Policy and Procedures for Research Involving Human Subjects
Muhlenberg College Institutional Review Board
October 2009

Between Fall 2008 and Fall 2009, the faculty members serving on the College's Institutional Review Board (IRB)[1] undertook a review of IRB policy and procedures. This involved examining the most recent version (2005) of the federal Health and Human Services Policy for the Protection of Human Research Subjects (CFR 45 Part 46, also known as the Common Rule), conducting a study of practices at benchmark liberal arts institutions, and updating our policy, which dates back to 1994. In accordance with federal guidelines, the Muhlenberg College IRB was also registered with the Office of Human Research Protections (OHRP). The College was also granted Federalwide Assurance (FWA), which states that whenever human subjects research that is supported by any federal department or agency that has adopted the Common Rule is conducted under the auspices of Muhlenberg College, the College will follow ethical guidelines and procedures outlined by the Common Rule and the Terms of the Federalwide Assurance.

In addition to considering federal guidelines, the committee thought deliberately about the role of the IRB at Muhlenberg, an environment in which faculty, staff, and students conduct human subjects research in a variety of disciplines. The committee recognized this liberal arts context as well as the fundamental principles of academic freedom in recommending changes to IRB policy and procedures. The proposed policy:

- *clarifies and streamlines the proposal submission and review processes. This is accomplished in part by providing new submission forms as well as questions to aid researchers in determining whether their work qualifies for expedited review or requires full review, or whether they may apply for an exemption (the limited review category has been dropped in accordance with federal guidelines). The policy articulates an educational role for IRB, encouraging researchers, including students, to consult with the IRB Chair or appropriate Departmental Coordinator prior to proposal submission.*

- *considers the context of an undergraduate liberal arts institution in recognizing students as researchers and therefore strives to promote their agency and bring them more fully into the research process.*

- *continues to empower Departmental Coordinators in the review process, as many ethical reviews may be appropriately carried out by a discipline-specific reviewer. Federal guidelines can be met by Departmental Coordinators and the IRB working together to ensure that there is consistency in the federally required processes of review and record keeping.*

- *carefully considers IRB membership and training. The student member will be selected through an application process requiring faculty recommendation, in consultation with the Student Body President. All new IRB members and Coordinators will be required to complete standard training and all reviewers will be encouraged to engage in further training as appropriate.*

[1] Committee members for 2008-2009 academic year included: Hark (Biology), Sinno (Psychology), and Taub-Pervizpour (Media and Communication); Fall 2009 included: Shive (Education), Sinno (Psychology), and Taub-Pervizpour (Media and Communication).

I. Overview (adapted from CFR 45 Part 46.101)

Muhlenberg College is committed to protecting the safety, welfare, rights, and privacy of all persons who participate as subjects in research projects conducted under its auspices by faculty, staff, and students. It is also committed to ensuring that the subjects of such research are fully aware of their rights and the protections available to them. In addition, the College is obligated by law to assure the federal government that such safeguards are being provided and implemented. These safeguards are derived from the following ethical principles, first articulated in the Belmont Report issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979:

> ***Respect for persons***: recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy or particular vulnerabilities, including prisoners, children, those who are mentally or cognitively disabled, pregnant women, or economically or educationally disadvantaged persons. Human subjects should enter into research voluntarily and with adequate information.
>
> ***Beneficence***: the obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks. Possible risks to human subjects should be weighed against possible benefits to the subjects, as well as against the possible improvement of knowledge.
>
> ***Justice***: fairness in the distribution of research benefits and burdens. In selecting human subjects for research, researchers should ensure that no group of participants is either consistently selected to participate in research, or consistently deprived of the opportunity to do so. When research participation is a course requirement or opportunity for extra credit, the prospective participant is given the choice of equitable alternative activities.

