Middlebury College

INSTITUTIONAL REVIEW BOARD

Policies and Procedures Manual

Maintained by the Office of Research Compliance

Record of Approval

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1. INTRODUCTION

Middlebury College is committed to the protection of human research subjects. The Middlebury College Institutional Review Board (IRB) was established to protect the rights and welfare of human research subjects. This manual is designed to assist Middlebury College faculty, staff, and students who plan to perform research involving human subjects. The manual describes Middlebury College policies and procedures concerning the involvement of humans in research and the requirements for submitting research protocols to the IRB for approval.

Before any research activity involving human subjects is initiated, a research application must be submitted to the IRB and approved. Research activities include all contact with human subjects, including advertising, recruitment, and screening of potential subjects.

The IRB is a committee that determines and certifies that all research involving human subjects conforms to the regulations and policies set forth by the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), Vermont State regulations, and Middlebury College policies regarding the health, welfare, safety, rights, and privileges of human subjects. The IRB also assists investigators in conducting ethical research that complies with these regulations and policies.

The IRB comprises faculty representatives from various academic disciplines at Middlebury College, including scientists and non-scientists, and a community representative not affiliated with Middlebury College. The IRB operates within federal guidelines concerning the review and approval of research applications involving human subjects. The welfare and dignity of individuals who participate in research is a central concern of everyone involved in protecting human research participants. Middlebury College's primary goal is to have a fair and transparent process in which participants voluntarily decide to take part in a study based on a knowledgeable assessment of the risks and benefits of the research.

Middlebury College administrators, research investigators, and the IRB share the collective responsibility for the ethical conduct of research. This collaboration must exist in a culture of trust, complete openness, and honesty by upholding the highest standards; we build public support to pursue greater knowledge in a safe research environment.

The Middlebury College IRB is here to help you with your human subjects research! If you have any questions or concerns, please do not hesitate to contact us.

2. ACTIVITIES OF THE MIDDLEBURY COLLEGE IRB AND FEDERAL REGULATIONS

The IRB is responsible for reviewing and overseeing human subjects research. The IRB review process is designed to protect the rights and welfare of human subjects by ensuring equitable subject selection, assuring adequate informed consent, assessing and minimizing risks, and maintaining privacy and confidentiality.

Two agencies within the U.S. Department of Health and Human Services (DHHS) share responsibility for IRB oversight: the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). Federal regulations for protecting human research subjects are outlined in *45 Code of Federal Regulations (CFR) 46*. Part A of *45 CFR 46* covers basic policies and is called "the Common Rule." Parts B, C, and D of *45 CFR 46* address additional protections for pregnant women, fetuses, and neonates; prisoners; and children involved as subjects in research, respectively. Many federal agencies and other funding sources have adopted "the Common Rule." Middlebury's IRB Policies have been written to ensure compliance with the Common Rule.

The OHRP's main oversight tools are the registration process and the assurance document. Any institution that intends to conduct DHHS-funded research must have a registered IRB or an association with a registered IRB. The Federal-Wide Assurance (FWA) is an institution's commitment to comply with federal regulations. Middlebury College has an FWA, and the Middlebury College IRB operates under this FWA. The OHRP also conducts site visits.

Other federal agencies that adopt the Common Rule may add specific requirements to these basic regulations. If you propose receiving funding from those agencies, you should check with them and the IRB Office to get information about such requirements. Additional regulations for research involving drugs and devices regulated by the FDA are outlined in *21 CFR 50, 56, 312, and 812*. The FDA's primary mechanism for IRB oversight is the inspection process. The FDA also inspects research sponsors and research investigators. If conducting research that is subject to FDA regulations, please contact the IRB for additional guidance on complying with the specific requirements for FDA-regulated research.

3. ETHICAL PRINCIPLES

Federal regulations protecting human research subjects are grounded in fundamental ethical principles set forth by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The *Belmont Report* encompasses three vital ethical principles: **respect for persons (autonomy), beneficence, and justice.** The Middlebury College IRB adheres to these ethical principles.

4. REQUIREMENT TO 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 as an agent of Middlebury, either on or off campus, must apply for IRB approval. Faculty and staff with at least a nine-month appointment at Middlebury are always considered agents of Middlebury in their research activities. Students are considered agents of Middlebury if one or both of the following are true:

- The student is carrying out the research activity as part of their degree requirements (This includes but is not limited to earning course credit and/or collecting data that will be used for an independent study or senior thesis).
- The research activities are funded in whole or part by Middlebury funds or grant money awarded to Middlebury.

If the student is not an agent of Middlebury and wishes to engage in human subjects research at another institution, then only the IRB requirements (or equivalent) of the other institution need apply. The Middlebury IRB does not need to be involved. If the student is an agent of Middlebury, then the following considerations apply when determining the nature of the involvement of the Middlebury IRB.

Collaborations and Conducting Research at Non-Middlebury Institutions
When Middlebury faculty, staff, or students (who are conducting the work as agents of Middlebury) are conducting research in collaboration with researchers at other U.S. institutions with federally registered IRBs, the research will usually be overseen by one IRB of record, to avoid duplicate review. Other cooperative review agreements are also possible depending on the specific details of the collaboration (see Cooperative Review Agreements in Section 25). Generally, the IRB at the institution that the primary faculty PI is affiliated with will oversee the project. Either a reliance agreement or administrative review by the Middlebury IRB will document which institution's IRB is responsible for ethical oversight of the project. If you are unsure about which IRB should oversee your research, please reach out to the Middlebury IRB to inquire.

What to submit:
- If a federally registered IRB at another institution will oversee the work, please email the Middlebury IRB (irb@middlebury.edu) and provide the approved protocol and IRB approval letter or exempt determination letter. We will work with the other institution's IRB to establish a reliance agreement when appropriate.
- If the Middlebury IRB will serve as the IRB of record, please submit an IRB application via Sitero Mentor with all external collaborators listed. We will work with the other institution's IRB to establish a reliance agreement when appropriate.

Please see International Research in Section 25 for details on IRB oversight when data collection takes place internationally or with international collaborators.

Middlebury Faculty and Staff with Temporary Appointments
Middlebury faculty and staff on less than a nine-month appointment are required to have a faculty or staff co-PI with at least a nine-month appointment at Middlebury in order to submit their research for review and oversight by the Middlebury IRB. Temporary faculty and staff should reach out to the Research Compliance Associate to set up an account in Sitero Mentor that they will be able to access when their Middlebury credentials are not active. Temporary faculty and staff may serve as faculty supervisors for student research, but they must have a co-faculty supervisor who holds at least a nine-month appointment.

Non-Middlebury Affiliated Researchers
If no one affiliated with Middlebury is engaged in the research and the investigator wishes to conduct research on one of Middlebury's campuses, the research must first be approved by another federally registered IRB. The researchers must send the approved protocol and approved letter to the IRB for consideration. An administrative review of the approved protocol may be conducted at the Chair's discretion

if there is sufficient staff availability. Note that these requests may be subject to additional Middlebury policies regarding the use of mass email lists, posting recruitment posters on campus, etc.

Classroom-based Research Activities
Students conducting research as part of a regular course assignment need not submit a proposal as long as the data and results are not shared or presented outside of the class context. Nonetheless, each faculty member engaging in such an instructional activity must maintain professional standards to protect any human subject following their field. See the Class Project policy in Section 8 of this manual for more information.

5. AUTHORITY OF THE IRB

The Middlebury College IRB can approve, disapprove, or require modifications in research activities within its authority, as specified by federal and state regulations and Middlebury College policies. The IRB also functions independently of other committees and makes independent determinations to approve or disapprove the application based on whether human subjects are adequately protected. The Middlebury College IRB has authority over all human subjects research.

Specifically, the Middlebury College IRB has the authority to:

- **Approve, disapprove, or modify studies based upon consideration of the protection of human research subjects.** Research that has been reviewed and approved by the Middlebury College IRB may be subject to further review and disapproval by officials of the Institution. However, those officials may not approve research if the IRB has disapproved it.
- **Require progress reports from investigators and oversee the conduct of the study.** Any approved Full Board Review research is subject to continuing Middlebury College IRB review and must be reevaluated at least annually. The intent is not to interfere with ongoing research but to protect human participants.
- **Suspend or terminate approval of a study.** Middlebury College has the authority to suspend or terminate approval of research not being conducted following the IRB's requirements or 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 Principal Investigator (PI). The suspension or termination of an application will also be reported to the Institutional Official (IO) and any federal funding agency as required by regulations.
- **Conduct post-approval reviews.** The Middlebury College IRB has the authority to conduct post-approval reviews on any application. The review may consist of reviewing documents and activities to determine whether the research is being conducted according to the IRB's requirements (the approved application).
- **Review FDA-Regulated Research.**
- **Determine Investigator Qualifications.** The Middlebury College IRB will review the qualifications of the investigator(s) and study staff and the adequacy of the site where the research will be conducted, when appropriate. This includes any institutional requirements for sponsor-investigator studies, if applicable.
- **Require Source Verification.** In some circumstances, the Middlebury College IRB will determine whether the proposed research requires verification from sources other than the investigator, such as the sponsor or other third parties, that no material changes have occurred since the last IRB review, including the general criteria utilized to make the determination (e.g., complex projects;

investigators with previous compliance issues; continuing review report indicates changes not previously reported; randomly selected projects).

6. HUMAN SUBJECTS RESEARCH

Federal, state, and Middlebury College regulations require the IRB to review and monitor ***human subjects research***. Terms are defined below to help investigators determine if an IRB review of a project is needed. In support of Middlebury College's mission to protect human research subjects and the regulatory consequences of not obtaining IRB review and approval, investigators should consult with the IRB office if they doubt whether a study involves human subjects research.

Research: Federal regulations define research as: "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program that is considered research for other purposes. For example, some demonstrations and service programs may include research activities." 45 CFR 46.102(l)

The following activities are deemed not to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including information collection and use, focus directly on the specific individuals about whom the information is collected.
2. Public health surveillance activities, including collecting and testing information or biospecimens, are conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or manufactured disasters).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. [45 CFR 46.102(l)]

Human subjects: The DHHS regulations define a human subject as "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 biospecimens." [45 CFR 46.102(e)]

Intervention includes both physical procedures (e.g., venipuncture) for obtaining information or biospecimens and manipulations of the subject or the subject's environment for research purposes (e.g. presenting visual stimuli and measuring responses).

Interaction includes communication or interpersonal contact between the investigator and the 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., a medical record).

Identifiable private information is private information for which the subject's identity is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the subject's identity is or may readily be ascertained by the investigator or associated with the biospecimen. [45 CFR 46.102(e)]

Coded private information or biological specimens: DHHS Office of Human Research Protection (OHRP) policy considers private information or biospecimens individually identifiable when they can be linked to specific individuals directly or indirectly through coding systems. The IRB must determine if coded private information or biospecimen(s) constitute research. Investigators do not have the authority to independently determine that research involving coded private information or biospecimen(s) does not involve human subjects.

7. IRB MEMBERSHIP AND MANAGEMENT

IRB Members

Numbers and qualifications of IRB members. The IRB is a standing committee with a minimum of seven members with varying backgrounds to promote a complete and adequate review of research activities commonly conducted by the institution, 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 member who is not otherwise affiliated with the institution and is not part of the immediate family of a person affiliated with the institution.
- Two faculty members from the Middlebury Institution of International Studies (MIIS), any discipline
- An administrator (ex officio)

No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the IRB. At its discretion, the IRB may invite individuals with competence in special areas to assist in reviewing issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence) and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall, therefore, include people knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-

making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

The IRB Chair will serve on the IRB as a member with voting privileges.

IRB membership roster. The IRB Chair maintains the IRB membership roster and works with the ADRC and the RCA to submit a copy of the IRB membership roster to the U.S. Department of Health and Human Services Office for Human Research Protections, along with registration renewals or updates as necessary.

Selection and Appointment. Middlebury faculty members are appointed by the Committee on Committees and serve for one academic year from September 1 through August 31 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 IRB 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.

Alternates and non-voting members may also be appointed by the Dean of the Faculty, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting. Alternate IRB members are matched to primary members with similar member roles (e.g., non-scientist, scientist) and, when applicable, with similar expertise.

Duties. IRB members are responsible for protecting the rights and welfare of human research subjects by reviewing, approving, and monitoring human subject research in a manner consistent with federal regulations, state and local laws, and institutional guidelines and policies. Members must complete the IRB member training through CITI.

Removal. IRB members may be removed or replaced by the Institutional Official, the Committee on Committees and the Dean's Office. Additionally, IRB members may be excused from participation in matters being decided by the IRB for conflict of interest or other reasons.

The IRB Chair

Selection and Appointment. The Middlebury Committee on Committees appoints the IRB Chair, who serves for one academic year.

Duties. The Chair directs the IRB meetings following institutional, state, and federal requirements. The Chair works closely with the IRB members, the Associate Director of Research Compliance (ADRC), the Research Compliance Associate (RCA), institutional officials, and investigators to ensure that the rights and welfare of research participants are protected. The Chair also designates the RCA to send official letters and some IRB-related correspondence on behalf of the Chair.

The Chair carries broad responsibilities and an obligation to:

1. Lead and manage IRB meetings, ensuring they are conducted efficiently and effectively.

2. Guide discussions, ensure all viewpoints are heard, and facilitate decision-making.
3. Make final decisions on approving, modifying, or disapproving research protocols when a clear answer is unavailable.
4. Promote awareness of human subject protection principles.
5. Assist the ADRC and RCA in communicating Conflict of Interest(s) management plans or concerns with Researchers and IRB Members.
6. Review and approve any modifications to research protocols.
7. Assist the ADRC with addressing and resolving complaints, concerns, or incidents related to human subjects research.
8. Encourage feedback from IRB members, researchers, and other stakeholders to enhance the effectiveness of the IRB.
9. Provide ethical guidance to researchers and IRB members on complex issues in human subjects research.
10. Ensure that research participants' rights, welfare, and safety are always protected.
11. Monitor the IRB's compliance with federal, state, and institutional regulations and policies.

Removal. The Committee on Committees or the Institutional Official may remove or replace the Chair.

Associate Director of Research Compliance (ADRC)

Selection and Appointment. The ADRC is a Middlebury staff position.

Duties. The ADRC is responsible for providing strategic direction and oversight to ensure all research involving human subjects complies with ethical standards and regulatory requirements. This role involves developing, implementing, and updating IRB policies and procedures to align with federal, state, and institutional regulations. The ADRC monitors research activities for compliance, conducts audits, and addresses any non-compliance issues.

The ADRC:

1. Oversees the review process of research proposals to ensure they meet ethical standards and comply with relevant regulations.
2. Ensures all IRB activities comply with federal, state, and institutional regulations and policies.
3. Stays updated on changes in regulations and best practices in human subjects research.
4. Provides training and educational resources to IRB members and researchers on ethical standards and regulatory requirements.
5. Develops and implements IRB policies and procedures to ensure effective and consistent review processes. This includes updating and revising policies as necessary to reflect regulations or changes in institutional requirements.
6. Serves as the primary point of contact between the IRB, researchers, and other institutional entities.
7. Monitors ongoing research projects to ensure compliance with IRB requirements and ethical standards.
8. Addresses and resolve complaints, concerns, or incidents related to human subjects research.
9. Ensures appropriate reporting and follow-up on adverse events or non-compliance.
10. Promotes continuous improvement in IRB processes and practices.
11. Manages compliance with institutional policies on Financial Conflict of Interest (FCOI) for grant-funded (sponsored) research and supports the Institutional Official responsible for Middlebury's Research Misconduct Policy. Including but not limited to developing management plans when

conflicts of interest are found among IRB members and researchers and when the COI cannot be avoided.

Research Compliance Associate (RCA)

Selection and Appointment. The RCA is a Middlebury staff position. The RCA may be appointed as a voting member or alternate member, if deemed sufficiently qualified.

Duties. The RCA is an administrative support staff member responsible for coordinating the privileged and confidential institutional review and approval process of proposed research activities involving human subjects.

