Middlebury

Policy on Protection of Human Subjects

I. Purpose of the Policy

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

Although these policies are influenced by the guidelines of numerous federal regulatory agencies, the Middlebury Institutional Review Board is ultimately the agency for creating and overseeing them.

Middlebury applies a single, comprehensive standard to original research involving human subjects. This policy applies to all original human subject research as defined in section III.

II. Who Must Complete A Request for Approval of Human Subjects Research?

Anyone formally affiliated with Middlebury (faculty, staff, students) who engages in scholarly research involving human subjects, either on- or off-campus, must apply for IRB approval.

Researchers who are not affiliated with Middlebury but want to conduct research with human subjects on campus also must have their research reviewed by the IRB unless it has been approved by another federally registered IRB, in which case an authorization agreement may be signed to avoid duplicate review. If no one affiliated with Middlebury is engaged in the research and the investigator already has IRB approval, an administrative review may be conducted (in order to ensure all the necessary documents are on file), at the Chair's discretion.

Finally, anyone using unpublished data from human subjects that was collected at Middlebury must submit their research protocol to the IRB for approval.

Faculty teaching courses in which the curriculum consists substantially of independent student research with human subjects should contact the IRB to determine if each student engaged in research should submit a protocol to the committee.

Students who conduct research as part of a regular course assignment 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 their field.

"Human subject research" involves systematic collection of personal or private data from living human beings. Please see Section III, Definitions, for additional markers of research that falls under the purview of this committee. Any scholarly discipline may involve human subject research. Sociological, anthropological, and psychological studies often involve human subjects; biological studies sometimes involve human subjects. Increasingly, research in the humanities involves human subjects.

All faculty and students are urged to evaluate their research agendas in light of this policy in order to determine whether or not their research qualifies as "human subjects research," even if human subjects or concerns regarding human subjects are traditionally not common in their disciplines.

III. Definitions

anonymous data: data that by virtue of the method of collection can *never* reasonably be connected with the person providing them. Anonymous data can be obtained by using questionnaires that are returned by mail (in envelopes with no return address or other identifying markers), questionnaires that are collected by one of a group of subjects and returned to the researcher, or internet surveys (with software that renders it virtually impossible to connect answers with respondents). Questionnaires that collect data anonymously do not require separate written consent; consent to use the data is implied when the respondent completes the questionnaire (a statement that explains this principle should be printed at the beginning of any such survey). *See also non-anonymous data.*

confidential data: non-anonymous data that a human subject gives an investigator with the understanding or assumption that the human subject's privacy will be honored. Divulging the source of non-anonymous data to an outside party, or failing to ensure that no outside parties will be able to connect data with their source, normally constitutes a violation of confidentiality. This IRB presumes that all data collected from human subjects is properly considered confidential, unless subjects have explicitly waived their presumption of confidentiality in writing.

deception: intentionally misleading or providing untruthful information; any concealment or withholding of information from a participant; use of trickery or deceit.

human subject: a living individual about whom an investigator (whether professional or student) conducting research: 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g. 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g. medical record). Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Experts sharing facts or professional opinions in the area of their expertise are *not* considered human subjects for the purposes of this policy.

IRB: the Institutional Review Board. Middlebury's IRB is responsible for the ethical oversight of all research involving human subjects conducted by Middlebury faculty, students, or staff, as well as such research conducted on any of the Middlebury campuses by outside investigators.

non-anonymous data: data that, by virtue of how it is collected or the nature of the information, can be connected at some point, no matter how brief, to the person providing them. This category includes questionnaires that the researcher collects personally from a group of subjects (unless a ballot box or envelopes are used). It also may include cases in which the researcher can recognize the handwriting of one or more of their subjects and could therefore potentially match the data with a specific respondent. *See also anonymous data.*

oral history: a method of gathering and preserving historical information through interviews with participants about past events and ways of life. Oral history is not subject to IRB review if the researcher does not seek to generalize to a larger population beyond the oral history case study. Researchers using oral history methods should follow the ethical guidelines of the Oral History Association, available at http://www.oralhistory.org/do-oral-history/principles-and-practices/

research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (i.e. designed to draw general conclusions, inform policy, or generalizable findings beyond the people, programs, or organizations being studied). Research using human subjects, even if it is done simply to verify existing hypotheses, theses, theories, or ideas, is considered original research.