Research in which human beings participate as subjects conducted under the auspices of Muhlenberg College, by its faculty, students, and staff, is subject to review by the College's Institutional Review Board (IRB). The IRB is the body charged with reviewing, prior to its commencement, all research and experimental activities in which human beings participate as subjects, as well as research by external researchers seeking to use Muhlenberg College students or personnel as research subjects. "Research" is defined as "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" (45 CFR 46.102d). Research subject to review thus includes, but is not limited to, pilot studies, class projects

to be published or presented beyond class, independent research, and senior theses, whether such research takes place on or off the Muhlenberg campus, including work done outside of the United States. Researchers should remember that research conducted outside the United States may also be submit to foreign law. Section VI includes a discussion of activities that are beyond the scope of IRB; however, note that exemption from IRB review does not imply that ethical considerations do not exist in conducting research involving human subjects. The ethical and legal standards appropriate to one's discipline always apply, as discussed below.

Muhlenberg College's IRB procedures for review adhere to the regulations of the Department of Health and Human Services (45 CFR 46, as revised and published in the Federal Register on June 23, 2005), and to the Federalwide Assurances filed with the HHS. In addition, the IRB has consulted Protecting Human Subjects: Institutional Review Guidebook (1993), prepared by the Office for Protection from Research Risks of the National Institutes of Health, and has adopted sections from the policies of other liberal arts institutions, all of which are based on the same federal standards.

This policy affirms Muhlenberg College's commitment to academic freedom. It will not be used to discourage or disapprove innovative research. The IRB at Muhlenberg College understands and is sensitive to enduring debates about the appropriate reach of IRBs and the tensions that may emerge in applying review policies originally designed for the experimental sciences to research in the social sciences and humanities.[2] Furthermore, in promoting the establishment of Departmental Coordinators of Human Subjects Research and supporting Departmental Coordinators through ongoing training and education, the IRB recognizes that different disciplines have their own professional codes of ethics that are most appropriate to their fields of research. Most academic professional associations have codified and published ethical guidelines that researchers should consult.

Beyond fulfilling its obligations to the federal government as summarized below, as an institution focused on undergraduate learning, Muhlenberg's IRB has an educational role to play in helping members of the College community think about the ethical implications of their research projects and supporting faculty in the development and training of students as ethical researchers. Rather than an elaborate process, the IRB hopes to be viewed as a resource for support and education in the best liberal arts tradition. Faculty supervisors of independent research and instructors of research methods courses, or similar courses in

[2] See a statement on IRBs and academic freedom by the AAUP at http://www.aauup.org/AAUP/comm/rep/A/humansubs.htm

which students conduct research with human subjects, are responsible for oversight of student projects. Instructors should consult with their Departmental Coordinator or the IRB to determine appropriate procedures for assuring that student projects meet ethical guidelines.

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.

II. Definitions (adapted from CFR 45 Part 46.102)
The following definitions are key to understanding and applying this policy:

Anonymity involves the researcher's ability to limit the possible linkage between a participant and the data.

Benefit describes a valued or desired outcome; an advantage.

Confidentiality[3] is the assurance to subjects that the access of others to information about themselves will be controlled in a way that is acceptable to them.

Federalwide assurance (FWA) is an assurance of compliance with the federal regulations for the protection of human subjects in research. Institutions engaged in human subjects research that is supported by the U.S. Department of Health and Human Services must submit an FWA to the Office of Human Research Protections (OHRP).

Human subject means a living individual about whom a researcher (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual and/or (2) 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.

[3] http://www.dhhs.gov/ohrp/nhrpac/documents/nhrpac14.pdf and http://www.apa.org/ethics/code2002.html#4 for further information on complex issues of anonymity and confidentiality in research with human subjects.

IRB means an Institutional Review Board established in accord with and for the purposes expressed in this policy.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional requirements.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

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

Registration refers to institutional review board/institutional ethic committee (IRB/IEC) organization (IORG) registration with the OHRP.

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

Signatory Official should be a high-level institutional official who has the authority to represent the institution named in the Federalwide Assurance (FWA), as well as all the institutional components listed in the FWA. This person is usually the President, Chancellor, Director General, Chief Executive Officer, or Chief Operating Officer. OHRP recommends that the Signatory Official not be the chair or member of any IRB designated under the FWA.

Vulnerable populations include those persons who are likely to be subject to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

III. Review of research (adapted from CFR 45 Parts 46.108-46.110 & 46.112-46.113)

Muhlenberg College's IRB shall review and have the authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. In reviewing research, the IRB is committed to protecting the interests and rights of human subjects and to carry out its charge in a way that minimizes interference with the autonomy and objectives of individual researchers.