The RCA:

1. Manages the IRB inbox, responding to requests for information and forwarding messages for further review, as necessary.
2. Provides administrative support to the IRB Chair and members.
3. Schedules and organizes IRB meetings, including securing meeting space and preparing materials.
4. Ensures all necessary documents are available for IRB members to review before meetings.
5. Prepares and distributes meeting agendas, minutes, and other relevant documents.
6. Coordinates the initial and continuing review of research protocols, amendments, and reports.
7. Ensures timely and efficient processing of submissions to the IRB.
8. Serves as the primary contact for researchers submitting protocols and inquiries to the IRB.
9. Communicates IRB decisions, modification requests, and other correspondence to researchers.
10. Identifies potential conflicts of interest among IRB members and researchers and notifies the Associate Director of Research Compliance.
11. Ensures that conflict of interest policies are followed and any conflicts are disclosed and managed appropriately.
12. Maintains accurate and organized records of all IRB activities, including protocols, consent forms, correspondence, and meeting minutes.
13. Ensures documentation complies with institutional and regulatory requirements.
14. Monitors the IRB's compliance with federal, state, and institutional regulations and policies.
15. Assists in preparing and submitting required reports to regulatory agencies.
16. Assists in developing and delivering training programs for IRB members and researchers.
17. Guides researchers on IRB processes, policies, and regulatory requirements.
18. Tracks the status of all research protocols, including submission, review, approval, and continuing review.
19. Generates reports on IRB activities and metrics as needed.
20. Assists the ADRC in developing, implementing, and revising IRB policies and procedures.
21. Ensures IRB members and researchers are informed of any changes to policies or procedures.
22. Participates in quality assurance activities to ensure the IRB's processes are effective and compliant.
23. Assists in the development and implementation of quality improvement initiatives.
24. Assists the ADRC in coordinating the reporting and review of adverse events, unanticipated problems, and non-compliance.
25. Ensures timely and appropriate follow-up and documentation of these events.
26. Acts as a liaison between the IRB, researchers, and other institutional offices.
27. Coordinates with other institutional review boards or regulatory bodies as necessary.
28. Assists the IRB Chair with Exempt determinations when appropriate.

Use of Consultants by the IRB

The IRB is encouraged to use non-member consultants for advice and information in specialized areas as needed. These consultants may be Middlebury College faculty or staff, affiliates, or experts not affiliated with Middlebury College. The consultants may present their assessments in writing, by telephone, or in person.

1. **Identifying the Need for a Consultant.** The IRB may identify the need for a consultant under several circumstances. If a research protocol includes elements requiring specialized knowledge or expertise not possessed by current IRB members, such as specific scientific, medical, or ethical issues, the IRB Chair or a designated IRB member may propose a consultant. Additionally, if during the initial review of a research proposal, IRB members recognize the need for specialized expertise to adequately assess the risks, benefits, and ethical implications of the study, they can request the assistance of a consultant.
2. **Choosing a Consultant.** Once the need for a consultant is identified, the IRB Chair or their designee will seek a qualified individual with the necessary expertise. Potential consultants can be identified from the institution's faculty, staff, or external experts in the relevant field. The consultant must have no conflict of interest with the research study, the investigators, or the sponsoring entities. The IRB will document the selection process, including the rationale for the consultant's expertise and the absence of any conflicts of interest.
3. **Consultant's Participation in the Review of Research.** The consultant's role is to provide expert advice and insight on specific aspects of the research protocol. The IRB Chair or designee will provide the consultant with relevant materials, including the research protocol, informed consent documents, and other pertinent information. The consultant will review these materials and provide a written report or verbal feedback on their findings and recommendations.
   The consultant's feedback will be presented to the full IRB during the convened meeting or shared with the IRB Chair for expedited reviews. The consultant does not have voting rights and will not participate in the IRB's final decision-making process. However, the IRB members will critically consider their expert input in their review and deliberation. Consultants must maintain confidentiality regarding all information related to the research protocols they review and must sign a confidentiality agreement before participating.
4. **Documentation.** All steps to identify, select, and utilize consultants will be documented. This includes identifying the need for a consultant, the selection process, the consultant's report, or feedback, and how this input was integrated into the IRB's review and decision-making process. Documentation will be maintained in the IRB records for the corresponding research study.

8. POLICIES ON CLASSROOM RESEARCH ACTIVITES INVOLVING HUMANS

The purpose of this section is to assist faculty and students in determining when IRB oversight is required for research activities that take place within a class context. All Middlebury College instructors who supervise students in a class-based research activity involving human subjects must have the professional expertise to oversee human subjects research activities and are expected to complete a web-based training on human subjects research protections.

Federal regulations and Middlebury policy require IRB approval for research with human subjects for both student and faculty-led research projects. Human subjects research is defined as a systematic investigation designed to contribute to generalizable knowledge. Some high-impact class projects involve hands-on research activities with human participants that are conducted as educational exercises and are not intended

to contribute to generalizable knowledge. These classroom-based research activities are not shared outside of the class context and are not subject to IRB review and approval.

NOTE: Undergraduate theses and research projects that may be presented outside the class context at a departmental or campus symposium, professional conference, or submitted for publication must undergo IRB review and approval *before* you begin research. If you want the option to present the work outside of the class context, you should submit an IRB application. IRB approval cannot be granted retroactively.

Classroom Project

Classroom Projects: Definition. Middlebury College recognizes that some student classroom projects conducted to fulfill course requirements involve activities that might be viewed as research in another context. Generally, when classroom projects are performed **solely** to fulfill a course requirement, an element of the definition of research is lacking, which is the intent to develop or contribute to generalizable knowledge. Classroom projects with human subjects for which the sole purpose is a student learning experience in the methods and procedures of research do not require the submission of a Human Subjects Research Protocol to the IRB if **ALL** the following conditions are satisfied:

a. The activity is a requirement for a Middlebury College undergraduate course.
b. The sole purpose of the activity is to give students a learning experience in the methods and procedures of research.
c. The instructor is aware of all aspects of the project and takes responsibility for overseeing the project and assuring that ethical principles are adhered to in all project activities.
d. There is no intent on the part of the instructor or student to produce generalizable knowledge, and findings from the study will **NEVER** be disseminated beyond presentation to instructors or peers in a Middlebury College classroom setting. If the possibility exists that the instructor or student would consider disseminating the data as generalizable knowledge (such as presenting the results in a master's thesis or a doctoral dissertation, poster or talk at an academic conference, publication, etc.), then the activity is a research project, and a Human Subjects Research Protocol must be submitted to the IRB **before** any research activities are performed.

Instructors may self-determine that their classroom research activity meets the above conditions, and if so, no submission to the IRB is necessary. The IRB is available to consult with faculty to assist in making this determination. If there is any doubt about whether a classroom research activity requires an IRB submission, the instructor should reach out to the IRB for guidance in advance.

Classroom Projects: Important Considerations for Instructors. Classroom project data may never be shared outside of the classroom setting, such as in a thesis or dissertation, poster, or talk at an academic conference, publication, etc. **The IRB cannot grant retroactive approval for a research project.** Therefore, you must consider submitting a Human Subjects Research Protocol to the IRB before your students begin your project. For example, suppose a classroom project results in essential findings, and you or your students want to present the data at an academic conference. In that case, this will not be possible because the project did not receive review and approval from the IRB before the study was conducted. However, suppose you first submit a Human Subjects Research Protocol to the IRB for your project, which is approved before your students begin the research. You and your students can present or publish the results in that case.

While classroom-based research activities may not meet the requirements for IRB oversight, the Middlebury IRB recognizes the importance of protecting the persons who support student learning by participating in

these research activities. The IRB provides the following recommendations to assist faculty in balancing rigorous pedagogy with the need to protect human participants.

- **Require that students complete training in ethical treatment of human participants.** Faculty members assume responsibility for ensuring that students are appropriately trained in ethical treatment of human subjects and that all activities are conducted ethically. Faculty are free to require students to complete the training available via CITI or to develop and provide their own. *The IRB strongly encourages all faculty leading these types of class projects to complete the CITI training for human subjects research themselves*.

- **Have students collect consent and fully inform potential participants about participation.** Remember that from the participant's viewpoint, participation does not differ for a class assignment or a research project. Instructors should advise students to identify the project to participants as a class assignment and be sensitive to the personal nature of the obtained information. Labeling the class project as "research" is inaccurate and misleading to participants. Information on what to include in a consent form/script is provided below.

- **Only have students conduct minimal risk research**. Do not have participants provide sensitive information (i.e. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation) or conduct research with vulnerable populations. *Research involving greater than minimal risk or vulnerable populations is better suited to more seasoned researchers who have had more training and experience with human subjects research***.**

- **Keep data privacy in mind**. If possible, collect data anonymously. If collecting identifiable information or if using methods that cannot be conducted anonymously (such as interviews), data should be de-identified as soon as possible. Always store the data on platforms accessed using Middlebury credentials (i.e. OneDrive) and delete from student devices. Students should never retain the data they collect. Only the faculty member should retain the data, and it should be deleted/destroyed at the conclusion of the class.

- **Always collect the least amount of information that you need to satisfy the goals of the activity.** For example, if it is not necessary to collect demographic information such as age, gender, etc. to address the goals of the activity, do not collect that information. Video recordings are generally not recommended. Audio recordings should only be collected if necessary to address the goals of the project.

- **Avoid use of deception or incomplete disclosure.** These types of research activities are better suited to more seasoned researchers.

Informed Consent Guidelines

Regardless of the purpose of the activity and whether it is subject to IRB oversight, it is always important to inform potential participants about the nature of the project and what participation will involve. Informed consent for classroom-based research activities should include the following at a minimum:

☐ The identity of the student, that this is a class project, and the purpose of the activity (i.e. "My name is Alex Brown and I am doing a class project for my sociology class at Middlebury College. We are learning about how X relates to Y and this project is designed to help us better understand that.")

- ☐ What the participants will be asked to do (i.e. "I will ask you some questions about XYZ". Or "You will complete an online survey about XYZ" or "You will complete a short task on the computer, and I will measure your responses.")
- ☐ How long participation will take to complete.
- ☐ That they do not have to participate and can stop at any time (i.e. "You do not have to participate, and you can change your mind and stop participating at any time. I won't mind.")
- ☐ Whether they will be identified in the dataset and who will have access to the data (i.e. "I will use a participant ID number instead of your name on all of the data and my notes. All data will be stored in a secure folder accessible only to my professor and me.")
- ☐ What will happen to the data they provide. (i.e. "The information will be used to write a paper for my class. It will not be shared outside of the class. All the data and my notes will be destroyed after the class is over.")
- ☐ The student's contact information and the faculty member's contact information for any questions or concerns.

Recruitment Guidelines

If students will be recruiting participants via social media posts, public forum posts, flyers, or email, the message should:

- Clearly identify the project as something that are completing to fulfill a class assignment with the course name identified
- Include the student and faculty member's contact information
- Contain no misleading information or coercive messaging such as "my grade depends on your participation!"

Student Research Projects

Research conducted for undergraduate theses, Master's theses, Doctoral dissertations, other forms of publication including talks, symposia, and posters at on-campus events and off-campus conferences, usually are intended to contribute to generalizable knowledge and fit the definition of research. These student research projects are subject to IRB oversight and IRB approval is required *prior to* beginning any research activities.

Middlebury College students may serve as the principal investigator (PI) on an IRB application for student-initiated research involving human subjects. However, student-initiated research involving human subjects, whether thesis, dissertation, or other research, must include a Middlebury faculty advisor. Faculty members with a temporary appointment (less than nine months) may serve as faculty advisors for student research, as long as there is a faculty or staff member with at least a nine-month appointment serving as co-advisor.

The faculty member(s) will share full responsibility with the students for all aspects of the protocol and research.

The IRB must review and grant final approval to projects before any research activity or study procedures can occur. There is no retroactive approval for data previously collected for the current study.

9. RESPONSIBILITIES OF ALL INDIVIDUALS CONDUCTING HUMAN SUBJECTS RESEARCH

All faculty, staff, and students associated with Middlebury College who perform research involving human subjects are required to:

- Ensure that all research activities have **IRB approval** and other approvals required by the institution **before human subjects are involved**.
- Complete a web-based training program in human research subject protection.
- Design and implement research that excludes or minimizes risks to human participants.
- Protect the rights and welfare of human subjects who participate in research.
- Understand the ethical standards and regulatory requirements governing research activities with human subjects.
- Personally conduct or supervise the research.
- Ensure that all staff, collaborators, and colleagues assisting in conducting the study are informed about the study, the regulations governing research, and the institutional policies.
- Implement the research activity as the IRB approves it.
- Obtain subjects' informed consent before they are involved in the research and document it as approved by the IRB, unless the IRB has approved a waiver or alteration of consent.
- Maintain written records of IRB reviews and decisions and obtain and keep documented evidence of the subjects or their legally authorized representatives' informed consent, unless the IRB has approved a waiver of documentation of informed consent.
- Obtain IRB approval for any proposed change to the research protocol before its implementation.
- Comply with the IRB requirements for timely reporting of unanticipated problems involving risks to subjects or others, including adverse events, safety reports received from the sponsor, or data safety and monitoring summary reports.
- Obtain continuation approval from the IRB on the schedule prescribed by the IRB.
- Make provisions for the secured retention of complete research records and all research materials.
- Ensure the confidentiality and security of all information obtained from and about human subjects.
- Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions.

10. REQUIRED TRAINING FOR HUMAN SUBJECTS RESEARCH

Middlebury College policy requires all faculty, staff, and students who wish to perform human subjects research to complete a web-based training program in protecting human research subjects. The training is administered through the Collaborative Institutional Training Initiative (CITI) and can be found at www.citiprogram.org. The CITI program is widely accepted as an industry standard among university and college IRBs and by the federal government and other funding agencies. The IRB members are also required to complete CITI training. This policy assures that all individuals performing or reviewing human subjects research receive the training necessary for Middlebury College's compliance with federal regulations. The web-based training program allows individuals to complete the training at their convenience. Initial CITI training is valid for four years. After the initial training period, a refresher course must be completed every four years.

CITI Training is only offered in English and Spanish. For non-English speakers, a fellow researcher may sit with them and go through the training with them. If, for some reason, the investigator is unable to access CITI, another Human Subjects Research Training may be substituted with approval of the ADRC.

The IRB will not approve human subjects research applications until all investigators associated with the project have completed Human Subjects Research Training and provided the IRB with a certificate of completion.

11. INFORMED CONSENT (ADULTS) AND ASSENT (CHILDREN)

Informed consent (of participants 18 years of age and older) is one of the primary requirements of research involving human subjects. Informed consent demonstrates how investigators and those involved in human subjects research show respect to research subjects, and the DHHS and FDA mandate it. It is important to remember that informed consent is an ongoing process, not a single event. Informed consent regulations were developed to:

- protect human subjects.
- ensure that potential study subjects clearly understand the benefits and risks associated with their participation in a study and
- provide potential study subjects with all the information needed to decide whether to participate in a research study.

