

MIDDLEBURY COLLEGE

POLICY ON PROTECTION OF HUMAN SUBJECTS¹

I. PURPOSE OF THE POLICY

This policy's purpose is to protect human subjects of original research conducted either at Middlebury College or by an employee or student of Middlebury College. It is intended to assure that subjects of research are aware of their rights and protections.

II. WHO MUST COMPLETE A REQUEST FOR APPROVAL OF HUMAN SUBJECTS RESEARCH?

Anyone who engages in scholarly research involving human subjects, either on- or off-campus. This includes:

- Middlebury College faculty and staff;
- Middlebury College students who conduct independent research;
- Researchers not affiliated with Middlebury College² conducting primary research with subjects on-campus; and
- Anyone analyzing unpublished data collected at the college.

Instructors assigning student research as part of a course need not submit a proposal, unless the instructor chooses to invite committee review. Nonetheless, each faculty member engaging in such an instructional activity is expected to maintain professional standards to protect any human subject in accordance with his or her field.

Human subject research is research involving data from or about living human beings. Any discipline may involve human subject research. Sociological, anthropological, and psychological studies usually involve human subjects; biological and historical studies often involve human subjects.

III. DEFINITIONS

anonymous data: data that can never be connected with the person providing them. This can be accomplished by questionnaires that are returned by mail, or questionnaires that are collected by one of a group of subjects, and returned to the researcher. Only questionnaires that fall within the totally anonymous category are eligible for the implied consent.

confidential data: data that can be connected at some point, no matter how brief, to the person providing them. This includes questionnaires that the researcher collects personally from a group of subjects (unless a ballot box or envelopes are used). In this case it is possible to put a specific questionnaire at some point in the pile that would allow the researcher to match the data

¹ Although these policies are influenced by the guidelines of numerous federal regulatory agencies, the Human Subjects Research Committee is ultimately the agency for their creation and oversight. This is because each government agency which has developed such a policy limits its oversight to activities funded by that agency, or to similar activities which might reasonably be expected to influence the behavior of scholars engaging in funded activities. Middlebury College applies a single, comprehensive standard to original research involving human subjects in which there is a potential for harm. This policy shall apply to all original human subject research as defined in section III.

² Visitors to the campus and off-campus scholars engaged in human subjects research involving subjects on campus, do so through the courtesy of an on-campus host and should do so only with the approval of the chair of the HSRC. The host should provide the visitor with appropriate institutional forms including this document and assure that the forms are transmitted to the committee in a timely manner. The host will serve as the primary institutional contact, while the committee will provide institutional approval as necessary.

with a specific respondent if he or she so desired. It also may apply in cases where the researcher is familiar with the handwriting of one or more of his or her subjects.

data: facts, figures, and information. For the purpose of this policy, the term “data” is considered to be material from primary sources analyzed as part of scholarly efforts.

deception: intentionally misleading or providing untruthful information, any concealment, withholding information from participant, trickery, or deceit.

HSRC: Human Subjects Research Committee (see section VI for composition). This is commonly called the Institutional (Internal) Review Board (IRB).

human subject: any specific living person, or information about a living person, who is the subject (participant) or object of study for the purpose of expanding our knowledge or understanding.

minimal risk: Federal guidelines state, “*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.”

naturalistic studies: observations performed without any intervention except the observations themselves.

original research: any activity conducted for the purpose of expanding knowledge or understanding, including the collection and analysis of data from questionnaires, observation, manipulation, sampling, experimentation, *etc.* Research using human subjects, even if it is simply verifying existing hypotheses, theses, theories, or ideas, is considered original research. This includes pilot projects and feasibility studies. Works dealing entirely with properly attributed secondary sources are not considered original research for the purposes of this policy.

Individual student projects (including 500, 555, 600, 700), even if conducted as part of the institutional curriculum, are subject to the same guidelines as other scholarship (*i.e.*, are original research) and require review.

Activities where human subjects perform exclusively for instructional purposes³ are not original research (*i.e.*, are not subject to these reviews).