All review of research requires the researcher(s) to submit the appropriate form as well as supporting documentation including the research protocol, informed consent forms, recruitment materials, and any grant application(s) relating to the proposed research. These materials shall be distributed to the appropriate reviewer(s), who will typically have between 5 to 10 days to consider the proposal before any action is taken. For proposed research requiring full committee review, the review shall occur at a convened meeting at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. The IRB committee will establish meeting dates of no less than twice a month and will distribute meeting dates to the faculty prior to the start of each semester. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. For expedited review or review to determine that proposed research is exempt, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB or Departmental Coordinators. 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 full committee review as described above.

The IRB shall notify researchers in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. Under expedited or exempt review categories, the reviewer will notify the researcher as well as the IRB chairperson, who will update other members of IRB at regular meetings. Reports from Departmental Coordinators are to be made to the IRB Chairperson annually (typically in April). The IRB chairperson will submit a written report of all proposal review decisions and other actions annually to the Signatory Official. A general report of IRB activities will be provided to the Faculty at or before the last regularly scheduled faculty meeting of the academic year.

If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision (e.g. risks outweigh benefits). A researcher(s) may initiate an appeal in writing to the IRB Chairperson. The researcher may submit information pertinent to the proposal and may request a meeting with the IRB. The IRB may request additional information relevant to the proposal from either the researchers or others. The appeal will be considered by the full IRB and the decision will be determined by a majority vote of all voting members of the IRB.

Muhlenberg College is committed to academic freedom, and given its educational function, the IRB is committed to working with researchers to develop proposals that meet ethical standards as articulated by this College policy and federal guidelines. As specified in federal guidelines, research covered by this policy that has been approved by the IRB may be subject to further review by College officials. While officials might be able to restrict an

approved project based on considerations **other than** ethical grounds, they may not approve the research if it has been disapproved by the IRB. College officials will provide the researchers with rationale for any administrative decision that restricts research.

Continuing research must be reviewed annually either by the IRB Chairperson or the Departmental Coordinator. It is the responsibility of the researcher to initiate this review (see Appendix D). The Chairperson may, at his/her discretion or in consultation with members of the IRB, deem a proposed project as involving higher risk to human subjects and specify in the approval letter the need for and terms of more frequent review. If at any time there are substantive changes in the research plan, the researcher must resubmit a modified proposal to the IRB Chairperson or Departmental Coordinator for review and further action.

Following approval, researchers are expected to proceed with their study in accordance with the research protocol as approved. Researchers must promptly report (within two weeks) any unanticipated problems involving risks to subjects or others to the IRB. 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 researcher and appropriate institutional officials (typically, within two weeks), and (if applicable) to the appropriate granting agency official within four weeks.

IV. Criteria for approval of research (adapted from CFR 45 Part 46.109, 46.111)

In order to approve research covered by this policy, the IRB shall conduct a risk benefit analysis that all of the following requirements are satisfied:

(1) Risks to subjects are minimized, by employing procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk.

(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 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 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) When appropriate, the research plan includes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(4) Selection of subjects is equitable. In making this assessment the IRB 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.

(5) Informed consent is sought from each prospective subject or the subject's legally authorized representative and appropriately documented, in accordance with the requirements described in the Informed Consent section of this policy.

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

(7) When some or all of the subjects are likely to be members of vulnerable populations, additional safeguards are included in the study to protect the rights and welfare of these subjects.

V. Informed consent guidelines (adapted from CFR 45 Part 46.116)

Informed consent is more than just a form; it is the basis of a dialogue between the researcher and research subject(s). Except under special conditions specified below (***Waiving the informed consent requirements)***, researchers are required to obtain written informed consent from all adult participants. Researchers are required to provide prospective adult participants with sufficient information and opportunity to consider that information. Every consent form should obtain a statement of the participants' rights. Basic elements of consent forms are summarized below.

When the participants are under 18 years of age, parental (or guardian) consent must be obtained. Parents and guardians may sign a consent form giving permission for their child(ren) to participate in a series of projects conducted over a period of an academic year. It is understood that although parental consent is obtained, child participants are free to decline invitations to participate without any penalty. Parent consent letters should provide information about the purpose of the research as well as information about the procedure itself from the child's point of view. As with research involving adult participants, this letter should indicate how confidentiality would be maintained.