General Requirements for Informed Consent

General requirements for informed consent, whether written or oral, are as follows:

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether to participate and that minimize the possibility of coercion or undue influence.
3. The information given to the subject or the legally authorized representative shall be in a language understandable to the subject or the legally authorized representative.
4. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have to make an informed decision about whether to participate and an opportunity to discuss that information.
5. Informed consent must begin with a concise and focused presentation of the key information most likely to assist a prospective subject or legally authorized representative in understanding why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. Informed consent must present information in sufficient detail relating to the research. It must be organized and presented in a way that does not merely provide lists of isolated facts but facilitates the prospective subject's or legally authorized representative's understanding of why one might or might not want to participate.
6. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Basic Elements of Informed Consent

In seeking informed consent, the following information shall be provided to each subject or the legally authorized representative:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any experimental procedures;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility the records may be inspected by regulatory bodies when applicable.
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained;
    - The Middlebury College injury compensation clause must include: “Middlebury College has not provided for any payment if you are harmed by participating in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.”
    - In studies that involve greater than minimal risk and are sponsored, include a statement regarding the sponsor's injury compensation policy. The sponsor’s injury compensation clause must be included if the sponsor will pay compensation to injured research participants or treat research-related injuries (Note: Investigator must verify sponsor’s injury compensation clause when sponsor will pay.)
    - If the sponsor does not provide any compensation for injuries related to the research, then include in the Middlebury College injury compensation clause, “Middlebury College and [name of sponsor] have not provided for any payment….”;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
    ii. A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements of Informed Consent

One or more of the following elements of information, when appropriate to the research being proposed, shall also be provided to each subject or the legally authorized representative:

1. A statement that the treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) that are currently unforeseeable. Examples of when the IRB requires this element are:
    - Phase 1, 2, 3, and 4 Drug Trials;
    - Experimental procedures or treatments with limited available data on risks;
2. Anticipated circumstances under which the investigator may terminate the subject's participation without regard to the subject's or the legally authorized representative's consent. Examples of when the IRB requires this element are:
    - If the sponsor may stop the study;
    - If the investigator reserves the discretion to remove the participant from the study;
    - If the investigator may remove the participant from the study should the investigator determine it is in the best interest of the participant;
    - If the participant does not follow study instructions,
3. Any additional costs to the subject that may result from participation in the research. Examples of when the IRB requires this element are:
    - If study procedures result in potential billing to the participant or third-party payers;
    - If participants may have out-of-pocket costs from participation in the research (e.g., parking, meals, transportation);
    - If a possibility exists that a study drug becomes commercially available and no longer provided at no cost to the participant;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. Examples of when the IRB requires this element are:
    - If drug dose tapering is required and has risks to participants;
    - When a follow-up visit or testing is required for safety reasons;
5. A statement that significant new findings developed during the research that may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For biospecimens research, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Middlebury College Informed Consent Form

Informed consent templates, which include the Basic Elements of Informed Consent and Additional Elements of Informed Consent, are available with the IRB submission platform. These are provided to assist researchers in creating consent forms that adhere to all the requirements above.

Requirement to Obtain Signatures

Unless the IRB waives the requirement to document informed consent, the IRB will require that informed consent be documented using a written consent form approved by the IRB. To document informed consent,

the investigator must obtain an individual's written, legally effective informed consent (or, in certain circumstances, the individual's legally authorized representative) **before** the individual can participate or be involved in **any research activities** involving human subjects. This consent form must contain the required elements of informed consent in language understandable to the subject. This form may be read to the subject or the subject's legally authorized representative. However, the investigator should allow the subject or the legally authorized representative adequate opportunity to read the consent document before it is signed.

Because the signed document is a written record of the consent discussion,

- the investigator must retain the **original, signed** document and
- each participant must be given a **copy of the signed** document.

Waiver of Documentation of Consent

In some situations (e.g., telephone or mail survey, internet research, specific international research), the IRB may waive the requirement for obtaining a signed informed consent form. Investigators can request a waiver by requesting a **Waiver of Consent Documentation** when completing the IRB application. Investigators must justify requesting a waiver of the requirement to obtain a signed consent form for some or all the subjects. As per 45 CFR 46.117(c), the IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

1. That the only record linking the subject and the research would be the informed consent form, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. **NOTE:** Documentation of consent cannot be waived for FDA-regulated research that meets these conditions.
2. The research presents minimal risk of harm to subjects and involves no procedures for which written consent is typically required outside the research context.
3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documentation that informed consent was obtained.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Waiver or Alteration of Informed Consent

Some research studies (e.g., medical record review, deception research, collection of biological specimens) would not be possible if some/all elements of informed consent were required from participants. The IRB may consider waiving the requirements for some/all elements of informed consent when the research meets **all the following conditions** (the researcher needs to explain for each condition how it applies to the research):

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects and

5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

NOTE: The investigator must describe the element(s) of consent for which a waiver or alteration will be requested and justify the waiver or alteration. The IRB does not approve a waiver of informed consent for research subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations.

Deception in Human Subjects Research

Research studies occasionally require researchers to deceive subjects or for researchers to withhold specific study details from study participants. Such procedures can be effective tools for the conduct of research; however, they also raise ethical concerns regarding subject autonomy and respect for persons, and regulatory issues regarding informed consent requirements.

The Middlebury IRB distinguishes between deception and incomplete disclosure. Deception involves intentionally providing inaccurate or false information to subjects. Examples include:

- In order to induce stress, study personnel tell subjects that they will give a speech that evaluators will observe on video, when the subjects' speeches will not actually be recorded or observed.
- Study personnel tell subjects that they will be engaged in a cooperative task with other subjects, but instead subjects will actually be interacting with study personnel.
- Study personnel tell subjects that they will play a competitive game involving financial rewards based on their performance. In fact, the game is rigged, and rewards are not based on performance.

Incomplete disclosure involves withholding information about the study purpose and/or reason for procedures, in order to prevent biasing the results. Examples include:

- In order to examine how race and gender impact people's perception of conflicts between individuals, subjects review several hypothetical scenarios describing confrontations between various characters, which include stock photos to represent the individuals involved, and then are asked to complete questions regarding their perception of each of the individuals involved. The subjects are not informed that the race and gender of the characters are manipulated by the researchers, but subjects will know that the scenarios are hypothetical.
- To further understanding of how representations of same sex couples depicted in commercials influence consumer behavior, subjects are exposed to advertisements featuring gay couples and straight couples while their heart rate, facial muscle movement, and sweat responses are recorded. Subjects are informed that their reactions to the commercials are being studied, but not that the researchers are examining if the sexual orientation of characters in commercials influences them.

Incomplete disclosure does not extend to withholding information from subjects about what they will be asked to do. A protocol that informs subjects that they will be asked to complete one 60-minute session but provides no information about the contents of this session would not be considered incomplete disclosure. Protocols that involve manipulating an individual's environment, without that person's prospective agreement to participate in research, are not considered incomplete disclosure. In such cases disclosure to subjects is entirely absent, not merely incomplete.

Protocols that include incomplete disclosure are eligible for exemption, assuming they would otherwise be eligible.

Protocols that involve deception are not eligible for exemption unless subjects are informed, before they agree to participate, that the study procedures include deception (i.e. prospective consent). Protocols that involve deception without prospective consent must request a waiver or alteration of informed consent as described above.

Posting of clinical trial consent form

The National Institutes of Health defines a clinical trial as any research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. This broad definition includes Basic Experimental Studies involving Humans (BESH).

For each clinical trial conducted or supported by a federal department or agency, the awardee or the federal department or agency component conducting the trial must post one IRB-approved informed consent form used to enroll subjects on a publicly available Federal website that will be established as a repository for such informed consent forms.

If the Federal department or agency supporting or conducting the clinical trial determines that certain information (e.g., confidential commercial information) should not be made publicly available on a federal website, the department or agency may permit or require redactions to the information posted.

The informed consent form must be posted on the Federal website after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol.

Requirement to Use Understandable Language

The informed consent document must be in a language understandable to the participant using lay terminology. When recruiting from the general population, the consent form should be written at or below an eighth grade reading level. When the prospective participant is fluent in English, and the informed consent discussion is conducted in English, the consent document should be in English. However, when and if the study population is to include non-English-speaking participants so that the principal investigator or the IRB anticipates that the consent discussion is likely to be conducted in a language other than English, the investigator should address the following criteria in the description of the informed consent process:

1. Describe research and other personnel (e.g., PI, staff, translator) who will conduct the consent procedures/discussion, communicate other information, and be available to answer questions in a language understandable to the participant.
2. Submit translations and back translations of the informed consent documents for targeted populations for review and approval. The IRB strongly encourages the use of a full translation of the entire informed consent document.
    - For international research with local IRB review, this requirement applies to locally approved documents.
    - For the Middlebury College IRB to approve, informed consent documents must include, at a minimum, the required elements of informed consent and the signatures of the participant, or legally authorized representative if applicable, and the person obtaining consent.
4. Provide certification that verifies that the informed consent document has been adequately translated into the non-English language.
5. Provide the qualifications of the individual or the service used to translate the informed consent documents (e.g., credentials, certifications, education, or native language fluency).

6. As part of the informed consent discussion, provide participants with the IRB-approved non-English-language informed consent document and give them an opportunity to read and discuss it with a fluent translator present.

Child Assent

Parental consent is a prerequisite to the recruitment of children (under the age of 18 in Vermont) as human research subjects. In addition to parental consent, assent from the child is also required. Assent is an "agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research."

Assent is generally required if:

1. subjects are minors between the ages of 7 and 17 (children below the age of 7 are generally not asked to provide assent, only the parental consent form is required); or
2. subjects are 18 or older and are intellectually or emotionally impaired and not legally competent to give their informed consent.

The child assent form should be brief and study-specific, with language appropriate to the age ranges and levels of mental development found within the proposed participant population. It should also have a simple format that is easy to read.

The assent form does not replace a thoughtful discussion with the child regarding participation in the research. The assent process should illustrate respect for the child and convey the essential information the child requires to decide about participating in the research.

Assent Form Requirements

During the assent process, the participant should be provided with the following information in understandable language (either as a written form, or through an oral assent process):

1. Study title
2. Study purpose (provide a brief explanation of the purpose of the study)
3. Procedures (describe what the subject is being asked to do)
4. Withdrawal privilege (describe how a subject can stop participation later even if they agree to start)
5. Voluntary participation (include a statement that the subject does not have to participate)
6. Confidentiality statement (indicate that the experimenter will not tell anyone – e.g., parents, teachers – what the subject says or does in the study)
7. Signature lines, for signed assent forms (include a signature line for the subject and the investigator)
8. Date line, for signed assent forms

12. PRIVACY AND CONFIDENTIALITY

Privacy and confidentiality are important issues in protecting human research subjects. They are extensions of the principles of autonomy (respect for persons) and beneficence from the Belmont Report.

Privacy can be defined as controlling the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways inconsistent with the understanding of the original disclosure without permission.

The investigator must describe plans to protect the subject's identity and the confidentiality of the research records. Care should be taken to explain the mechanisms devised to protect the subjects' privacy, such as using numbering or code or safely locked files in private offices. Furthermore, the investigator should describe who can access the data and under what circumstances a code may be broken. Without appropriate safeguards, problems may arise with the long-term retention of records. In special circumstances requiring additional safeguards to prevent potential criminal civil prosecution of the participating human subject, the IRB may require destroying all data that can identify the subjects. Subjects should be informed of whether the collected data will be retained, and if so, for what purpose, what time period, or whether and when data will be de-identified or destroyed.

A special situation arises for video or taped data and photographs since these media provide additional potential means for subject identification. Investigators must secure subject consent explicitly mentioning these practices. They should also explain plans for such records' final disposition or destruction.

Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act "Privacy Rule" (HIPAA) is a federal law that generally prohibits healthcare providers (such as physicians or other healthcare practitioners, hospitals, nursing facilities, and clinics) from using or disclosing "protected health information" without written authorization from the patient.

If an investigator intends to use or release to others (e.g., sponsors, other investigators, collaborators) any identifiable health information concerning their research, they must indicate that in the IRB application. Protected health information is health information transmitted or maintained in any form or medium that includes ALL three following characteristics:

- identifies or could be used to identify an individual; **and**
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; **and**
- relates to an individual's past, present, or future physical or mental health or condition; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

13. TYPES OF IRB REVIEW

The Middlebury College IRB reviews four categories of human subjects research:

1. Exempt Status Review
2. Limited Review
3. Expedited Review
4. Full Board Review

Exempt Status Review

Although this category is called “Exempt,” this type of research requires IRB review and approval. Only the IRB can assign Exempt status to a project. The **determination of Exempt status by the IRB must be made before initiation of the research**; it cannot be made retroactively. After initial approval, an exempt research project does not require continuing review by the IRB unless it is amended so that it no longer meets exemption

status. Although a project may be granted Exempt status, no interaction with human participants is exempt from the ethical principles described in the *Belmont Report*. The principal investigator is responsible for ensuring that informed consent is obtained from human subjects participating in research determined to be exempt.

Exempt research is research with human subjects that falls under one or more of the following six exempt categories listed in the federal regulations (45 CFR 46.104d):

1. Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, as well as research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
    a. The investigator records the information obtained in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects **or**
    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or damage their financial standing, employability, educational advancement, or reputation.
3. Research involving benign behavioral interventions (only for behavioral research, not biomedical research) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
    a. The investigator records the information obtained in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects **or**
    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or damage their financial standing, employability, educational advancement, or reputation.

    Benign behavioral interventions are brief, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, solve puzzles under various noise conditions, or decide how to allocate a nominal amount of received cash between themselves and someone else.

4. Secondary research for which consent is not required: Secondary research uses identifiable private information or identifiable biospecimens if at least one of the following criteria is met:
    a. The identifiable private information or identifiable biospecimens are publicly available;
    b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

c. The research involves only information collection and analysis concerning the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or
d. The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research, was collected subject to the Paperwork Reduction Act of 1995, 44U.S.C. 3501 *et seq*.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list before commencing the research involving human subjects.
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.

Currently, Middlebury does not plan to use the Revised Common Rule (2018 Requirements) Exempt Category 7 or 8.

Federal regulations specify that the following research activities **CANNOT be Exempt**:

1. Research that includes educational tests, survey procedures, interview procedures, observation of public behavior, or benign behavioral interventions, **if the information is recorded in such a way that it can be linked back to the subject either directly or indirectly through the use of a code AND any disclosure of the human subjects' responses would reasonably place the subjects at risk** of

criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
2. Research involving prisoners.
3. Surveys, interviews, or benign behavioral interventions given to children (individuals younger than 18 in Vermont), unless the research activities meet the criteria for Exemption 1, Normal Educational Practices.
4. Observations of public behavior when the investigator participates in the observed activities.

Limited Review

Limited Review research is research with human subjects that falls under one or both of the following two limited review categories listed in the federal regulations (45 CFR 46.104d):

1. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the investigator records the information obtained in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects; any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; and the IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
2. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects; any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; and the IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

   Benign behavioral interventions are brief, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, solve puzzles under various noise conditions, or decide how to allocate a nominal amount of received cash between themselves and someone else.

Expedited Review

If the research presents minimal risk to human participants and falls under one of nine expedited categories listed in the federal regulations, the IRB may determine that it qualifies for an expedited review.

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. ([45 CFR 46.102(j)] and [21 CFR 56.102(i)])

Expedited research is research with human subjects that falls under one or more of the following nine expedited categories in the federal regulations [45 CFR 46.110]:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application (21 CFR 312) is not required.
    b. Research on medical devices for which:
        i. An investigational device exemption application (21 CFR 812) is not required.
        ii. Or the medical device is cleared/approved for marketing and is being used following its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in 8 weeks and collection may not occur more frequently than 2 times per week.
    b. Or from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in 8 weeks, and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Data collection through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples in this category include:
    a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve the input of significant amounts of energy into the subject or an invasion of the subject's privacy.
    b. Weighing or testing sensory acuity.
    c. Magnetic resonance imaging.
    d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.
    e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate, given the individual's age, weight, and health.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for protecting human subjects. This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
    a. Where (i) the research is permanently closed to the enrollment of new subjects, (ii) all subjects have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of subjects.
    b. Or where no subjects have been enrolled, and no additional risks have been identified.
    c. Or where the remaining research activities are limited to data analysis.
9. Continuing review of research not conducted under an investigational new drug application or investigational device exemption where the following conditions apply:
    a. Categories two (2) through eight (8) do not apply, and
    b. The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk, and no additional risks have been identified.

Full Board Review

Research projects that involve more than minimal risk require Full Board Review at a convened meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of the members present. Categories of research that require a Full Board Review include, but are not limited to:

1. Studies with procedures that present more than minimal risk to human subjects.
2. Studies involving subjects likely to be vulnerable to coercion or undue influence, such as research with prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, and some research with children.
3. Studies involving active deception without prospective consent.
4. Studies that fall under the jurisdiction of the Food and Drug Administration.

Exempt, Limited, or Expedited Review

Projects classified as Exempt, Limited, or Expedited will be reviewed according to regulations by a voting board member. Acting as the primary reviewer, this member is responsible for the review and determination for these studies.