For the purposes of this policy, the following are *not* considered "research" and thus do not fall under the purview of the IRB:

- Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus only on the specific individuals about whom the information is collected
- works that deal entirely with secondary sources (public data sets are considered such secondary sources)

- activities in which human subjects perform exclusively for instructional purposes (though the intent or effort to publish data from such activities—at any time—converts these activities to original research involving human subjects)
- 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
- information collected for entertainment purposes

Individual student research projects (e.g. at the Vermont campus: 500, 600, 700; at the Middlebury Institute of International Studies: DPPG 8616, DPPG 8698, IEMG 8699, LING 9640, TIAG 8645), 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.

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

risk: potential for physical, psychological, social, or financial harm. Anonymous surveys often constitute no-risk research. By contrast, *minimal risk* means that some potential for harm exists, but that the probability and magnitude of harm 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.

unreasonable harm: any physical, psychological, social, or financial damage or injury that can be avoided without sacrificing the goals of the research. Unreasonable harm also includes any damage or injury so extensive that it cannot be justified by any contribution the research might make to 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 their courses or departmental/program curriculum. If there is any doubt about risks, the principal investigator should contact the IRB chair or a member of the IRB.

The principal investigator must complete training in the ethics of research with human subjects, either via the online Collaborative Institutional Training Initiative (CITI) Social/Behavioral Research course or an equivalent that the IRB deems acceptable. PIs should follow the guidelines of the relevant professional organizations and, where appropriate, those of governmental funding and regulatory agencies. Faculty members supervising student research are responsible for introducing the students to Middlebury's guidelines.

At a minimum, research activities at Middlebury should conform to the following standards:

1. Informed consent: The principal investigator must explain to subjects, before they participate, the objectives of the research, the procedures to be followed, the associated risks, and the potential benefits. Investigators must not use individuals as subjects unless they are satisfied that the subjects, or others legally responsible for the subjects' well-being, freely consent to participating and fully understand the consequences.

In general, subjects should signal their agreement to participate by signing a *written* consent form, though a researcher may make the case for using oral consent instead. The requirement for written consent *may* be waived under one of the following conditions:

- the research involves no or only minimal risk
- the consent form will be the only evidence linking the subject and the research, and the primary risk of harm is to the subject's privacy

Broad consent may be obtained in lieu of informed consent for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Anonymous surveys do *not* require written consent, though the explanations of the research protocol that are standard on a written consent form should be included at the beginning of the survey. Consent to participate is implied when a subject completes and returns the survey.

Research involving *deception* compromises a subject's ability to give truly informed consent. The Institutional Review Board will consider requests to waive some of the requirements for informed consent for research that intentionally involves deception, but only if *all* of the following criteria are met:

- The research cannot be done without the deception.
- The potential value of the research outweighs any potential risks to the subject.
- The subjects are informed of the true nature of the research as soon as possible.
- The research involves no more than minimal risk (federal requirement).

2. Confidentiality: Investigators must respect the privacy of their subjects. Investigators must protect confidential information given to them and must advise subjects in advance of any limits on their ability to ensure that the information will remain confidential.

If the data gathered by a student researcher is not anonymous, the IRB recommends that the data be turned over to the faculty sponsor, who then becomes responsible for either ensuring that it is destroyed or archiving it with his or her data. In cases in which 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 request permission from the IRB to retain the data. Permission is contingent on the student's agreement to protect the confidentiality of the data.

3. Coercion: Subjects, including students who are participating in classroom experiments or faculty scholarship, must not be induced to participate by means or in circumstances that might affect their ability to decide freely. When course credit is offered for participating 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 participating should be in line with the burden imposed by participating, to avoid presenting an undue influence on a person's ability to freely choose to participate (or not).

Researchers must inform subjects that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw will be allowed to do so promptly and without penalty or loss of benefits to which any subject is otherwise entitled. At the minimum, this condition must be clearly stated as part of the informed consent statement.

