform the IRB chair or Departmental Coordinator in writing.

RECORD-KEEPING

The following records must be maintained for three years:

1. Copies of all research proposals reviewed; scientific evaluations, if any, that accompanied the proposal; approved sample consent documents; progress reports and renewals submitted by investigators; and reports of injuries to subjects.

2. Minutes of IRB meetings which should be in sufficient detail to show attendance at the meeting, actions taken; the vote on these actions including the number voting for, against, and abstaining; the basis
for requiring changes in or disapproving research; and a summary of the discussion of controverted issues and their resolution.

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and Departmental Coordinators and the investigators.

5. A list of the IRB members detailing their name, earned degree, representative capacity, indications of experience sufficient to describe each member’s chief anticipated contribution to the IRB, and any employment or other relationship between the member and Muhlenberg College (e.g. full-time employee).

6. A statement of significant new findings provided to subjects, as required by the policy on informed consent, discussed above.