If the primary reviewer requests revisions, they will notify the RCA who will then inform the PI. The PI must submit the revised materials to the RCA, who will review them for completeness before forwarding them to the primary reviewer. The primary reviewer will document their review and may request further revisions if necessary.

Upon finalizing the review, the primary reviewer will notify the RCA, who will issue the final determination letter to the PI. In the case of non-exempt research, the RCA will also request chair approval prior to issuing the final determination letter. The primary reviewer does not have the authority to disapprove a project. If the primary reviewer believes the submission is inappropriate for expedited review and cannot approve it, they will recommend that the project undergo Full Board Review. The RCA will ensure that the submission is included on the next Institutional Review Board (IRB) agenda.

Continuing Review

Projects that receive IRB approval following a Full Board Review must apply for a **Continuing Review** at least annually from the initial approval date. Depending on the risks to human subjects, the IRB may require a more frequent review.

After a project is approved, an investigator is not permitted to make any revisions or modifications to an approved project without prior review and approval by the IRB.

Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:

- Research that received Exempt status from the IRB,
- Research approved by the IRB under Limited Review,
- Research approved by the IRB under Expedited Review,
- Research approved by the IRB under Full Board Review if the approved research has progressed to the point that it involves only one or both of the following:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens or
    - Accessing follow-up clinical data from procedures that subjects undergo as part of clinical care.

As a courtesy, the IRB will send Continuing Review reminders to investigators in advance of the project expiration date. However, it is ultimately the investigator's responsibility to initiate a Continuing Review in Sitero Mentor and to allow sufficient time for the review and re-approval process to be completed before the current approval expires.

Study Expiration

All research activities involving human subjects must stop if an IRB-approved project expires. These activities involve subject contact, data collection, and data analysis. As a courtesy, the IRB will send study expiration reminders to investigators in advance of the project expiration date. However, if the research is to continue beyond the expiration date, it is ultimately the investigator's responsibility to initiate a continuing review application or annual check-in, whichever is applicable, and allow sufficient time for the review and re-approval process to be completed before the approval expires.

All projects expire **one year** after the initial approval date. If the research is to continue beyond one year, researchers must submit a check-in report and renewal request or continuing review application, if applicable, prior to the deadline. If the study expiration date passes before a renewal has been submitted, researchers will receive a study expiration notification from the IRB indicating that all research activities must be stopped. Researchers must submit a study closure final report within 30 days of the expiration date or whenever the research activities are concluded.

14. MATERIALS REQUIRED FOR IRB REVIEW AND APPROVAL

Initial Review

The following materials are required for **initial review of all types of research**:

- Completed IRB application (functions as Protocol in most cases)
- Protocol (in addition to the IRB application if applicable)
- Data Collection forms, surveys, and questionnaires (if applicable)
- Recruitment and Screening materials
- Informed Consent Document(s) (if applicable)

The following materials are required if they are applicable to the study:

- Social-Behavioral Research Components
  - Investigator-authored Psychological or Educational Measures
  - Investigator-authored Surveys, Questionnaires
- Biomedical Research Components
  - Investigator's Drug Brochure or Package Insert
  - Device Brochure and/or other device information
- Sponsored Research
  - Detailed Sponsor's Protocol
  - Relevant Grant Applications or Contracts
  - For HHS-supported multi-center trials: HHS-approved Consent Forms and Protocol
- Other
  - Any additional documentation the Investigator deems pertinent

Continuing Review

The following materials are required for continuing review:

- Completed Continuing Review Application
- Any relevant multi-center reports
- Any proposed recruitment and screening materials
- Any proposed Informed consent document(s)
- Any related post-approval reports
- Any additional pertinent documentation

Amendments to Approved Research

The following materials are required for amendments to approved/exempted research:

- Completed Amendment application
- Relevant modified study documents
- Recruitment Materials, Screening Materials, and Consent Documents, as applicable
- Any related post-approval reports
- Any additional pertinent documentation

Post-Approval Reports (Adverse Events, Deviations, Unanticipated Problems, Data Safety Monitoring Board Reports, etc.)

The following materials are required for post-approval reports:

- Completed post-approval report application
- Relevant modified study documents

Non-English Language Translations

- Federal regulations require that informed consent information be presented in a language understandable to participants. Thus, participants who do not speak English should be presented with a consent document written in a language understandable to them.

15. STEPS IN THE IRB APPLICATION AND REVIEW PROCESS

To obtain IRB approval for a human subjects research project, researchers should take the following steps:

1. **Select the type of IRB review required for the project.** A pre-protocol questionnaire with the Mentor platform can help the investigator determine the type of review required. If the investigator has any doubt about the appropriate level of review for a project (Exempt, Limited, Expedited, or Full Board Review), staff are available to aid applicants in making this determination. The final determination of whether the proposed research meets federal criteria for the requested review category will be made by the IRB.
2. **Complete Human Subjects Research Training.** Before the IRB approves an application, all investigators associated with the project must complete Human Subjects Research Training. All investigators should submit a certificate of completion with the IRB application form. Directions for completing the training and obtaining a certificate are provided on the Middlebury College IRB website.
3. **Complete the IRB application form.** The **IRB application in Sitero Mentor** will be used for all projects. A student performing research must complete the IRB application under the guidance of their faculty advisor. The faculty advisor can serve as a co-PI on the IRB application form if they choose. The student's advisor is responsible for guiding the student investigator in the development of the research plan and the conduct of the research project.
4. **Apply to the IRB for review.** Upon receipt of the application, the RCA will pre-review the application for completion before it is submitted to the IRB Chair or assigned primary reviewer for review. An IRB application may be submitted to the IRB office at any time via Sitero Mentor. The IRB will attempt to complete Exempt, Limited, and Expedited Reviews within ten business days of receiving the completed application. Full Board Reviews occur once each month. The meeting dates are posted on the Middlebury College IRB website. To receive a review of a project requiring Full Board Review, the application must be complete and received by the IRB office a minimum of two weeks before the scheduled meeting.
5. **The IRB will notify the researcher of the review's outcome.** The IRB will attempt to notify the researcher of the outcome within five business days of the completion of the review. The IRB will notify the researcher in writing with one of the following outcomes after the application has been reviewed:
    - **Approved**. The application is complete, the risks to subjects are minimal/minimized, and the procedures are appropriate. The IRB approves the research to be conducted. Although the IRB has approved a project, institutional administrative officials may disapprove a project for considerations outside the scope of the IRB.
    - **Approved Pending Modifications**. The application is complete, but some minor issues/changes must be addressed before the project can begin. The review is complete once the IRB approves a satisfactory response to these contingencies.
    - **Revisions Required**. Applications with deficiencies (risk to subjects, unclear procedures, serious omissions, ethical issues, or major contingencies) will not be approved until the deficiencies are addressed. The researcher is sent a memorandum listing the concerns that must be addressed for approval to proceed. The IRB reviews the researcher's response and will approve or defer until all issues are addressed satisfactorily.
    - **Disapproved**. Criteria for IRB approval are not met. Only the Full Board may disapprove of a study. Institutional administrative officials may not override this decision.
    - **Not Human Subjects Research**. Projects that do not meet the definition of *research* and do not involve *human subjects*.
6. **Conduct the research and report to the IRB as necessary.** Once the application is approved, the researcher may begin recruiting subjects and conducting study procedures. The researcher must verify that IRB approval has been obtained from all participating institutions in collaborative

activities with other institutions. During the study, the researcher must submit reports to the IRB if any of the following occurs:

- **Revisions and Modifications to the approved protocol.** Before they are implemented, changes to the originally submitted study must be reviewed and approved by the IRB.
- **Adverse events/effects and unanticipated problems involving risks to subjects or others.** The IRB must be notified immediately if any undue harm results from the study.
- **Complaints regarding human subjects research.** The IRB must be notified immediately if any complaints from the subjects or the study staff are made regarding the research study.
- **Breach of confidentiality.** If any member of the study staff has inappropriately disclosed any personal/confidential data, the IRB must be notified immediately.

7. **Applying for Continuing Review to the IRB.** Projects that receive approval following a Full Board Review must apply for Continuing Review at least once every 364 days from the initial approval date. The IRB may require the Continuing Review to occur more frequently depending on the risk to participants compared to the potential benefits. Applying for Continuing Review occurs in Sitero Mentor.
8. **Submit a final report to the IRB.** The investigator must submit a final report to the IRB **within 30 days** of completing or terminating all research activity.
9. **Maintain secure records of the study.** The investigator will ensure the confidentiality and security of all information obtained from and about human subjects, both during and after the study. The investigator will make provisions for the secured retention of complete research records and all research materials for at least three years after the completion of the study.

16. CRITERIA FOR IRB APPROVAL

Federal policy lists criteria [45 CFR 46.111 and 21 CFR 56.111] that the IRB must apply when reviewing research involving human subjects. To approve a research project, the IRB must determine that the following conditions exist at the time of initial review and each subsequent review conducted by the IRB:

1. Risks to subjects are minimized: (i) By using procedures consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable about 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 the risks and benefits of therapies subjects would receive even if not participating). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the potential effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment, the IRB should consider the purposes of the research and the setting in which the study will be conducted. The IRB should be particularly cognizant of the unique problems of research that involve a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented or appropriately waived.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, adequate provisions protect subjects' privacy and maintain data confidentiality.

17. REPORTING PROJECT REVISIONS AND MODIFICATIONS

All revisions and modifications to a project need IRB approval before they are implemented. Suppose the investigator wants to change anything in the research that would impact the subjects, such as recruitment procedures, key personnel, inclusion/exclusion criteria, research procedures, the informed consent document/process, or data elements collected. In that case, the investigator must obtain IRB review and approval before implementing the changes.

The only exceptions are changes necessary to protect the safety of subjects immediately.

To request revisions or changes to an approved protocol, submit an amendment in Sitero Mentor.

Commonly Reviewed Modifications

The list below includes some common modifications that the Middlebury College IRB reviews:

1. A change in the **procedures of the protocol**, such as:
    - when the inclusion/exclusion criteria change,
    - when the protocol is no longer open for enrollment of new participants,
    - when a sponsor suspends enrollment,
    - when the protocol ends.
2. A change in the **procedures used to recruit or enroll participants**, such as:
    - new or newly revised advertisements,
    - new or newly revised script or questionnaire for screening
    - a change in the circumstances under which informed consent is discussed or obtained,
    - a change in the wording or format of the informed consent document.
3. Changes in **study personnel**, such as:
    - adding or removing an investigator,
    - adding or removing key personnel,
    - adding or removing persons who are involved in the informed consent process,
    - changing the Principal Investigator.

Applying for Modifications

Any planned modification must be submitted to the IRB for review and approval before being implemented or used with participants. Investigators submit an Amendment via Sitero Mentor for review of any change in the protocol, including changes undertaken as necessary to eliminate a hazard. Some modifications require that the investigator include materials in addition to amendment submission. For example, sponsors often initiate modifications in procedures or documents used with participants. In these cases, the investigator also provides the IRB with a copy of all investigator-sponsor correspondence and other documents related to the change.

Change in the principal investigator. The outgoing investigator submits the Project Revision or Amendment Form. In addition, the following written and signed notifications must be submitted:

1. The current Principal Investigator notifies the IRB that they have relinquished the responsibilities of Principal Investigator to the person named or will do so on a specified date.
2. The newly named Principal Investigator notifies the IRB that they have read the protocol and agrees to accept the Principal Investigator's responsibilities.

Changes in the informed consent document. When a modification makes it necessary to change the informed consent document, regardless of whether any participants are enrolled, provide a description of the changes made in addition to the revised consent document.

Addendum informed consent documents. If participants have already signed a consent document and it becomes necessary to inform them of modifications or new information, an addendum informed consent document may be required when:

1. The protocol is open for recruitment and enrollment,
2. some participants are already enrolled, **and**
3. the change might be related to the participant's willingness to continue participating in the study.

OR

1. The protocol is closed to enrollment **and**
2. the change might be related to the participant's willingness to allow the continued use of data from their participation.

The FDA does not require re-consenting of participants who have completed their active participation in the study or who are still actively participating when the change will not affect their participation, for example, when the change is implemented only for subsequently enrolled participants.

Modifications to eliminate apparent immediate hazards to human subjects. In some situations, a serious unanticipated event or adverse event requires an immediate change to an application to relieve an apparent hazard to research subjects. In these situations, the principal investigator may implement a change necessary to protect the welfare of the research subjects. Investigators are encouraged to contact the IRB if this type of situation arises before implementation of the application change if the time taken for notification does not place the subject in danger.

Investigators must notify the IRB in writing of the change within five working days and include a written description of the change and the events that necessitated immediate implementation of a modification to the approved protocol. Notify the IRB of unanticipated or adverse events using Sitero Mentor. Notify the IRB of changes to the protocol that were necessary to eliminate apparent immediate hazards to human subjects.

18. REPORTING RESEARCH-RELATED PROBLEMS

Reportable Problems

Middlebury College policy requires that "unanticipated problems involving risks to research subjects or others" be promptly reported to the IRB, the Institutional Official, the sponsor, and appropriate federal agencies. **In "research subjects or others," others include** investigators, research staff, or other individuals affected by the research project.

In accordance with this policy, the IRB has published a list of problems (below) that investigators must report to the IRB. The Principal Investigator must report the problems listed to the IRB within the indicated

timeframes. The IRB may request further information as necessary and will determine whether any research project associated with unexpected serious harm to the participants must be terminated.

Investigators are responsible for meeting all reporting requirements that apply to their projects. For example, investigators have reporting responsibilities to sponsors of FDA-regulated research. Investigators serving as sponsors of FDA-regulated research have additional reporting responsibilities.

Investigator Reports to the IRB

Adverse events and safety reports that require prompt reporting should be submitted to the IRB using Sitero Mentor. If the event being reported changes the informed consent document, follow the directions in this manual for modifications.

Within five working days. As soon as possible, but in all cases within five working days, the investigator must report to the IRB:

- Any changes to the protocol that were taken to eliminate an apparent hazard to a participant in an emergency.
- Any deviations from the investigational plan for an investigational device to protect a participant's life or physical well-being in an emergency.
- Any emergency use of an FDA-regulated test article or Humanitarian Use Device before IRB approval.
- Any serious adverse event that is related or possibly related to the research, regardless of whether the event occurred at a Middlebury College site or non-Middlebury College performance site**.**

Within ten working days. As soon as possible, but in all cases within ten working days, the investigator must report to the IRB:

- Any adverse event occurring at a performance site under Middlebury College IRB oversight that, in the opinion of the principal investigator, is both unexpected and related or possibly related to the research.
- Information that indicates a change to the risks or potential benefits of the research. For example:
    - An interim analysis or safety monitoring report indicates that the frequency or magnitude of harms or benefits may differ from those initially presented to the IRB.
    - A paper published in another study shows that the research risks or potential benefits might differ from those initially presented to the IRB.
- A breach of confidentiality.
- Change in FDA labeling or withdrawal from marketing a drug, device, or biologic used in a research protocol.
- Change to the protocol without prior IRB review to eliminate an apparent immediate hazard to a research subject.
- Incarceration of a subject enrolled in a protocol not approved to enroll prisoners.
- Event that requires prompt reporting to the sponsor.
- Sponsor-imposed suspension for risk.
- Complaint of a subject when the complaint indicates unexpected risks or cannot be resolved by the research team.

- Protocol violation (i.e., an accidental or unintentional change to the IRB-approved protocol) that harmed subjects or others or indicates subjects or others may be at increased risk of harm.
- Safety monitoring reports and Data and Safety Monitoring Board (DSMB) reports from the sponsor.

At the time of Continuing Review and in the Final Study Report. Along with the continuing Review Form in Sitero Mentor, the investigator must report to the IRB:

- Summary of all adverse events at performance sites under Middlebury College IRB oversight if not previously reported.
- Summary of all problems reported to the Middlebury College IRB, including serious adverse events, if not previously reported.
- Safety monitoring or DSMB reports received from the sponsor and not previously forwarded to the IRB, if any. The investigator will be notified in writing if the IRB requires that all such reports be submitted for continuing review.