4. Disclosure: An investigator must disclose to a subject, upon request, the source of support for the research.

V. Composition of the IRB

The Institutional Review Board is a standing committee with a minimum of seven members, including:

- a member of the Psychology Department
- a member from either the Sociology or Anthropology Department, on a rotating basis
- a member whose primary concerns are in non-scientific areas
- a representative from the public without active ties[*] to Middlebury or to the organization sponsoring the research
- two faculty members from MIIS (any discipline)
- an administrator (ex officio)

The chair of the committee is appointed by the Middlebury administration. Records of the committee are stored electronically. The IRB is staffed by the Associate Director for Research Compliance.

Institutional members of the Institutional Review Board 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

[*] People with active ties to Middlebury include employees, students, and alumni. Spouses, parents, or offspring of employees, students, or alumni of Middlebury 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 Middlebury serves as a member of the Institutional Review Board, that person should be replaced by another community member in the deliberations about particular cases where a conflict of interest might exist.

during the summer months if the need arises. The community member representative of the Institutional Review Board is invited by the Dean of the Faculty to serve on a yearly basis. The community member may serve as many consecutive terms as they are invited and willing. All members of the committee must have certification of training regarding research with human participants within the past four years from the start of their term with the board.

VI. Procedures for IRB Review

Research using human subjects falls into one of two review categories:

> **Minimal risk:** Research that involves only minimal risk (see definition above) can be reviewed by: 1) the Chair, 2) the Chair's designee, or 3) the Chair plus another IRB member, at the Chair's discretion. Examples of research that may qualify for minimal risk review:
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> - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
> - Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if subjects cannot be readily identified and/or disclosure of their responses does not place them at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation.
> - Research involving benign behavioral interventions (e.g. having subjects play an online game, solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else) that are brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact, and there is no reason to think subjects will find the interventions offensive or embarrassing.
> - Secondary research uses of identifiable private information or identifiable biospecimens, if the identifiable private information or identifiable biospecimens are publicly available, and information is recorded so that the identity of subjects cannot be readily ascertained.
> - Collection of physiological data through noninvasive procedures (not involving x-rays, anesthesia, or sedation) routinely employed in clinical practice or that use FDA approved medical devices (e.g. MRI, MEG, EEG, VO_2 max testing).
> - Storage or maintenance (repository) of identifiable private information or identifiable biospecimens for potential secondary research use.
> - Collection of data from voice, video, digital, or image recordings made for research purposes
> - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
> - Minor changes to previously approved research.

More than minimal risk: Research that falls into at least one of these categories, must be reviewed by the full board of the IRB:

- presents more than minimal risk
- involves deception, unless the subject authorizes the deception through prospective agreement (i.e. the subject is told)
- involves subjects from a group awarded special protections, such as children or prisoners (note that minimal risk research projects that include, but do not target pregnant women, are NOT considered to include vulnerable subjects)

The Institutional Review Board Chair determines which level of review is necessary for a given project. This means that **all research proposals involving human subjects must be submitted for IRB review and approval.**

New protocol applications, amendments, and annual check-ins are all completed through Axiom Mentor. Applicants will log in to Axiom Mentor (with their Middlebury credentials).
No application can be submitted without the following attachments:

- a research protocol
- a certificate or certificates that is no greater than four years old at the time of the submission to show that all researchers on the project who will have access to identifiable data or who will interact directly with subjects, have completed the online Collaborative Institutional Training Initiative (CITI) Social/Behavioral Researchers module or or other equivalent training approved by the IRB.
- copies of any source instruments (e.g., questionnaires, interview scripts, manipulation protocols, debriefing forms, etc.), translated if these items are not in English
- a proposed informed consent document or script
- for students, an email from the researcher's faculty advisor certifying that the advisor has read and approved the research protocol

An application may also include these attachments as appropriate:

- evidence of permission from cooperating institutions (if any)
- any relevant grant application(s)
- non-disclosure or other agreements with owners of restricted data sets
- for renewals and extensions, a status report

Hard copy applications are not accepted.

Applications are acknowledged by email to the PI (and the PI's advisor, if the PI is a student) immediately upon submission. Minimal risk proposals typically are reviewed within one to two weeks; full board proposals are reviewed once a month.