Child participants should be given an age-appropriate explanation about the procedures used and what to expect by way of participation. Children should be asked if they want to participate. Mere failure to object on the child participant's part should not, in the absence of an affirmative response, be interpreted as assent. In the proposal, the researcher should indicate how assent would be

obtained and documented. The researcher should also indicate how parental consent would be obtained including an example of the letter of consent (if relevant).

Eight basic elements of informed consent for adults

1. A statement that the study involves research, a readily understood explanation of the purpose(s) of the research, the expected duration of the subject's participation, a brief description of the procedures to be followed, and identification of any procedures which are experimental.

2. A description of any reasonably foreseeable risks or discomforts to the subject. These may include not only physical injury, but also possible psychological, social or economic harm, discomfort or inconvenience.

3. A description of any benefits to the subject or to others that may reasonably be expected from the research (if no direct benefit, this should be stated).

4. A statement concerning costs or compensation to the subject, if any.

5. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject. Possible contacts include: the Primary Researcher, the Departmental Coordinator of Human Subjects Research, or the IRB Chairperson. Student researchers must include contact information for their faculty sponsor. Phone numbers and emails should be provided.

6. Description of the extent, if any, to which confidentiality of records identifying the subject will be maintained.

7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

8. Signature of subject indicating agreement to participate and date of signature.

Waiving the informed consent requirements (adapted from CFR 45 Part 46.116 C and D)

Federal guidelines allow that there are some situations where a written consent form may not be required or where the above elements may be modified: (1) if the principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research; (2) if the consent document is the only record linking the subject with the research; (3) if the research involves no more than minimal risk to the subjects and involves procedures that

do not require written consent when they are performed outside of a research setting; or (4) the research could not be carried out in any other practical way.

If there is no written consent form, an oral presentation of the research should be provided to the subjects by the researcher, with documentation that such a presentation was made to the subjects. In this instance, researchers should maintain a written summary of the oral presentation and some record that consent was provided by the participant.

For more information on informed consent, see Tips on Informed Consent, prepared by the Office for Protection from Research Risks (as well as Appendix E). Researchers who believe their proposal may qualify for a waiver of informed consent should refer to CFR 45 Part 46.116 C and D and then consult with the IRB Chairperson or their Departmental Coordinator.

VI. Procedures for submitting a project for review (adapted from CFR 45 Parts 46.109 and 46.110)

Review for faculty and student research projects involving human subjects is initiated by the researcher(s) by submitting a research proposal to the IRB or the appropriate Departmental Coordinator. Before submission, it is important for the researcher(s) to review the material below to understand the categories of review. Full review must always be conducted by the IRB. Expedited and Exempt review may be reviewed by Departmental Coordinators. If the researchers are in a department with a Coordinator (see http://www.muhlenberg.edu/mgt/provost/committees/irb/Departmental%20Review.html for a listing), they should inquire about Expedited or Exempt forms which may be particular for their department. If the researchers are in a department that does not have a Coordinator they should use the forms accompanying this policy. If the researcher(s) have any questions they can contact the IRB Chairperson or, if available, their Departmental Coordinator. The researcher(s) should complete the questions below for each category of review and follow the procedures listed for their project's appropriate category.

Categories of Review

A. Criteria for Full Review

Research projects involving human subjects are subject to full review of the IRB if the following criteria are met. Projects are deemed eligible for full review, if the researcher(s) respond YES to *any* of the following questions:

1. Does this project involve participants from a vulnerable population, including individuals under 18, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons? YES

2. Does this project involve the collection of information that could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation?
   YES
3. Does this project involve the collection of information regarding sensitive aspects of the subject's behavior, such as drug or alcohol use, illegal conduct, or sexual behavior? YES
4. Is the project sponsored or funded by an agency or organization outside of Muhlenberg College? YES

If the researcher(s) answers YES to question 1or 4 above, they should fill out *Appendix A* and submit to the IRB Chairperson. If the researcher answers YES to question 2 or 3 the project may qualify for expedited review only if the following three criteria are met:
1) anonymity of the participant is guaranteed;
2) when possible, potential participants are informed of the sensitive nature of the topics prior to their participation;
3) the study does not exceed minimal risk.
If the researcher(s) believes these qualifications are met, the researcher(s) should read Section B below and submit proposal as instructed. If the IRB determines these criteria are not adequately met the proposal must go to full review and the researchers should fill out Appendix A and submit to the IRB Chairperson.