IRB and Institutional Reporting

Suppose the IRB determines that a reported event constitutes an unanticipated problem that alters the risk of the research. In that case, it promptly reports its determination and actions to the investigator and the Institutional Official. The Institutional Official or their designee, in turn, is responsible for promptly reporting the IRB findings to the sponsor and applicable federal agencies.

Definitions Related to Research-Related Problems

An event's "correct" terminology can vary because different agencies use different terms. For example, a "serious adverse drug experience" under FDA regulations may or may not be an "unanticipated problem involving risks to subjects or others" under DHHS regulations. This section defines these terms concerning Middlebury College requirements to help investigators plan their reporting strategies.

Unanticipated problems involving risks to research subjects or others include any incident, experience, or outcome that meets **all** of the criteria below:

1. Is unexpected in terms of nature, severity, or frequency given
    a. the research procedures that are described in the protocol-related documents, such as the IRB-approved Human Subjects Research Protocol and informed consent documents; **and**
    b. the characteristics of the subject population being studied; **and**
2. Is related or possibly related to participation in the research (**perhaps related** means there is some likelihood in the judgment of a reasonable investigator that the incident, experience, or outcome may have been caused by the procedures involved in the research); **and**
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

An adverse event is any untoward or unfavorable medical occurrence in a human subject, encompassing both physical and psychological harm. Adverse events include any abnormal sign (for example, abnormal physical exam or laboratory findings), symptom, or disease temporally associated with the subject's participation in the research, whether considered related to the subject's participation in research.

A serious adverse event (includes *serious adverse drug or biological experience* and *unanticipated adverse device experiences* under FDA regulations) is any adverse event temporally associated with the subject's participation in research that meets **any** of the following criteria:

- Results in death.
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred).
- Requires inpatient hospitalization or prolongation of existing hospitalization.
- Results in a persistent or significant disability/incapacity.
- Results in a congenital anomaly/congenital disability.
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

19. SERIOUS OR CONTINUING NONCOMPLIANCE

Definition of Noncompliance

All researchers conducting human subjects research are expected to comply with the provisions of the IRB-approved study and 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 before 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 breach of personally identifiable information)
- Implementation of changes in research procedures before IRB approval

If a researcher becomes aware of any noncompliance concerning 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). The IRB will inquire into all allegations of noncompliance, determining if the noncompliance is serious or continuing. During the inquiry, an investigation will be conducted, and if appropriate, a subcommittee will be appointed to evaluate the noncompliance further. The IRB Chair, ADRC, and the RCA 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.

Definition of Serious or Continuing Noncompliance

Serious Noncompliance. Any failure to adhere to federal regulations, institutional policies, or IRB requirements may affect the rights and welfare of research participants. Examples include, but are not limited to:

- Conducting research without IRB approval.
- Deviating from the approved protocol in a way that impacts participant safety or data integrity.
- Failing to obtain informed consent when required.

Continuing Noncompliance. A pattern of repeated noncompliance actions or omissions that indicate a lack of understanding or disregard for regulatory requirements or IRB directives. This may include, but is not limited to:

- Repeated minor deviations from the protocol.
- Persistent tardiness in submitting required reports or amendments.
- Ongoing issues identified during continuing reviews or audits.

Documentation Submitted to the IRB for Serious or Continuing Noncompliance Inquiries

For cases of serious or continuing noncompliance, the following documentation must be submitted to the IRB:

1. **Written Summary of the Noncompliance.** A detailed description of the noncompliance incident(s), including dates, specific regulations or policies violated, and the individuals involved.
2. **Outcome of the Noncompliance.** An analysis of the impact on the research participants and the integrity of the study. This should include any adverse events or harm caused.
3. **Corrective Actions Taken.** A description of the steps taken to address the noncompliance, including immediate corrective actions and long-term strategies to prevent recurrence.
4. **Preventive Measures.** Details on any additional measures implemented to ensure compliance moving forward, such as training sessions, policy changes, or enhanced oversight.

Type of Review for Serious or Continuing Noncompliance Inquiries

The type of review for noncompliance cases depends on the severity and nature of the incident:

Full Board Review. Required for all instances of serious noncompliance and significant continuing noncompliance. This involves a discussion at a convened IRB meeting with a quorum present.

Expedited Review. This review may be appropriate for minor noncompliance issues or cases where the noncompliance does not significantly affect participant safety or study integrity. It can be conducted by the IRB Chair or a designated voting member.

Range of Possible Actions by the IRB for Serious or Continuing Noncompliance Inquiries

The IRB may take a range of actions in response to serious or continuing noncompliance, including but not limited to:

1. **Requiring Modifications.** Mandating changes to the study protocol, informed consent documents, or other study materials.
2. **Suspension or Termination.** Suspending or terminating the study or specific components of the study.
3. **Increased Monitoring.** Implementing more frequent continuing reviews or additional monitoring of the study.
4. **Training Requirements.** The research team must undergo additional training or education on regulatory requirements and IRB policies.
5. **Notification to Institutional Officials.** Reporting the noncompliance to appropriate institutional officials or external agencies as required.
6. **Administrative Actions.** Recommending administrative actions such as restricting the PI's ability to conduct research to relevant institutional officials.

20. SUSPENDING OR TERMINATING APPROVAL OF RESEARCH

Circumstances for Suspending or Terminating IRB Approval

The IRB may suspend or terminate approval of research under the following circumstances:

- **Noncompliance.** The research is not being conducted in accordance with IRB requirements, federal regulations, or institutional policies.
- **Unexpected Serious Harm.** The research has been associated with unexpected serious harm to subjects.
- **Safety Concerns.** New information suggests that the risks to subjects are greater than initially assessed.
- **Failure to Protect Subjects.** There is evidence that the subjects' rights and welfare are not adequately protected.
- **Administrative Closure.** Process of formally terminating an IRB-approved study due to expiration of the study approval or the departure of the PI from Middlebury College.

Consideration of Enrolled Subjects

When suspending or terminating IRB approval, the following considerations for enrolled subjects will be addressed:

- **Notification.** Subjects will be informed promptly about the suspension or termination, the reasons for the decision, and any changes to their participation status.
- **Protection.** Ensure measures are taken to protect the rights and welfare of subjects during the transition period.
- **Follow-up.** Provide guidance to subjects on any follow-up care or procedures that may be necessary because of the suspension or termination.

Orderly Termination or Transfer of the Study

For the orderly termination or transfer of the study, the following steps will be followed:

1. **Termination Plan.** Develop a plan for the safe and ethical termination of the study. This plan should include stopping subject recruitment, halting data collection, and addressing any immediate health or safety concerns for subjects.
2. **Transfer of Study or Subjects**. If applicable, arrange for the transfer of the study or subjects to another IRB-approved research study. Ensure that subjects are informed and consent to the transfer.
3. **Data Handling.** Ensure that all collected data is handled in compliance with privacy regulations and institutional policies.

Communication of the IRB's Decision

The IRB will communicate the reasons for the suspension or termination of research approval as follows:

- **Written Notification.** Provide a written notification to the Principal Investigator (PI) detailing the reasons for the suspension or termination, the effective date, and any required actions.
- **Institutional Officials.** Inform appropriate institutional officials about the decision and the reasons behind it.
- **Regulatory Agencies.** Notify relevant regulatory agencies, if applicable, as required by federal regulations.
- **Subjects.** Ensure that subjects are informed about the suspension or termination, including reasons for the decision and any changes to their participation status.

Steps for Implementation of Suspension or Termination

1. **Identify Noncompliance or Harm.** The IRB identifies noncompliance or unexpected serious harm through reports, audits, or other means.

2. **Initial Review.** The IRB conducts an initial review to assess the severity of the issue and decide on immediate actions.
3. **Suspend or Terminate Approval.** The IRB votes to suspend or terminate the research approval. A quorum must be present for this decision.
4. **Notification.** Issue written notifications to the PI, subjects, institutional officials, and regulatory agencies (if required).
5. **Implement a Termination Plan.** Follow the termination or transfer plan to protect the subjects' rights and welfare.

Steps for Implementation of Administrative Closure

1. The IRB office will examine the study file to ensure all necessary documents are present, such as confirming that the Principal Investigator has departed from the institution and that all research activities have ceased.
2. The IRB will issue the PI a formal administrative closure letter, copying relevant institutional offices and sponsors as required. Administrative Closure of IRB-approved studies due to the principal investigator's expiration or departure is not reportable to any regulatory agency.
3. The study will be marked as "Closed" in Sitero Mentor, and all research activities must cease.
4. Data retention and handling must comply with institutional policies and any applicable sponsor or regulatory requirements.

21. REGULAR SELF-ASSESSMENT OF THE BOARD AND QUALITY ASSURANCE

Summary of Responsibilities

The Institutional Official is tasked with evaluating the IRB Chair and members periodically. Together, the Institutional Official, ADRC, and RCA collaborate to adjust IRB membership as needed for those who decide to extend their membership past their one-year appointment, ensuring the ethical and regulatory review of research and appropriate representation at convened meetings.

IRB Member Evaluations

IRB committee composition and IRB membership are evaluated periodically, as appropriate, by the ADRC and the Institutional Official to ensure members' understanding of the ethical principles, policies and procedures, and federal regulations that govern research with human subjects. This ongoing informal evaluation process aims to promptly identify areas for improvement of processes or individual board members. Areas of evaluation include:

1. the quality of the member's pre-review and/or review for the convened meeting in identifying substantive scientific and ethical issues,
2. meeting attendance,
3. being adequately prepared for the meeting,
4. knowledge of regulatory criteria for approval,
5. knowledge of other clinical, ethical, and institutional issues.
6. contributions to the board (i.e., number of reviews conducted, subcommittee attendance)

When warranted by a member's sub-par performance on the board, the Institutional Official and ADRC develop an informal plan to address areas for improvement (e.g., provide additional education, meet with the board member to discuss specific issues, provide feedback to the member as appropriate, etc.). If the informal improvement plan does not result in the desired improvements, the Institutional Official may take

other actions (e.g., not reappointing the member at the next scheduled period or dismissing the member from the board).

IRB Chair Evaluations

The Institutional Official is responsible for evaluating the IRB Chair. If concerns arise regarding the IRB Chair's performance, this is discussed with the ADRC and RCA as appropriate. This informal ongoing evaluation process aims to identify areas for an individual chair's improvement promptly. As needed, the Institutional Official develops an informal plan with the IRB Chair to address areas for improvement (e.g., provide additional education, meet with the chair to discuss specific issues, provide feedback as appropriate, etc.). If the informal improvement plan does not result in the expected improved performance by the Chair, the Institutional Official may take other actions (e.g., not reappointing the chair at the next scheduled period, dismissing the chair from the board)

Annual Assessment of Membership

Due to federal requirements that membership on an IRB includes representatives from specific disciplines and areas of expertise, the committee on committees appoints the IRB faculty and staff members who can meet the required roles of the IRB. As part of this process, the Institutional Official completes a comprehensive evaluation of the IRB membership and individual evaluations of each Board member, including the IRB Chair. For the comprehensive evaluation, the Institutional Official determines whether the membership, collectively, has the appropriate:

1. knowledge of applicable regulatory and legal requirements;
2. knowledge of professional standards and practices;
3. knowledge of the local research context and research sites and their capabilities;
4. knowledge of community standards and attitudes;
5. scientific, scholarly, clinical, and professional expertise;
6. racial, ethnic, and cultural diversity; and
7. representation of participants' perspectives.

Based on these assessments and considering the nature and volume of research reviewed, the IO adjusts the composition and membership of each IRB. Prospective members are recommended for appointment to fulfill the needs of the IRB identified during the comprehensive evaluation of the membership. Whenever possible, appointments should be made at least three months before the appointment begins.

Quality Assurance of the IRB

The IRB continually monitors the effectiveness and fidelity of its policies and procedures. The ADRC and RCA meet regularly to discuss whether IRB policies and practices are adequate to sufficiently protect human subjects in research and to ensure that researchers adhere to the ethical principles in the Belmont Report. When adjustments to policies, guidance, and practices are needed, the ADRC and RCA work together to develop and implement a quality assurance plan to address areas of concern. The ADRC ensures this quality assurance plan is implemented, reviewed periodically, and revised as necessary. The following issues shall serve as guidelines for the periodic review:

1. Which metrics does the IRB use to benchmark standards and measure progress?
2. Do the college's Human Subject Research Investigators understand their obligations under the Belmont Principles?

3. Is the IRB documentation and recordkeeping system complete, accurate, and flexible enough to provide the necessary documentation to comply with federal regulations and satisfactorily serve the college's human research community?
4. Is the system sufficiently responsive so that human research investigators can plan, obtain approval, and meet reporting requirements in a timely manner that facilitates the institution's educational and research missions?
5. Does the IRB provide adequate support and education for its members and staff to fulfill their responsibilities under the Middlebury IRB Policies and Procedures? Are the opinions of all IRB members sought and respected?
6. Are IRB committee meetings functioning consistently?
7. Is the burden of IRB membership equitably shared across the institution? Are experts outside the IRB consulted when appropriate?
8. Are IRB decisions communicated efficiently and effectively? Do letter templates require revision?
9. Are reports to federal agencies submitted and monitored for follow-up?
10. Do IRB administrative staff members understand their duties clearly? Can they keep pace with the volume of work without losing quality?
11. How are delays in reviews monitored and handled? What difficulties does the IRB face, and how do they impact the college's research program?
12. Is there clear evidence of ongoing quality improvement? If so, in which areas?

22. IRB MEMBER CONFLICT OF INTEREST (COI)

No Board Member shall participate in the review of research in which they have a conflict of interest except to provide information as requested by the Board. A Consultant may present information or participate in discussion to the extent requested by the Board. A conflict of interest shall include, but is not limited to, any interest that may cause the individual (or the individual's immediate family member) to experience a financial or non-financial gain or loss from the Board's review of research. A conflict of interest may arise by an individual's status in relationship to the reviewed research, such as being an investigator or sub-investigator of the study, being employed by or consultant to the Sponsor of the research or having a significant ownership interest in the Sponsor of the research. Board Members and Consultants shall agree to abide by the standards for conflicts of interest by signing the Conflict-of-Interest Questionnaire upon appointment and re-appointment to the IRB.

No selection of IRB members by investigators. Investigators are not allowed to select which IRB member will review their application.

Prohibition of participation in IRB deliberations and voting by investigators. A review of applications will be conducted objectively and in a manner that ensures the exercise of independent judgment by each member. Members may not participate in a vote by the IRB on actions concerning research in which they have an active role or conflict of interest related to any person or entity connected with the application. Failure to abide by these provisions may cause the removal of a member from the IRB.

IRB members must not vote on an application if they are investigators on the application or have any other conflict of interest with any person or entity connected to an application. The IRB member must inform the ADRC, RCA, and IRB Chair of any conflict of interest. The member may provide information to the IRB if

requested. The fact that an application is submitted by another investigator from an IRB member's department or area does not constitute a conflict of interest.

The member is not required to identify the exact nature of the conflict of interest. They may inform the ADRC, RCA, and IRB Chair that one exists. If the member has been assigned to review an application, they should notify the IRB chair as soon as possible of their unavailability to review the protocol so that the application can be reassigned to another reviewer.

The member with the conflict of interest may participate in the discussion or deliberation to answer questions from the committee regarding the application under review to the same extent as any investigator when attending an IRB meeting. If there are no questions for the conflicted member, or after they have answered any questions, they will be recused for the committee's deliberation and vote. The meeting minutes and recorded vote tally note that the member (by name) was recused and did not count toward the quorum for the vote. If the quorum is lost, the board will table the review until a meeting with a full quorum, excluding any conflicted IRB members, can be held.

23. OPERATIONS OF THE IRB

Scheduling of Meetings

IRB meeting dates are posted on the Middlebury College IRB website. Federal guidelines require IRBs to hold convened meetings of the full board to evaluate Full Board Review protocols. Convened meetings may be held remotely or in-person. The IRB will convene once each month, as necessary, to evaluate Full Board Review protocols. The Chair may call additional full-board meetings or subcommittee meetings. The IRB will hold a convened meeting of the full board at least once per calendar year, even if no Full Board Review protocols are received. A convened meeting of the full board will occur in December if no other convened meetings occur during the calendar year. The RCA will arrange monthly meetings. The RCA will make meeting sites available on campus and via online access and notify committee members of the meeting details, i.e., location and time.