Applications that require full-board review are distributed to the Board by IRB staff at least one weekbefore each meeting. A majority of the committee members must be present to constitute a quorum at a convened meeting. They may act in the case of a full board review only on applications submitted at least one week before the scheduled meeting or by the unanimous consent of the entire committee. The committee generally acts by consensus; if consensus cannot be reached, the committee decides in favor of the major opinion.

The initial approval letter sent to the principal investigator must ask the PI to promptly report to the Institutional Review Board any unanticipated problems or adverse effects that the PI encounters in the process of completing the research.

Researchers whose applications are not approved by the IRB will be provided a list of the concerns cited by the committee. Normally such researchers will be invited to respond, revise, and resubmit their application for a new review.

Continuing Review: The IRB assigns the approval period at intervals appropriate to the degree of risk. In most cases, minimal risk research will not be subject to annual review by the IRB. However, at its discretion, the IRB may require continuing review of studies that meet certain criteria, including, but not limited to the following: inclusion of vulnerable populations, criminal behavior, substance abuse and/or mental health data, involvement of external sites (e.g. secondary schools). The approval period will be indicated in the approval letter. If continuing review is required, the principal investigator must submit, before the date indicated in the approval letter, 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
- a copy of the current informed consent document and any newly proposed consent document

Appeals: If an application is denied because the Institutional Review Board 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 writing a letter of appeal presenting the researcher's arguments for approval with any other pertinent information in support of the appeal. The letter should be directed to the Chair of the Board and emailed with enclosures to irb@middlebury.edu. Applications submitted for appeal are considered

by the full board at the next scheduled meeting date. The final decision of the IRB is delivered in writing to the investigator. If the proposal is not approved, the research cannot be conducted.

Nature of Middlebury Records: Middlebury keeps records of all applications for approval of human subjects research, including any research documents (informed consent forms, questionnaires, interview scripts, stress protocols, behavioral manipulation protocols, drug protocols, non-FDA device protocols, debriefing forms, etc.) and documentation of the researcher's research ethics training. The application form is signed electronically by the researcher and (if the researcher is a student) "co-signed" by attaching an email from the faculty sponsor. All email correspondence between the applicant and IRB, including documentation of the final IRB decision, must be retained. The aforementioned documentation constitutes the full Middlebury records of any project approved by the Committee. Copies of the meeting minutes must also be retained. Records are kept for three years after the conclusion of the research.

The researcher is responsible for keeping all data and documentation gathered during the research, including all signed informed consent forms and any publications resulting from the research. In the case of student research, the student's advisor will arrange for this documentation to be stored. These records are also kept for three years after the conclusion of the research unless otherwise indicated during approval.

Human Participant Training

All individuals submitting for project approval for a research project must have a valid training certificate, approved by the IRB, that is no greater than four years old at the time of submission.

VII. Non-Compliance

All researchers conducting human subjects research are expected to comply with the provisions of the IRB-approved study as well as all related federal regulations, Middlebury policies, and state and local laws. Examples of noncompliance include, but are not limited to:

- Failure to obtain IRB approval prior to conducting human subjects research
- Continuation of research activities (i.e. enrolling new subjects, collecting data) after a study has expired
- Failure to obtain informed consent of research subjects
- Failure to follow research procedures as outlined in the protocol that was reviewed/approved by the IRB
- Failure to protect participant privacy and confidentiality (e.g. a breah of personally identifiable information)
- Implementation of changes in research procedures prior to IRB approval

If a researcher becomes aware of any noncompliance with respect to a specific study, a report must be made to the IRB via the IRB email address or anonymously via campus mail (sent to MBH 329). All allegations of noncompliance will be investigated by the IRB, which will determine if the noncompliance is serious or continuing. During the investigation, a fact finding

will be conducted, and if appropriate, a subcommittee will be appointed to further evaluate the noncompliance. The IRB Chair, or if deemed necessary, the fully convened IRB will review the investigation findings and determine whether the noncompliance is serious or continuing and any necessary corrective actions. If serious or continuing noncompliance is found and the study is federally funded, a letter will be sent to the Office for Human Research Protections. In some cases (such as a data breach), the IRB may also notify funding agencies.

VIII. Oversight and Authority

The Middlebury IRB, as informed by the guidelines and regulations of various government agencies, is the author of these policies and shall change these policies only by consensus at official meetings of that body.