Data gathering for the purposes of fundraising by the external affairs offices; market research for the purposes of admissions recruiting; recruiting efforts for faculty or staff; statistical data collected for the management of institutional affairs; and attitudinal research of alumni, students, or parents are excluded from the category of original research under the purview of this committee.

principal investigator: the primary person conducting the research. The principal investigator can be a professional or a student.

review: a process of oversight resulting in an acknowledgment of the status (“approved,” “pending required amendments,” or “not approved”) of a project under the guidelines of this policy.

risk: potential for physical, psychological, social, or financial harm.

unreasonable harm: any physical, psychological, social, or financial damage or injury, which might have been avoided without sacrificing the goals of the activity, as well as any damage or

³ Any publication issuing from the research precludes this exemption.
Page 2 of 9

injury whatsoever whose extent can not be justified by the contribution of the research to the expansion of human understanding.

IV. GENERAL PRINCIPLES

All researchers conducting original research are responsible for protecting their subjects from the risk of unreasonable harm.

The principal investigator has initial responsibility for determining whether such a risk exists. A faculty member is responsible for supervising research undertaken by students in the context of his/her courses or departmental/program curriculum.

If there is any doubt about risks, or if the research involves any of the circumstances outlined in *V.B.* or *V.C.* below, the principal investigator should contact the HSRC chair or a member of the HSRC.

The principal investigator should refer to and follow the guidelines of the relevant professional organizations and, where appropriate, those of governmental funding and regulatory agencies. Faculty members supervising student research have a responsibility for introducing the students to Middlebury College's guidelines.

At the minimum, research activities should conform to the following.

1. The principal investigator has a certificate on file with the Human Subjects Review Committee showing that they have completed the National Institutes of Health Human Participant Protections Education for Research Teams. (<http://cme.nci.nih.gov>)
2. Subjects should be made fully aware of any risks.
3. The principal investigator shall explain to subjects, prior to their participation, the objectives of the research, the procedures to be followed, and the risks and potential benefits. In general this explanation should also be offered in writing. Investigators shall not use individuals as subjects unless satisfied that the subjects, or others legally responsible for the subject's well being, freely consent to participation with a full understanding of the consequences. The Human Subjects Review Committee may waive these requirements only if **all** of the following three criteria are met.
 - a) The committee is persuaded that the research cannot otherwise be done.
 - b) The committee is convinced that the potential value of the research outweighs any potential risks to the subject.
 - c) The research involves minimal risk.

In general, subject consent is indicated in writing on an "informed consent" form. Please note that written consent is required even for totally anonymous questionnaires

4. If the data gathered by a student researcher is not anonymous, the faculty research sponsor should ensure that the data are properly archived or destroyed. The HSRC recommends that student data be turned over to the faculty sponsor, who would then become responsible for either ensuring that it is destroyed, or for archiving it with his or her data, in cases where it is related to the faculty member's research. In a case where a student is planning to go on to graduate school, and may want to continue the research or use the data in future projects, he or she may petition to retain the data. Permission would be contingent upon agreement to protect the confidentiality of the data.
5. Investigators shall respect the privacy of their subjects. Investigators shall protect confidential information given them, advising subjects in advance of any limits upon their ability to ensure that the information will remain confidential.

6. Subjects, including students who are participating in classroom experiments or faculty scholarship, shall not be induced to participate by means or in circumstances that might affect their ability to decide freely. When course credit is offered for participation in research, some other mechanism to “earn” that credit must also be made available to those students who choose not to participate as human subjects. Rewards for participation should be in line with the burden imposed by participation.
7. It shall be made clear to subjects that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw shall be allowed to do so promptly and **without** penalty or loss of benefits to which any subject is otherwise entitled. At the minimum, this shall be clearly stated as part of the informed consent statement.
8. Teachers who assign or supervise research conducted by students are responsible for ensuring that these students are qualified to safeguard adequately the well being of the subjects.
9. Subjects of human research are generally provided the opportunity of access to the benefits of that research at its conclusion.
10. An investigator shall disclose to a subject, upon request, the source of support for the research.

V. PROCEDURES

Research using human subjects falls into one of three categories: Level I: Exempt (no foreseeable risk), Level II: Expedited (minimal risk), and Level III: Full Board (more than minimal risk and protected subjects). The Human Subjects Review Committee Chair will determine which level of review is necessary for a given project. All original research must be submitted for HSRC review and approval.

The Human Subjects Review Committee will review a list of all projects initiated or completed at the College or by College employees at least once a year.