Receipt of Applications

Investigators may submit applications to the IRB office anytime via Sitero Mentor. The IRB will attempt to review Exempt Status, Limited Review, and Expedited Review protocols within 10 business days of receipt of a complete application. Projects requiring Full Board Review must be submitted at least two weeks before the next convened meeting of the Full Board.

Review of Applications

Pre-review. Upon receipt of all applications, the RCA will pre-review them for completeness before submitting them to an IRB reviewer for review. The RCA will verify that the proposed research meets federal criteria for the requested review category. The RCA or IRB Chair will contact the investigator(s) in writing via Sitero Mentor if any additional materials are required.

Exempt Status Review. The IRB Chair or any IRB member designated by the Chair is authorized to review exempt status applications independently. If the reviewer needs additional information, they will communicate their request to the RCA, who will ask the investigator for the information in writing via Sitero Mentor.

Upon receipt of the additional information, the reviewer determines whether the research activities qualify under one or more exemption categories. The reviewer will make a determination within 10 business days of receipt of the application. After review of the application, the reviewer will make one of the following determinations:

- **Certification of Exemption.** The reviewer determines that the protocol qualifies under one or more of the exemption categories; the project is certified exempt from IRB continuing review with no changes required. An exemption notice is issued that specifies the exemption category(ies). The investigator is notified in writing that their project has been certified as exempt and does not require continuing IRB review.
- **Certification of Exemption Pending Modifications.** The reviewer determines that minor issues/changes must be addressed before the project can begin. The IRB Chair will notify the investigator in writing of the requested revisions. Upon receipt of the investigator's response, the reviewer determines if the revisions are sufficient. If the reviewer determines the revisions are insufficient, the investigator may be asked to make additional modifications. This process will repeat until the reviewer determines whether the research activities qualify under one or more of the exemption categories.
- **Recommend to Re-review.** If the reviewer determines that the project does not qualify for exemption from IRB review, the IRB Chair or designee will notify the investigator in writing that the request for exemption status has been denied and that the protocol will be reviewed via either Limited, Expedited, or Full Board Review process.
- **Not Human Subjects Research.** If the reviewer determines that the project does not meet the definition of research and/or does not involve human subjects, the IRB Chair will provide the investigator with a "Not Human Subjects Research" determination letter.

All members of the IRB committee will be informed of applications receiving exemption through Exempt Status Review in the monthly meeting minutes.

Limited Review. The IRB Chair, or any IRB member designated by the Chair, is authorized to review limited review applications independently. If the reviewer needs additional information, they will communicate requests for additional information to the RCA, who will ask the investigator for the information in writing via Sitero Mentor. Upon receipt of the additional information, the reviewer determines whether the research activities qualify under one or both limited review categories. The reviewer will decide within 10 business days of receipt of the application. After review of the application, the reviewer will make one of the following determinations:

- **Approved.** The reviewer determines that the protocol qualifies under one or more of the limited review categories; no changes are required; all criteria for IRB approval are met.
- **Approved Pending Modifications.** The reviewer determines that minor issues/changes must be addressed before the project can begin. The IRB Chair will notify the investigator in writing of the requested revisions. Upon receipt of the investigator's response, the reviewer determines if the revisions are sufficient. If the reviewer determines the revisions are insufficient, the investigator may be asked to make additional modifications. This process will repeat until the reviewer determines whether the research activities qualify under one or more of the limited review categories.
- **Recommend to Re-review.** If the reviewer determines that the project does not qualify for or require limited review, the IRB Chair will notify the investigator in writing that the request for limited review status has been denied and that the protocol will be reviewed via Exempt Status Review process, Expedited Review process, or Full Board Review process, as appropriate.

- **Not Human Subjects Research.** If the reviewer determines that the project does not meet the definition of *research* and/or does not involve *human subjects*, the IRB Chair or designee will provide the investigator with a "Not Human Subjects Research" determination letter.

All members of the IRB committee will be informed of applications approved through Limited Review in the monthly meeting minutes.

Expedited Review. The RCA pre-reviews the application for completeness before submitting it to the IRB Chair or designee for review. The IRB Chair or designee verifies that the proposed research meets federal criteria for Expedited Review. The IRB Chair or designee selects a subcommittee of two members of the IRB to review the application. The IRB Chair may serve as one of the reviewers at his or her discretion. The IRB Chair may independently review the application at his or her discretion. If the reviewers need additional information to determine expedited status, they will request additional information to the RCA, who will ask the investigator for the information in writing via Sitero Mentor. Upon receipt of the additional information, the reviewers will determine whether the research activities qualify under one or more of the expedited categories. The reviewers will decide within 10 business days of receipt of the application. After review of the application, the reviewers will make one of the following determinations:

- **Approved.** Both reviewers (or the Chair, if a single reviewer) determine that the protocol qualifies under one or more of the expedited categories; no changes are required; all criteria for IRB approval are met. The approval letter will indicate whether a continuing review is required.
- **Approved Pending Modifications.** One or both reviewers determine that minor issues/changes must be addressed before the project begins. The IRB Chair will notify the investigator in writing of the requested revisions. Upon receipt of the investigator's response, the reviewer(s) determine if the revisions are sufficient. If the reviewer(s) determines the revisions are insufficient, the investigator may be asked to make additional modifications. This process will repeat until the reviewer(s) determine whether the research activities qualify under one or more expedited categories.
- **Recommend to Re-review.** If one or both reviewers determine that the project does not qualify for or require expedited review, the RCA will notify the investigator in writing that the request for expedited review status has been denied and that the protocol will be reviewed via Exempt Status Review process, Limited Review process, or Full Board Review process, as appropriate.
- **Not Human Subjects Research.** If the reviewer determines that the project does not meet the definition of research and/or does not involve human subjects, the IRB Chair will provide the investigator with a "Not Human Subjects Research" determination letter.

Only the Full Board may disapprove a study if the criteria for IRB approval are not met. If the reviewer determines that the protocol cannot be approved, it must be reviewed via the Full Board Review process.

All members of the IRB committee will be informed of applications approved through Expedited Review in the monthly meeting minutes.

Full Board Review. All human subjects' research that does not qualify for Exempt, Limited, or Expedited Review must receive Full Board Review. Also evaluated by a Full Board Review are reports of unanticipated problems and allegations of serious and/or continuing noncompliance.

The RCA conducts a pre-review of the application to ensure its completeness and determines that the project requires a Full Board Review. The entire board reviews the new study.

If the IRB Chair determines that the appropriate scientific expertise is unavailable within the IRB, the IRB Chair may invite an internal or external consultant to serve as one of the primary reviewers. If the application involves vulnerable populations, such as children or cognitively impaired, the IRB Chair may invite a special subject population representative to serve as one of the primary reviewers.

The RCA distributes the application and related study materials to all IRB members at least one week before the scheduled meeting date to allow sufficient review of the materials. If IRB members identify the need for additional information about an application, they will communicate these requests to the IRB Chair. The RCA will ask the investigator for the information in writing via Sitero Mentor.

Any additional information needed to review an application should be obtained before the Full Board convenes at the scheduled meeting. All IRB members must review and be familiar with all protocols before the Full Board Review.

The Full Board Review must be conducted at a convened meeting at which a quorum consisting of a majority of the members of the IRB is present, including at least one member whose primary concerns are in non-scientific areas. If an IRB Member is unable to attend a convened meeting, they are responsible for informing the IRB Chair and RCA with sufficient lead time so that an IRB Alternate Member may be assigned to review the proposal and attend the convened meeting. Approval of research is by a majority vote of the quorum. An IRB member with a conflicting interest in a project may be present to answer questions about the project but must recuse himself/herself and may not participate in the subsequent discussion and voting. The RCA is responsible for documenting a quorum in the meeting minutes and monitoring the maintenance of a quorum during the meeting. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests, early departures, or absence of a non-scientist member), all Board review activities shall cease. The Board meeting may reconvene when quorum requirements are subsequently satisfied.

At the discretion of the IRB Chair, ADRC, RCA, or any IRB members, the investigator may be invited to attend the Full Board Review meeting (in person or by phone) for additional clarification or discussion. The investigator is required to leave the meeting for subsequent discussion and voting.

After the discussion of the application is completed, all IRB members will vote on one of the following determinations:

- **Approved.** A majority vote of the quorum determines that all criteria for IRB approval are met and that no changes are required. Based on the committee's determination, the approval letter will indicate if a project review is required more often than annually.
- **Approved Pending Modifications**. A majority vote of the quorum determines that there are minor issues/changes that must be addressed before the project can begin. The RCA will notify the investigator in writing of the requested revisions. Upon receipt of the investigator’s response, the IRB Chair will determine if the revisions are sufficient. If the IRB Chair determines insufficient revisions, the investigator may be asked to make additional modifications. This process will repeat until the IRB Chair determines that the issues/changes raised by the Full Board have been adequately addressed.

- **Deferred:** A majority vote of the quorum determines that it is unable to approve research and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB. The RCA will notify the investigator of the suggested modifications. If the IRB Chair determines insufficient revisions, the investigator may be asked to make additional modifications. The revised materials and the investigator's response will be discussed at the next IRB meeting.
- **Disapproved.** A majority vote of the quorum determines that the criteria for IRB approval have not been met. Only the Full Board may disapprove of a study. Institutional administrative officials may not override this decision.
- **Tabled.** Criteria for a convened Full Board Review are unmet, and/or appropriate expertise is unavailable at the meeting.
- **Recommend to Re-review**. If a majority vote of the quorum determines that the project does not require Full Board Review, the IRB Chair will notify the investigator in writing that the protocol will be reviewed via the Exempt Status Review process, Limited Review process, or Expedited Review process, as appropriate.
- **Not Human Subjects Research.** If a majority vote of the quorum determines that the project does not meet the definition of *research* and/or does not involve *human subjects*, the IRB Chair will provide the investigator with a "Not Human Subjects Research" determination letter.

Continuing Review. All projects initially approved by Full Board Review must undergo continuing review at least annually. The IRB may require more frequent review depending on the nature of the study, the degree of risk involved to human subjects, and the vulnerability of the study population. The initial approval letter sent to investigators will include the date of approval and the date on which the project will expire without receiving approval for a Continuing Review application. Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:

- research reviewed by the IRB under the limited IRB review;
- research eligible for expedited review; and
- research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

As a courtesy, the IRB will send Continuing Review reminders to investigators in advance of the project expiration date. However, it is ultimately the investigator's responsibility to initiate a Continuing Review application and allow sufficient time for the review and re-approval process to be completed before the current approval expires. All research activities involving human subjects must stop if an IRB-approved project expires. These activities involve subject contact, data collection, and data analysis.

Communication from the IRB to Investigators

The RCA communicates IRB actions to investigators in writing via Sitero Mentor within five business days of the decision's rendering.

Stamping the Materials with IRB Approval

After the study materials have been reviewed and approved by the IRB, before sending the approval letter on non-exempt applications, the RCA stamps the English and non-English signed consent, parent permission, and assent forms. Once the approval letter is sent, the documents will be stamped within Sitero Mentor and

available to the PI and study staff. The stamp includes the Middlebury College IRB number, along with the activity number, the word "Approved," the date of approval (MM/DD/YYYY), and the valid until date (MM/DD/YYYY). The IRB approval stamp will appear at the bottom of the forms. The researchers should use the approved materials during the consent process. This requirement does not apply when the consent process is via e-mail, verbal, or consent is embedded in a survey or questionnaire on the online system.

During the continuing review, the investigator indicates on the continuing review form if there are any changes to the forms and submits the new forms to the IRB. The IRB will review the changes and re-stamp the materials if necessary. If there are no changes, the IRB will use the previously approved consent forms to re-stamp with a new approval date.

Appeal of IRB Decisions

If an IRB application receiving Full Board Review is disapproved, the reasons for disapproval will be conveyed to the investigator in writing. The investigator may request the IRB reconsider by responding in writing and requesting an opportunity to appear before the IRB. If the reasons for disapproval have been corrected, the application may be resubmitted.

Cooperative Agreements and Individual Investigator Agreements

The Middlebury College IRB enters into written cooperative agreements or individual investigator agreements with the IRBs of other institutions when such agreements facilitate and streamline the IRB process while ensuring that the rights and welfare of human participants are fully protected. The cooperative agreements allow Middlebury College faculty, staff, and students to complete the review forms for the other institution's IRB and submit the form to the Middlebury College IRB. The Middlebury College RCA documents the application form, completes administrative review, and forwards the material to the other institution's IRB for review. The Middlebury College IRB will receive documentation of actions taken on the application and subsequent reviews of the application from the other institution's IRB. This allows Middlebury College faculty, staff, and students to complete one IRB application and receive review from only one IRB, thus facilitating the review and approval of specific research covered by the appropriate cooperative agreement while ensuring that human participants are fully protected. See additional discussion of cooperative review agreements in Section 25.

Allegations of Non-compliance

The IRB will investigate any allegations of non-compliance as stipulated in the federal regulations. Any allegation will be discussed with the principal investigator of the IRB application in question. Any investigation of alleged non-compliance will require close cooperation and coordination with the principal investigator of the research.

If credible evidence of non-compliance appears, it will be presented to the Institutional Official, who will then inform the relevant Dean, Director, or Department Chair if applicable. Any non-compliance based on federal regulations will be reported to federal and funding agencies as required. Based on the nature of any non-compliant activity, the IRB has the authority to suspend or terminate approval of the project.

Complaints

The ADRC and RCA will communicate any research participants' complaints or concerns that may arise to the Institutional Official. In general, the IRB can respond to complaints or concerns regarding the participant's rights as a paid participant or a volunteer participant in the research. The IRB Chair will assist the participant in getting answers to any other complaints or concerns from the principal investigator.

Post-approval Review and Monitoring

The IRB may initiate reviews of approved IRB applications at any time. Post-approval reviews may be initiated for cause (request of the principal investigator, allegation of non-compliance, questions from research participants, post-approval monitoring, etc.) or for no cause (random sampling of approved applications, etc.). Post-approval review findings that indicate variances from approved applications, adverse events, or unanticipated events will be reported to the Institutional Official and federal agencies as required by federal regulations. Based on the nature of any non-compliant activity, the IRB has the authority to suspend or terminate the project.

24. IRB RECORD REQUIREMENTS

The IRB will prepare and maintain adequate documentation of IRB activities, including:

1. Copies of all research proposals reviewed, scientific evaluations (if any) accompanying the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. Minutes of IRB meetings that are in sufficient detail to show:
    - attendance at the meetings,
    - actions taken by the IRB,
    - the vote on these actions, including the number of members voting for, against, and abstaining,
    - the basis for requiring changes in or disapproving research; and
    - a written summary of the discussion of controverted issues and their resolution.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the investigators.
5. A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example; full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head unless the existence of an HHS-approved assurance is accepted. In this case, a change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.
6. Written procedures that the IRB will follow:
    - for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;
    - for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since the previous IRB review; and
    - for ensuring prompt reporting to the IRB of proposed changes in research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.
7. Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of:

- any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and
- any suspension or termination of IRB approval.

8. A statement in the informed consent documents that significant new findings developed during the study that may relate to the subject's willingness to continue participation will be provided to the subject.

IRB records will be retained for at least 3 years, and records relating to research that is conducted will be retained for at least 3 years after completion of the research. All records will be accessible for inspection and copying by authorized representatives of the federal department or agency at reasonable times and in a reasonable manner. The RCA and ADRC will maintain IRB meeting agendas, meeting minutes, and IRB rosters as a permanent record of the committee's activities. Policy guidance and forms will be disseminated from and stored by the RCA and ADRC until new and/or revised documents are replaced.

25. DISCUSSION OF SPECIAL TOPICS AND ACTIVITIES

Certificate of Confidentiality

A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical, and other forms of sensitive research. The NIH issues these certificates. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Any research that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for the Certificate. For more information:
https://humansubjects.nih.gov/coc/index

Children

Middlebury College adheres to Subpart D of the DHHS regulations (Additional Protections for Children Involved as Subjects in Research). Children are people who have not attained the legal age of 18 years. The IRB will require that children 7 years old and older provide their assent to participate in research activities. Written assent should be obtained from children 7 through 17 years of age, but oral assent may be approved if justified.