B. Criteria for Expedited Review

Research projects involving human subjects may be eligible for an expedited review if the following criteria are met. In order for the project to be deemed appropriate for an expedited review, the researcher(s) must have answered NO to all of the questions above for full review and be able to respond YES to *any* of the following questions:

1. Is this project presenting minor changes to a project previously approved by the IRB? (within one year or less of initial IRB approval)
   YES
   a. If the researcher(s) answers YES to question 1, they should consult with the Departmental Coordinator for appropriate forms. If there is no Departmental Coordinator, proceed to *Appendix B* and submit as instructed.
2. Does this project involve only minimal risk to the participants?
   YES
   a. Minimal risk, as defined by federal guidelines (46.102i.), means that the probability or magnitude of harm or discomfort anticipated are not greater than those ordinarily encountered in daily life or during routine physical or psychological examinations.

b. **Note**: If the researcher(s) answers YES to question 2, they should review Section C and D below. If the project does not qualify for exemption, or is not beyond the scope of the IRB, the next appropriate step is to consult with the Departmental Coordinator for appropriate forms. If there is no Departmental Coordinator, proceed to *Appendix B* and submit as instructed.

C. Criteria for Exemption

Research projects involving human subjects may be exempt from IRB full and expedited review if the following criteria are met. The researcher(s) must answer NO to all of the questions for full review and be able to respond YES *to at least one* of the following questions:

1. Does this project involve the use of diagnostic educational tests, survey procedures, interview procedures, or observations of public behavior in which individual demographic information obtained from participants is not recorded and therefore is not directly or indirectly identifiable or damaging to the subject? YES
2. Does this project involve the use of existing data that is publicly available or in which the subjects cannot be identified? YES
3. Is this project designed to evaluate a public benefit or service program? YES
4. Does this project involve a taste or food quality evaluation using wholesome foods, or those deemed safe by the FDA? YES

If the researcher(s) answers YES to at least one of the above questions, they should consult with their Departmental Coordinator about appropriate forms. If there is not a Departmental Coordinator they complete *Appendix C* and submit as instructed.

D. Criteria for Projects that are Beyond the Scope of IRB and Excluded from IRB Review

If reviewing the above checklists has not led to an Appendix for guidelines on preparing a submission to IRB, it may be that the research does not fall under the purview of this policy and does not require IRB review. A project does not require submission to the IRB if the researcher(s) can answer YES to any of the following questions:

1. Does this project involve faculty members' assessment of the effectiveness of their pedagogical strategies that is solely for their individual use? YES
2. Does this project involve student research that is not reported beyond the classroom? YES
3. Does this project involve the informal collection of information by students from respondents -- for example, informally interviewing friends or

relatives for purposes of class discussion or assignments – rather than a systematic investigation? YES

4. Does this project constitute institutional research or internal research, including 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? YES
5. Is this project being conducted as an oral history, a journalistic investigation, or a documentary film? YES

Answering YES to at least one of the above questions indicates that the proposed research does not fall under the purview of the IRB and does not require review. If the researcher(s) answera NO to all of the above questions, they should review all of the above categories again and complete the appropriate Appendix. The researcher(s) should contact the IRB Chairperson or their Departmental Coordinator with any questions regarding Categories of Review.

E. Criteria for Projects Already Approved by another Institution's IRB

If the researcher(s) is conducting research that has been previously approved, within a one-year time limit, by another Institution's IRB they should provide the IRB Chairperson with signed documentation of the approval. 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 for other Categories of Review listed above.