Submit for approval: Submit two copies of the following to the HSRC Coordinator (Trish Dougherty, BIH 412):

- The Request for Approval form
- The full protocol and/or any relevant grant application(s)
- Copies of any source instruments (e.g., questionnaires, interview scripts, manipulation protocols, debriefing forms, *etc.*) please provide translations if these are not in English.
- A proposed informed consent document or narrative.
- Your NIH certificate of completion (<http://cme.nci.nih.gov>).
- Approval of a human subject research proposal is good for one year, unless the project has acceptable but potential risk, in which case approval is given for a six-month period. If the project will continue beyond the approval period, Principle Investigators are required to resubmit documents for review prior to the expiration date of the initial approval. These documents should include a status report of the project to date including:
 - The number of subjects accrued;

- A summary of adverse events and any unanticipated problems involving risks to subjects or others and withdrawal of subjects from the research or complaints about the research since the last review;
- A summary of any relevant amendments or modifications to the research since the last review;
- Any other relevant information, especially information about risks associated with the research; and
- A copy of the current informed consent document and any newly proposed consent document.

In the initial approval letter, principle investigators are asked to promptly report any unanticipated problems or adverse effects of the research to the Human Subjects Review Committee.

Appeals: In the event that an application is denied because the Human Subjects Review Committee feels the risks outweigh the benefits of the research, and the investigator disagrees with the committee's disapproval decision, the researcher may appeal the decision by re-submitting the *same* application form and: 1) a letter of appeal presenting the researcher's arguments for approval; and 2) any other pertinent information in support of the appeal. The letter should be directed to the Chair of the Committee and mailed with enclosures to Trish Dougherty, HSRC Coordinator, Bicentennial Hall 412. Applications submitted for appeal will be considered by the full board at the next scheduled meeting date. The final decision of the HSRC will be stated in writing to the investigator. If the proposal is not approved, the research cannot be conducted.

The researcher may at any point submit a revised proposal, which will be reviewed as a new application.

Nature of the College Records: The College keeps records of all original human subjects research on the Review Form, along with copies of any research documents (informed consent forms, questionnaires, interview scripts, stress protocols, behavioral manipulation protocols, drug protocols, non-FDA device protocols, debriefing forms, *etc.*), and a copy of any publication resulting from the research. Part A and Part B of the Review Form are signed by the researcher and co-signed by a faculty sponsor if the PI is a student. The Cover Sheet (Part A) should also identify the Human Subjects Research Committee members who have performed the review. The aforementioned documentation constitutes the full College records of any project approved by the Committee.

A) Level I: Exempt Research and Review (no foreseeable risk)

Nature of the Study: Research activities involving "no foreseeable risk" and in which the only involvement of human subjects will be in one or more of the following categories:

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:**

- a. information is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects; **and**
 - b. any disclosure of the human subjects' responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation.
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
- a. the human subjects are elected or appointed public officials or candidates for public office; **or**
 - b. Federal statute(s) require(s) without exception that the confidentiality of 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 that subjects cannot be identified directly or through identifiers linked to the subjects
5. Research and demonstration projects which are conducted by or subject to the approval of the Department or Agency heads and which are designed to study, evaluate, or otherwise examine;
- a. public benefit or service programs;
 - b. procedures for obtaining benefits or services under those programs;
 - c. possible changes in or alternatives to those programs or procedures; **or**
 - d. 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,
- a. if wholesome foods without additives are consumed **or**
 - b. 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.

<p style="text-align: center;">EXCEPTIONS TO LEVEL I: EXEMPT RESEARCH—PROJECT AUTOMATICALLY MOVES TO A LEVEL II: EXPEDITED OR III: FULL BOARD REVIEW</p>

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| <ol style="list-style-type: none">1. Research involving subjects under 18 years of age when survey, interview, or participant observation methods are used (participant observation is any observation that entails interaction between an investigator and a subject);2. Prisoners, pregnant women, people not competent to provide informed consent, or fetuses;3. Use of tissue from autopsy;4. Use of personal records such as health care information, drug and alcohol treatment records, psychiatric treatment records, educational records, and other records protected by the Federal Privacy Act and other federal and state laws. |
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Nature of the Review: Review is conducted by the HSRC chair.