The regulations contain specific requirements and documentation for research involving children. Research that does not involve greater than minimal risk can be approved only if the IRB finds that adequate provisions are made for soliciting the assent of children and the parents' permission. Research involving greater than minimal risk may be approved under three general conditions:

1. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects;
2. Research involving greater than minimal risk and no prospect of direct benefit to the individual subjects but likely to yield generalized knowledge about the subject's disorder or condition; and
3. Research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

The IRB Chair has discretion for determining the level of review for research involving children and may require Full Board review even if a research project otherwise meets the criteria for exemption or expedited

review. The IRB Chair will consider the methodology, experience and expertise of the research team, as well as the characteristics of the population of children to be studied when deciding about level of review. Research with children may be eligible for exempt review when the research involves observing public behavior and the investigator does not participate in the observed activities or when the research involves normal educational practices. Unless there are compelling reasons not to obtain parental permission and/or child assent, the IRB will generally expect both to be obtained.

Confidentiality Agreements

Depending on the confidentiality of the collected material, the IRB may request signed confidentiality agreements with certain study personnel (depending on their role in the research). Individuals with limited involvement (e.g., translator, transcriptionist, and specific data analysis duties) may be asked to sign confidentiality agreements.

The IRB does not require confidentiality agreements in all situations except when the confidentiality (sensitivity of the material) warrants such consideration.

NOTE: A certificate of confidentiality is different from a confidentiality agreement.

Cooperative Review Agreements

This section outlines the procedures for implementing cooperative IRB review arrangements, including joint review, reliance on the review of another qualified IRB, or similar arrangements, to streamline the review process, avoid duplication of effort, and ensure efficient and effective oversight of research activities. Cooperative review arrangements may be considered in the circumstances such as multi-site studies where it is advantageous to rely on a single IRB to coordinate review efforts, when another IRB has specific expertise or resources that enhance the review process, when institutions have formal agreements to rely on each other's IRB reviews to reduce redundancy and administrative burden, and when required or permitted by federal regulations or guidelines.

There are different types of cooperative review arrangements. Joint review involves two or more IRBs collaborating to conduct a single, unified review of a research project. IRB reliance occurs when one IRB relies on the review and approval of another qualified IRB, often called the "IRB of Record." A central IRB is used to review multi-site studies, where the central IRB serves as the single IRB for all participating sites. An initial assessment is conducted to establish cooperative review arrangements to determine the appropriateness and feasibility of such an arrangement for the specific research project. Formal agreements or memoranda of understanding (MOUs) are established between the institutions involved, outlining the responsibilities and authority of each IRB. Clear and ongoing communication is ensured between the cooperating IRBs and the research team, with designated points of contact for coordination. Detailed documentation of the cooperative arrangement, including agreements, correspondence, and review outcomes, is maintained.

The relying IRB has responsibilities that include assessing the qualifications of the IRB of Record to ensure it is qualified, accredited (if applicable), and operates in compliance with federal regulations and institutional policies. The reliance agreement is carefully reviewed and approved, specifying the roles and responsibilities of each party, and ongoing oversight is maintained to ensure compliance and address any local context issues. The IRB of Record is responsible for thoroughly reviewing the research protocol, informed consent documents, and other relevant materials. It must provide timely and detailed review decisions, including

required modifications, approval, or disapproval, to the relying IRBs and the research team, and monitor the research for compliance with approved protocols, addressing any issues of noncompliance or adverse events.

Considerations for enrolled subjects include ensuring that the informed consent process addresses the involvement of multiple institutions and the cooperative review arrangement, and informing subjects about the IRB overseeing their study, providing contact information for questions or concerns. Following IRB decisions, the approval is communicated to all parties, including any conditions or modifications required. The research team is coordinated to address required modifications and obtain necessary approvals. In cases of disapproval or suspension, the reasons are communicated, and steps for addressing the issues or appealing the decision are outlined.

Monitoring and quality assurance involve conducting regular audits and reviews to ensure compliance with the cooperative arrangement and the research protocol and implementing mechanisms for feedback and continuous improvement of the cooperative review process.

Facilities/Locations

Whenever Middlebury College faculty, staff, or students are conducting human subjects research at other facilities (such as hospitals, clinics, schools, school districts, factories, offices, etc.), the researcher must ensure that the outside entity is aware of the proposed research activity and has no objections (i.e., agrees to participate). The investigator is responsible for obtaining each site's support letter if the research is conducted at any location other than Middlebury College. The letter will be from someone in authority to grant permission to perform research at the site. The letter will be addressed to the investigator and indicate that they are knowledgeable about the nature of the research project that will be performed and that they approve of this research being conducted in their business or facility. A copy of the letter should be attached to the submitted research protocol.

Internet (or On-line, Computer) Based Research

The Internet and other computer-based research methods offer many new methods for researchers to contact research participants and collect data for research (including opportunities for large numbers of participants, ease of data collection, possibilities for anonymity, etc.). All the same IRB considerations and federal regulations apply; however, using the Internet also creates challenges for the IRB.

- **Recruitment.** There are many methods of recruitment. Indirect recruitment would include using flyers and announcements that direct individuals to websites to participate in the research. Direct recruitment may include sending e-mails or letters to individuals the researcher would like to recruit. Researchers should ask themselves the following questions: For direct recruitment, would the participants reasonably expect the researcher to contact them regarding the research topic? Authentication can be a major challenge for internet-based research. How does the researcher know who the researcher is communicating with/recruiting?
- **Informed consent.** Minimal risk research may qualify for a waiver or alteration of consent or a waiver of documentation of consent. The IRB would generally require the information normally contained in the consent form to be provided to participants so that participants may make an informed decision about whether to participate. Greater than minimal risk research may require more traditional methods, such as mailing an informed consent document and receiving the participant's signed copy, although researchers may present suggestions to the IRB. Again, authentication may be a challenge for internet-based consent.

- **Anonymity/confidentiality.** The Internet and computer-based research can offer a "false sense" of anonymity/confidentiality. The researcher must explain to the IRB how anonymity/confidentiality will be maintained. This will often rely on server administration/security. The use of encryption should be considered and may be encouraged or required by the IRB. Whenever possible, identifiable data should be de-identified. Any code linking data to identities should not be stored on the same server as the data.
- **Data collection.** Encryption may be suggested or required depending on the type of data being collected.
- **Data storage/disposal.** Personal identifiers should be stored separately from the data and/or the codes linking the data to individuals whenever possible. Back-up storage is always a consideration with electronic media. The IRB will be as concerned with the security of the backup material as it is with the original material. Final data destruction of electronic media can be complex. The IRB will want assurance that the data deleted is truly not recoverable.

International Research

All human subjects research activities conducted internationally by Middlebury faculty, staff, or students who are conducting the work as agents of Middlebury are subject to Middlebury policies and procedures. Conducting research in foreign countries poses unique and complex ethical challenges. Please reach out to the IRB well in advance of beginning any international research with human participants, as the specific requirements will vary depending on the nature of the research, laws and regulations in the other country, and other factors. Even simple, low-risk studies will generally take longer to approve, particularly because often, a local ethical review will be required before the Middlebury IRB can approve the work. *Please be in touch with the IRB early in the process and plan to submit your application at least two months before you plan to collect data from participants internationally.*

Please note that all international research projects involving travel must also be approved by the Global Operations committee, which is a separate process, but can be completed simultaneous with IRB review.

If the host country or institution has a mandatory process for reviewing and approving human subjects research, the Middlebury IRB will require documentation of that approval before approving any international research. Where there is no equivalent board or group, investigators are expected to address how they will ensure the research meets local requirements as part of the IRB application. This may involve consultation with local experts or community leaders about the project to secure their support for the conduct of the research. The IRB requires that there be good faith effort applied to secure local cooperation for the research and to document those efforts as part of the IRB application.

The IRB expects researchers to acknowledge and understand the following:

- **You must obtain IRB approval before your study can begin.** Whether you are a faculty member, staff or student, your research study must be approved by the IRB before it can begin. *To reduce confusion, make sure you have the IRB's approval before you leave the country. We suggest you apply to the IRB at least two months before you plan to leave.*
- **Demonstrate cultural understanding and sensitivity.** Your IRB protocol should describe any anticipated cultural sensitivities of conducting your research and how you intend to overcome those barriers. The researcher should be familiar with local customs, culture and religious norms in the country where the study will be conducted. Is the typical process of signing an informed consent document culturally acceptable for your study? How should recruitment be done? Are there other

cultural barriers you might encounter once you arrive? The IRB will consider alternative consent form formats or methods if culturally appropriate.

- **Understand the research ethics guidelines of the host country.** It is the investigators' responsibility to ensure that the research project adheres to the local ethical and legal requirements as well as cultural norms. The Middlebury IRB requires that you submit documentation showing that the project meets local requirements.
    - If the research is being conducted in collaboration with researchers at a foreign institution with its own ethical review process, the research will need to be reviewed and approved by that institution's IRB equivalent *before* submitting to the Middlebury IRB. Where there is no equivalent board or group, Middlebury researchers must rely on local experts or community leaders to provide approval. In some situations, the Middlebury IRB may need to only conduct an administrative review of the protocol that has been reviewed and approved by an IRB equivalent at the foreign institution. Please reach out to the IRB to determine if you need to create and submit a new protocol in Mentor, or if you can provide the approved protocol via email for administrative review.
    - If the research is being conducted without collaborators in the foreign country, then the investigators will need to include documentation that the research adheres to local requirements and cultural norms with their IRB application. This may be a letter from a local expert or community leader who has the knowledge and experience necessary to provide an ethical review and to assure the IRB that the protocol meets local regulatory requirements.

- **It is ultimately the researchers' responsibility to understand host country's requirements for reviewing and approving human subject research.** Some countries have clear ethical guidelines that must be met for conducting domestic and/or international research. Other countries will not have a formal process but might rely on other neighboring countries to assist with the review.
    - The Office of Human Research Protections (OHRP) publishes the **International Compilation of Human Research Standards,** a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and several international organizations. Researchers should check this document to determine the countries applicable laws, regulations and guidelines on Human Subjects Researcher.
    - The Office of Human Research Protection (OHRP) has issued a Listing of 27 Social-Behavioral Research Standards . This includes laws, guidelines, and regulations applicable to social-behavioral research around the world.
    - **Know the data laws.** While not specifically under the IRB's domain, you should know that there are some restrictions on bringing identifiable data into/out of some countries. The EU, for example, has laws surrounding what kind of identifiable information can be taken out of Europe and brought to the US (this applies to electronic data that will be housed on a US server as well). Data export laws may also affect your research in countries with which the US has embargoes or trade restrictions, such as Iran.

- **Please contact the IRB while abroad if you encounter any problems or need to change your IRB-approved protocol.** If you find that upon arrival in the host country, some aspects of your research study must be modified for whatever reason, *please notify the IRB office immediately*. The IRB will do its best to quickly respond to your notification with further instructions and guidance. Please wait to hear back from the IRB before making any changes to your protocol!

Please note that while outside the purview of the IRB, import and export control regulations, overseen by several federal agencies, may affect those traveling to, collaborating with, or conducting research with entities or individuals in sanctioned countries, triggering further review. These regulations have identified several countries under heavy embargo or sanctions via the Office of Foreign Assets Control (OFAC). For detailed information, please refer to the OFAC Sanctions Programs and Country Information and the Sanctions List Search. Further information on import controls, export controls, and sanctions is available via the provided Middlebury link.

If investigators and their teams plan to travel to, collaborate with, conduct research activities with, or export or import any items to or from embargoed or sanctioned countries, they should first consult the Global Operations Committee at global@middlebury.edu. It's recommended to consult before submitting an IRB proposal, as this consultation will clarify whether further action is necessary or if the activity can proceed.

Prisoners

Middlebury College IRB does not currently review prisoner research.

Recording (Photographs, Audio, Video)

Research involving voice, video, or image recordings may be considered Exempt if the research otherwise meets one of the Exemption categories. If the recording introduces additional risk, then otherwise Exempt research may be reviewed via the Expedited or Full Board process.

The type of recording must be disclosed in the informed consent document. The investigator must specify the steps taken to maintain the confidentiality of this identifiable information, both in the IRB application and in the informed consent documents. When the recording is deemed necessary to the research, the informed consent must indicate such. When recording is not necessary for the research, a separate signature line for the recording acceptance should be included on the consent form so that the participant can choose to participate in the study but decline the recording of their participation.

Transferring Oversight

The Middlebury College IRB is responsible for transferring oversight of one or more studies to another institution or IRB if the current IRB cannot continue its oversight duties due to closure, fire, natural disaster, or other unforeseen circumstances.

Identifying the Need for Transfer of Oversight. In circumstances where the IRB can no longer provide oversight, such as closure, fire, natural disaster, or other significant disruptions, the need for transferring oversight of ongoing studies must be promptly identified. The IRB Chair, institutional officials, or their designees will determine this.

Notification and Initial Actions. Upon identifying the need to transfer oversight, the following steps will be taken immediately:

1. **Notification.** The IRB Chair, Institutional Official, ADRC, or the RCA will notify all relevant stakeholders, including Principal Investigators (PIs), research staff, study sponsors, and regulatory agencies, about the situation and the necessity to transfer oversight.
2. **Assessment.** To facilitate a smooth transition, a rapid assessment of the impacted studies will be conducted to determine their status, phase, and specific needs.

3. **Documentation.** All documentation related to the studies, including protocols, informed consent forms, review history, and correspondence, will be gathered and prepared for transfer.

Identifying a Receiving IRB. The IRB Chair, Institutional Official, or ADRC will identify a suitable receiving IRB to take over oversight responsibilities. If available, this can be another IRB within the same institution or an external IRB with the appropriate qualifications and capacity. The criteria for selecting a receiving IRB include:

1. **Accreditation and Compliance.** The receiving IRB must be accredited (if applicable) and comply with all federal regulations and institutional policies.
2. **Expertise.** The receiving IRB must have the necessary expertise to oversee the specific studies being transferred.
3. **Capacity.** The receiving IRB must have the capacity to take on additional oversight responsibilities without compromising the quality of its review process.

Formalizing the Transfer. The transfer of oversight will be formalized through the following steps:

1. **Agreements.** Establish formal agreements or memoranda of understanding (MOUs) between the originating and receiving IRBs. These agreements should outline each party's responsibilities and the terms of the transfer.
2. **Regulatory Approvals.** If applicable, obtain necessary approvals from regulatory agencies to ensure compliance with federal requirements.
3. **Information Transfer.** Transfer all relevant study documentation to the receiving IRB. This includes electronic and hard copy records, databases, and other pertinent materials.

Communication with Stakeholders. Clear and transparent communication with all stakeholders is essential throughout the transfer process. This includes:

1. **Principal Investigators and Research Teams.** Provide detailed instructions on any actions they must take during the transfer, including submitting documents to the receiving IRB and addressing any immediate compliance issues.
2. **Study Participants.** If required, inform study participants about the change in IRB oversight and provide updated contact information for the receiving IRB.
3. **Sponsors and Funding Agencies.** Notify study sponsors and funding agencies about the transfer and ensure continuity of funding and support.

Ensuring Continuity and Compliance. The receiving IRB will oversee all oversight responsibilities, including continuing review, monitoring ongoing studies, and addressing compliance issues. Both the originating and receiving IRBs will coordinate to ensure there is no lapse in oversight and that the rights and welfare of research participants are continuously protected.

Documentation and Record-Keeping. All actions taken during the transfer process, including notifications, agreements, and the actual transfer of documents, will be thoroughly documented. Both the originating and receiving IRBs will maintain these records as part of their regulatory compliance and institutional record-keeping requirements.

26. DEFINITIONS

Adverse event: any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory findings), symptom, or disease, temporally associated with the subject's participation in the research, whether considered related to the subjects' participation in research. Adverse events encompass both physical and psychological harm.