VII. IRB Membership (adapted from CFR 45 Part 46.107)

In accordance with Federal regulations, Muhlenberg College's IRB shall have five members, with varying backgrounds to promote complete and adequate review of human subject research activities conducted by members of the College community. The IRB at Muhlenberg College is constituted by:

- 3 faculty members elected by the faculty at large for 3-year terms
- 1 student member selected through an application process by IRB members in consultation with the Student Council President for a 1-year renewable term
- 1 community member appointed by the Signatory Official in consultation with IRB for a 1-year renewable term

In compliance with federal guidelines, the IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB must also include at least

one external member who is not affiliated with Muhlenberg College and who is not part of the immediate family of a person who is affiliated with Muhlenberg College. These regulations shall inform the selection of the community members who may serve on IRB. In addition, the Signatory Official will ensure that the committee is sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, professional and cultural backgrounds, and sensitivity to such issues as community attitudes.

The standing faculty members of IRB shall identify students who may serve as members of the IRB through an application process requiring faculty recommendation and selection.

A member of the IRB may not participate in the Board's review of a proposal that they have submitted, sponsored, or in which they otherwise have a direct conflicting interest, except to provide information requested by the IRB.

The IRB may, in its discretion, invite individuals with competence in special areas to aid the review of issues which require expertise beyond that available on the IRB. These individuals may not vote with the IRB.

Departmental Coordinators

The IRB will work with academic departments to support departmental efforts to oversee research with human subjects conducted by faculty and students .

Departments are encouraged to select a faculty member(s) to serve as a Departmental Coordinator of Human Subjects Research. Until the proposed faculty member has been selected and trained, all human subject research proposals from the department must be submitted to the 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.

Departmental Coordinators are ex officio members of IRB and may be invited by the IRB Chairperson to attend a particular meeting, but, in general, they are non-voting members and do not attend IRB meetings on a regular basis, except in cases where they are selected by the IRB chairperson to replace a board member. At the beginning of each academic year, the IRB Chairperson will call a meeting of these ex officio members to review the criteria for classifying proposals (as exempt, expedited, or requiring full review by the IRB) and for reviewing training requirements. IRB will consult with Departmental Coordinators throughout the year and receive a report of proposals reviewed annually. Departmental Coordinators must employ forms substantially similar to those used

by the IRB and must follow the same record keeping requirements. In the event that the Departmental 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, in accordance with federal guidelines and discipline-specific ethical standards.

VIII. Training of IRB Members and Departmental Coordinators

All Muhlenberg College IRB members (voting and ex-officio, including Departmental Coordinators) are required to complete OHRP approved training and to provide documentation of completion to the IRB Chair. All IRB members are expected to have familiarized themselves with 45 CFR, Subtitle A, Part 46, and The Belmont Report and understand the regulations, guidelines, and policies applicable to human subjects research. Once a year, the IRB shall review training requirements in these guidelines, policies and procedures with new members and Departmental Coordinators.

Currently, OHRP supported training programs do not distinguish between the experimental sciences, social sciences and humanities. As the American Historical Association has recently commented, the criteria for OHRP training and assessment demonstrate "a tendency to treat all research as if it was conducted in the experimental sciences."[4] IRB recognizes that research conducted at Muhlenberg is carried out across a wide range of scholarly disciplines applying various types of research methods. For this reason, IRB members and Departmental Coordinators are encouraged to engage in further training that is specific to their professional discipline via workshops, online modules, books, articles, CDRoms, and videos.

IX. Record keeping (adapted from CFR 45 Part 46.115)

The IRB shall maintain the following records (in electronic or hard copy form):
1. Copies of all research proposals (including supporting documentation such as sample consent forms) reviewed; progress reports and renewals submitted by researchers; and reports of injuries to subjects.

2. Minutes of IRB meetings which should be in sufficient detail to show attendance at the meetings, 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.

[4] Letter to the Office of Human Research Protections from the American Historical Association, September 29, 2008. accessed on February 5, 2009 at http://www.historians.org/press/OralHistoryExclusionLetter.pdf.

3. Copies of all correspondence between the IRB and researchers.

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

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. Written procedures for review of research.

The records required by this policy shall be retained for at least 3 years; records relating to research conducted shall be retained for 3 years after completion of the research. All records shall be accessible for inspection and copying by the Institutional Officer and if applicable, the appropriate granting agency official, at reasonable times and in a reasonable manner.