B) Level II: Expedited Research and Review (minimal risk)

Nature of the Study: Research activities involving “no more than minimal risk” and in which the only involvement of human subjects will be in one or more of the following categories:

1. Collection of hair and nail clippings, in a non-disfiguring 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 non-invasive 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 8-week period and no more often than two times per week, from subjects 18 years of age or older and who are 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 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.

Nature of the Review: Two members of the committee (usually including the chair) review the documentation presented with the proposal. Recommendations for improvements are sent in writing (electronic text is acceptable as long as a paper copy is kept for the records of the institution). Questions of clarity require a written response from the researcher (electronic text is acceptable as long as a paper copy is kept for the records of the institution).

C) Level III Research and Full Board Review (more than minimal risk and protected subjects)

Nature of the Study: Research published with the identity of the subject, photographs, video or audio recordings, invasive collection of body fluid (lymph and blood —except blood from healthy adults) or tissue samples, manipulative observations including deception, or stressful physiological recordings fall into this category. Research involving subjects

under the age of 18, subjects unable to provide informed consent due to cognitive impairment, and subjects who are under the professional care of the researcher, fall into this category. Procedures which are potentially harmful to the subjects (even if the researcher views the harm as not unreasonable) are also subject to Level III: Full Board review.

Nature of the Review: At least three members of the committee (including the chair and the representative from the public), review the documentation presented with the proposal at a scheduled meeting of the committee to which all members have been invited. Recommendations for improvements may be sent in writing (electronic text is acceptable as long as a paper copy is kept for the records of the institution) or the committee may choose to meet with the researcher as appropriate. Questions of clarity require a written response from the researcher (electronic text is acceptable as long as a paper copy is kept for the records of the institution). Minutes from any face-to-face meeting become part of the permanent record of the committee.

VI. HUMAN SUBJECTS REVIEW COMMITTEE

Composition: the Human Subjects Research Committee will have a minimum of five members including

- a member of the Psychology Department
- a member of the Sociology-Anthropology Department
- a member whose primary concerns are in non-scientific areas
- a representative from the public without active ties⁴ to the College or to the organization sponsoring the research.
- an administrator (ex officio)
- an alternate

The chair of the committee is appointed by the administration of the College. Records of the committee are stored in the office of the committee's coordinator, Trish Dougherty, Bicentennial Hall 412. All members of the committee must complete training as specified by the committee chair.

Institutional members of the Human Subjects Review Committee are appointed by the Committee on Committees and serve from September through August with the understanding that, although the committee does not typically meet during June, July, and August, members may be contacted during the summer months if the need arises.

The community member representative of the Human Subjects Review Committee is invited by the Dean of the Faculty to serve on a yearly basis. The community member may serve as many consecutive terms as he or she is invited and willing.

Procedures: The Human Subjects Research Committee exists as a standing committee. The committee reviews Level I: Exempt and Level II: Expedited proposals every two weeks

⁴ People with active ties to the College include employees, students, and alumni of the College. Spouses, parents, or offspring of employees, students, or alumni of the College should decline to serve as members of the committee if they feel they will be biased by their relationship to such individuals. In such cases where a spouse, parent, or offspring of an employee or student of the College serves as a member of the Human Subjects Research Committee, that person should be replaced by another community member in the deliberations about particular cases where a conflict of interest might exist.

and Level III: Full Board proposals once a month. A majority of the committee members must be present to constitute a quorum. They may only act in the case of a Level III: full board review on materials distributed one week before the scheduled meeting or by the unanimous consent of the entire committee. The action of the committee is generally by consensus; if there is no consensus, the committee will decide in favor of the major opinion. If the committee is split, the administrator will vote.

The human subjects research committee as informed by the guidelines and regulations of various government agencies will be the author of these policies and shall change these policies only by consensus at official meetings of that body.

Applicants should submit in advance of the committee meetings appropriate materials documenting original human subjects research (see above) to the HSRC Coordinator (Trish Dougherty, BIH 412). Forms are available from Trish Dougherty (x5970) or the Human Subjects web site, <http://www.middlebury.edu/~hsrc>.

This Policy was reviewed and revised by the immediate past, Michelle McCauley, and incoming, Carlos Velez, chair of the committee in August of 2002.