Advisor: the advisor on Student Research Protocols is a faculty member or professional who provides guidance and oversight to students conducting academic research. This role involves ensuring that research projects adhere to ethical standards, institutional guidelines, and relevant legal requirements. The advisor must be a subject matter expert in the research, possessing comprehensive knowledge and experience in the specific field of study. Responsibilities include mentoring students on research design, methodology, data analysis, and the dissemination of findings. Additionally, the advisor assists in navigating Middlebury's IRB and other regulatory bodies to secure necessary approvals for the research.

Amendment: Adds something new, such as a person who will obtain informed consent, to a research study; a type of Modification.

Anonymous: The investigator does not request, have access to, or give subjects' identities. If the only time the investigator asks for a name is for a signature on a consent form, the investigator should use implied consent to preserve anonymity.

Anonymous Data: Data that by virtue of the collection method 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.

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.

Application: The formal design or plan of a study's activity; specifically, the plan submitted to an IRB for review and to an agency for support. The application includes a description of the design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Assent: Agreement by subjects not competent to give legally valid informed consent (e.g., children or cognitively impaired people) to participate in the study. Assent refers to a child's affirmative agreement to participate in the research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Assurance: A formal written, binding commitment submitted to a federal agency, in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

Belmont Report: A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1979.

Benefit: A valued or desired outcome to the study that will be an advantage to the subjects participating. Compensation is not considered as a benefit.

Biomedical Research: Studies that are designed to evaluate the safety, effectiveness, or usefulness of an intervention including research on therapies (e.g., drugs, diet, exercise, surgical interventions, medical devices), diagnostic procedures (e.g., CAT scans, prenatal diagnosis through amniocentesis, chronic villi testing) and preventive measures (e.g., vaccines, diet, fluoridated toothpaste). It can also include normal human functioning and development, comparing the functioning of a particular physiological system at different stages of development (e.g., infancy, childhood, adolescence, adulthood, old age), or define normal childhood development. It includes research used to develop and refine hypotheses. Research on specific disease (e.g., research on the biochemical changes associated with AIDS or schizophrenia, the neurological changes associated with senile dementia of the Alzheimer type) and the human genome and genetic markers fall under biomedical research.
Biomedical research is focused on:

- Specific diseases and health conditions (mental or physical), including detection, cause, treatment, prevention, and rehabilitation.
- Evaluation and testing of the safety, effectiveness, or usefulness of an intervention, treatment, or therapy.
- Normal and abnormal physiology, human functioning, and development.
- Cognitive, emotional, and behavioral responses to real or potential health problems.
- The human genome and genetic markers.
- The incidence and prevalence of illness and injury among populations and strategies for prevention and health promotion.

Certificate of Confidentiality: A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical, and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Any research that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for the Certificate. For more information:
stigatohttp://grants.nih.gov/grants/policy/coc/

Certification: Certification means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Classroom Projects: Middlebury College recognizes that some student classroom projects conducted to fulfill course requirements involve activities that might be viewed as research in another context. Generally, when classroom projects are conducted **solely** to fulfill a course requirement, an element of the definition of research is lacking, which is the intent to develop or contribute to generalizable knowledge. Classroom projects with human subjects for which the sole purpose is a student learning experience in the methods and procedures of research do not require the submission of a Human Subjects Research Protocol to the IRB if **ALL** the following conditions are satisfied:

a. The activity is a requirement for a Middlebury College undergraduate course.
b. The sole purpose of the activity is to give students a learning experience in the methods and procedures of research.
c. The instructor is aware of all aspects of the project and takes responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of all project activities.
d. There is no intent on the part of the instructor or student to produce generalizable knowledge and findings from the study will **NEVER** be disseminated beyond presentation to instructors or peers in a Middlebury College classroom setting. If the possibility exists that the instructor or student would consider disseminating the data as generalizable knowledge (such as presenting the results in a master's thesis or a doctoral dissertation, poster, or talk at an academic conference, publication, etc.), then the activity is a research project, and a Human Subjects Research Protocol must be submitted to the IRB **before** any research activities are performed.

Clinical Investigation: The Food and Drug Administration (FDA) defines clinical investigation as "any experiment that involves a test article and one or more human subjects and that either must meet the requirements for prior submission to the Food and Drug Administration... or need not meet the requirements for prior submission to the Food and Drug Administration... but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit." [21 CFR 56.102(c)]

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. The NIH definition of Clinical Trial includes Basic Experimental Studies involving Humans (BESH). Basic research uses a range of probes or experimental manipulations to perturb a physiological process (including cognitive and perceptual processes). Under the NIH definition of a clinical trial, most experimental manipulations involving humans are considered to be interventions.

Coded private information or biological specimens: DHHS Office of Human Research Protection (OHRP) policy considers private information or biospecimens to be individually identifiable when they can be linked to specific individuals either directly or indirectly through coding systems. The IRB must determine if coded private information or biospecimen(s) constitute research. Investigators do not have the authority to independently determine that research involving coded private information or biospecimen(s) does not involve human subjects.

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.

Common Rule: A large majority of Federal Agencies simultaneously published a regulation or "Common Rule" on June 18, 1991, to regulate the conduct or support of human subject research. The rule is outlined in 45 CFR Part 46, Subpart A. Subpart A consists of 45 CFR 46.101 to 46.124. On January 18, 2017, The U.S. Department of Health and Human Services and 15 other federal agencies issued a final rule to update regulations that safeguard individuals participating in research. Most of the revisions to the Common Rule will go into effect on January 19, 2018.

Confidential: Subjects' names are known to the investigator and are usually coded to a master list and/or kept separately from the data and results. This is usually used, for example, when the investigator must match test results with surveys or if there will be a follow-up survey. The investigator must know the subjects' names.

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.

Confidentiality: the state of keeping or being kept secret or private.

Continuing Noncompliance. A pattern of repeated noncompliance actions or omissions that indicate a lack of understanding or disregard for regulatory requirements or IRB directives. This may include, but is not limited to:

- Repeated minor deviations from the protocol.
- Persistent tardiness in submitting required reports or amendments.
- Ongoing issues identified during continuing reviews or audits

Continuing Review: All projects initially approved by Full Board Review are required to undergo continuing review at least annually. The IRB may require more frequent review depending on the nature of the study, the degree of risk involved to human subjects, and the vulnerability of the study population.

Crime: A crime is a wrongdoing that has been classified by the state or federal legislative body as a felony or misdemeanor.

Data: Refers to information that is collected for analysis or used to reason or make decisions.

Deception: Deception involves intentionally providing inaccurate or false information to subjects. Examples include:

- In order to induce stress, study personnel tell subjects that they will give a speech that evaluators will observe on video, when the subjects' speeches will not actually be recorded or observed.
- Study personnel tell subjects that they will be engaged in a cooperative task with other subjects, but instead subjects will actually be interacting with study personnel.
- Study personnel tell subjects that they will play a competitive game involving financial rewards based on their performance. In fact, the game is rigged and rewards are not based on performance.

Deception increases ethical concerns because it interferes with the ability of the subject to give informed consent. However, deception is arguably necessary for certain types of behavioral research. Because humans act differently depending on circumstances, full knowledge by the subject might bias the results.

De-identified Data: De-identified data excludes all eighteen HIPAA Identifiers. De-identified data is not "anonymous data" under the Common Rule.

Directly or Indirectly Identifiable: Identities of individual subjects are kept by the investigator. If subjects' identities are inseparable from data, then data is directly identifiable. If subjects' identities are kept separate from data with information connecting them maintained by codes and a master list, then the data is indirectly identifiable. In either case, the investigator must assure that confidentiality will be maintained, and must explain how subjects' identities will be protected.

- **Direct identifiers (HIPAA Identifiers):** Direct identifiers in research data or records include: names; geographic subdivisions smaller than a State; dates (except year) directly related to patient; telephone numbers; fax numbers; e-mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers; device identifiers and serial numbers; web URLs; Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images and any comparable images; and any other unique identifying number, characteristic, or code, except as permitted under HIPAA to re-identify data.
- **Identifiable data or records:** Contains information that reveals or can likely associate with the identity of the person or persons to whom the data or records pertain. Research data or records with direct identifiers removed, but which retain indirect identifiers, are still considered identifiable.
- **In-direct identifiers:** Indirect identifiers in research data or records include all geographic identifiers smaller than a state, including street address, city, county, precinct, zip code, and their equivalent postal codes, except for the initial three digits of a zip codes; all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such age and elements may be aggregated into a single category of age 90 or older.

Educational Setting: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management method.

Exempt: The Common Rule specifies that research activities may be classified as exempt in the policy if human subjects' involvement is limited to one of the listed scenarios, including studies involving the collection or study of existing data when those data either are publicly available or not personally identifiable. Exempt Status Reviews are evaluated by the IRB and will take approximately 10 working days.

Generalized Knowledge: Knowledge that could be applied to populations outside of the population served by the covered entity. This definition can vary. Examples of activities that typically are not generalized include:

- Biographies.
- Oral histories that are designed solely to a create record of specific historical events.
- Service or course evaluations unless they can be generalized to other individuals.

- Services, or concepts where it is not the intention to share the results beyond Middlebury College or any agency supporting the research.
- Classroom exercises solely to fulfill course requirements or to train students in the use of methods or devices.
- Quality assurance activities are designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the Middlebury College community.

HIPAA: Health Insurance Portability and Accountability Act (HIPAA) of 1996 that protects certain health information. The Privacy Rule was issued to protect the privacy of health information that identifies individuals who are living or deceased.

HIPAA Research Authorization: The Research Authorization required under the HIPAA Privacy Rule is a written patient authorization that must specify:

- Who can use or disclose Protected Health Information (PHI)
- To whom PHI may be disclosed
- What PHI may be used or disclosed
- The purposes of the used or disclosed PHI
- The duration of the authorization (expiration date or event)

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Identifiable Private Information: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Incomplete disclosure: Incomplete disclosure involves withholding information about the study purpose and/or reason for procedures, in order to prevent biasing the results. Examples include:

- In order to examine how race and gender impact people's perception of conflicts between individuals, subjects review several hypothetical scenarios describing confrontations between various characters, which include stock photos to represent the individuals involved, and then are asked to complete questions regarding their perception of each of the individuals involved. The subjects are not informed that the race and gender of the characters are manipulated by the researchers but subjects will know that the scenarios are hypothetical.
- To further understanding of how representations of same sex couples depicted in commercials influence consumer behavior, subjects are exposed to advertisements featuring gay couples and straight couples while their heart rate, facial muscle movement, and sweat responses are recorded. Subjects are informed that their reactions to the commercials are being studied, but not that the researchers are examining if the sexual orientation of characters in commercials influences them.

Limits on Incomplete disclosure:

Incomplete disclosure does not extend to withholding information from subjects about what they will be asked to do. A protocol that informs subjects that they will be asked to complete one 60-minute session but provides no information about the contents of this session would not be considered incomplete disclosure. Protocols that involve manipulating an individual's environment, without that person's prospective agreement to participate in research, are not considered incomplete disclosure. In such cases disclosure to subjects is entirely absent, not merely incomplete.

Informed Consent: The knowing, legally effective consent of any individual or the individual's legally authorized representative; such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether to participate and minimize the possibility of coercion or undue influence.

In general, the principal investigator must explain to subjects, before participating, the research objectives, 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 are legally responsible for their well-being, freely consent to participate, 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. Requests to waive documentation of informed consent or waive or alter informed consent must meet specific requirements.

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.

Institutional Review Board (IRB): A committee formed to facilitate the protection of human subjects in research.

Intentionally Identified: Subjects' names are identified in connection with the data when the research results are presented to the public. This procedure is common for journalistic-type interview studies, where subjects are public figures or in oral histories. In these cases, the investigator should seek explicit consent from the subjects for the use of their names in connection with their data.

Interaction: Includes communication or interpersonal contact between investigator and subject.

Interpreter/Translator: An agent of the researcher(s), who assists in the facilitation of communication between the researcher(s) and participants who are not fluent in the language of the researcher(s).

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.

IRB Approval: The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Legally Authorized Representative: 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. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Mentor: The Sitero Mentor suite is a site as a service (SAS) that leverages intelligent automation to enable efficient reporting, communication, and process management functions for research, clinical, and higher education institutions. Sitero Mentor streamlines IRB, IBC, IACUC, accreditation record keeping, committee workflows, internship management, course evaluations, and more.

Minimal Risk: 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.

Modification: means any change. It encompasses two commonly used terms: A revision is a change in something that exists, such as increasing the number of participants. An amendment adds something new, such as a person who will obtain informed consent.

Neonate: Newborn.

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 it. This category includes questionnaires 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/

Personally Identifiable Health Information: Health or medical data or information that can be linked manifestly or inferentially to an individual.

Population: A group of people in society meeting certain criteria to be eligible as subjects in a research protocol.

Principal Investigator (PI): The individual with primary responsibility for designing and conducting a research study. When a Middlebury College student serves as the PI, a Middlebury College faculty member must serve as the Co-PI, and the faculty member shares full responsibility for the design and conduct of the study.

Prisoner: Federal regulations define a prisoner as any individual involuntarily confined or detained in a penal institution and/or individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to incarceration. The Middlebury College IRB does not review prisoner research.

Privacy: Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Private Information: 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., a medical record). Private information must be individually identifiable to obtain the information to constitute research involving human subjects.

Protected Health Information (PHI): Individually identifiable health information recorded in any form or medium that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

Public Health Authority: An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from a contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Publicly Available Data: Public sources of data, such as census data.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Quorum: the minimum number of members of an assembly or society that must be present at any of its meetings to make the proceedings of that meeting valid. Middlebury College has defined quorum as fifty percent (50%) of the total membership plus one (1) additional member.

Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring due to participation in a study. The probability and magnitude of possible harm may vary from minimal to significant.

Revision: A change in something that exists, such as increasing the number of participants in a research study; a type of Modification.

Secondary Research: Re-using identifiable information and identifiable biospecimens collected for some other ‘primary’ or ‘initial’ activity.

Serious Adverse Event (SAE): (includes *serious adverse drug or biological experience* and *unanticipated adverse device experiences* under FDA regulations) is any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

- Results in death.
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred).
- Requires inpatient hospitalization or prolongation of existing hospitalization.
- Results in a persistent or significant disability/incapacity.
- Results in a congenital anomaly/birth defect.
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health, and require medical or surgical intervention to prevent one of the other outcomes listed in this definition. Examples include allergic bronchospasms requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, and the development of drug dependency or drug abuse.

Serious Noncompliance. Any failure to adhere to federal regulations, institutional policies, or IRB requirements that may affect the rights and welfare of research participants. Examples include, but are not limited to:

- Conducting research without IRB approval.
- Deviating from the approved protocol in a way that impacts participant safety or data integrity.
- Failing to obtain informed consent when required.

Significant Risk: A study's design that presents a potential for serious risk to the health, safety, or welfare of the subjects.

Social and Behavioral Research: Behavioral and social sciences research is a large, multifaceted field encompassing many disciplines. The field employs a variety of methodological approaches including surveys and questionnaires, interviews, randomized clinical trials, direct observation, physiological manipulations and recording, descriptive methods, laboratory and field experiments, standardized tests, economic analyses, statistical modeling, ethnography, and evaluation. Yet, behavioral, and social sciences research is not restricted to a set of disciplines or methodological approaches. Instead, the field is defined by substantive areas of research that transcend disciplinary and methodological boundaries. In addition, several key cross-cutting themes characterize social and behavioral sciences research. These include an emphasis on theory-driven research; the search for general principles of behavioral and social functioning; the importance ascribed to a developmental, lifespan perspective; an emphasis on individual variation, and variation across sociodemographic categories such as gender, age, and sociocultural status; and a focus on both the social and biological contexts of behavior.

Systematic: Step-by-step, methodical procedure presented or formulated as a coherent body of ideas or principles.

Unreasonable Harm: 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.

Vulnerability: Vulnerable to coercion and undue influence, in recognition that coercion or undue influence refers to the ability to make an informed decision about participating in research.

Voluntary: Free of coercion, duress, or undue inducement.

Written, or In Writing: Writing on a tangible medium (e.g., paper) or in an electronic format.