



Middlebury

RESEARCH COMPLIANCE REPORT
2015-2016

Statement of Purpose/Introduction

Middlebury is committed to fostering a vibrant and diverse academic community through the promotion of research and scholarly activity. In order to support research activities and ensure a safe research environment, Middlebury strives to adhere to the highest standards of ethics, integrity, and responsibility.

The Research Compliance Manager is responsible for coordinating and monitoring research programs to assure compliance with applicable regulations, statutes, and institutional policies. This is accomplished, in part, through compliance committees, reports to federal agencies, and training programs. Middlebury's compliance committees are composed of faculty, staff, and community members who thoroughly review research conducted with vertebrate animals, human subjects, and recombinant DNA. The compliance committees include: the Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee (IBC), and the Institutional Review Board (IRB). This report summarizes the work of Middlebury's compliance committees, and the creation of a new laboratory safety working group, in order to promote the responsible conduct of research.

This report covers the time period from September 1, 2015 through August 31, 2016.

1. Compliance Committee: Institutional Animal Care and Use Committee (IACUC) – Research with Vertebrate Animals

1.1 Responsible Individuals

<u>Role</u>	<u>Individual</u>
Institutional Official	Steve Trombulak, PhD
Chair	Bob Cluss, PhD
Attending Veterinarian	Joanne Huyler, DVM

1.2 Committee Membership

The members of the 2015-2016 Middlebury IACUC were: Rev. Molly Bidwell (non-affiliated member), Marcia Collaer (scientist, Psychology), Bob Cluss (chair, Chemistry), Joanne Huyler (veterinarian), Deb Mazza (non-affiliated member), Clarissa Parker (scientist, Psychology), Mark Spritzer (scientist, Biology), Steve Viner (non-scientist, Philosophy).

1.3 Work Flow Summary

Meetings

The Middlebury IACUC met six times during the academic year and approved: five new protocols, two third-year renewals, two significant amendments, and one minor amendment. Volunteers from the full committee also conducted two animal facility inspections and program reviews, which were approved by the full committee and submitted to Institutional Official Steve Trombulak. One facility inspection and program review took place on December 17th and the second inspection and program review took place on June 7th.

Administration and Reporting

During the academic year, IACUC staff processed and approved: three minor amendments, 15 annual reviews, and 15 personnel amendments. IACUC staff prepared and submitted an annual report to the United States Department of Agriculture (USDA) in November 2015. IACUC staff also prepared and submitted an annual report to the Public Health Services Office of Laboratory Animal Welfare in January 2016. On Monday, February 29, 2016, Dr. Paula Gladue from USDA conducted the annual facility inspection; no non-compliant items were found.

Training

Training programs are a key part of any compliance program. During the 2015-2016 academic year, 129 students and 6 faculty or staff completed or renewed animal welfare training through the Collaborative Institutional Training Institute (CITI) online modules. Animal Facility Manager Vicki Major trained 59 students and 3 faculty/staff members on safe work practices in the Animal Facility. The Middlebury IACUC has an Occupational Health & Safety Program in order to protect employees and students working with animals. This year 30 students and 8 faculty/staff members submitted risk assessment forms and were cleared for work with animals by a medical professional.

1.4 Policy Changes/Updates

As a result of the December program review minor updates were made to the following policies, which were then approved by the full board and posted on the IACUC website: Amending Animal Subjects Approval Forms, Guidelines for Survival Surgery, Maintenance of Animal Records, Process for Review and Approval of Animal Care and Use Protocols, Reporting Concerns About the Care and Use of Research and Teaching Animals, Tissue Sampling for Genetic Monitoring in Mice. From the June program review, two new policies were reviewed (Analgesia Guidelines for Rats and Mice, Authority of the Attending Veterinarian) and one existing policy was modified (Euthanasia Criteria for Rodents). All three policies were approved by the full board at the July meeting and posted on the IACUC website.

2. Compliance Committee: Institutional Biosafety Committee (IBC) – Research with Recombinant DNA

2.1 Responsible Individuals

<u>Role</u>	<u>Individual</u>
Responsible Official	Steve Trombulak, PhD
Chair	Grace Spatafora, PhD

2.2 Committee Membership

The members of the 2015-2016 Middlebury IBC were: Tim Allen (laboratory staff, Science Technical Support Services), Nick Artim (non-affiliated member), Katie Gillespie (NIH contact, Academic Affairs), Jill Mikucki (scientist, Biology), Tom Scanlon (non-affiliated member), Grace Spatafora (chair, Biology), Jeremy Ward (scientist, Biology).

2.3 Work Flow Summary

Meetings

There was no formal business to review, but the chair deemed one project exempt from the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Administration and Reporting

IBC staff prepared and submitted an annual report to the NIH Office of Science Policy in March 2016.

2.4 Policy Changes/Updates

The draft IBC policy was revised and streamlined to reduce the total number of committee members to the number recommended in the NIH Guidelines. New application forms were created in order to streamline the application process. The new process includes one application for exempt determinations and one for full IBC review; the new application process will be implemented in the next academic year.

3. Compliance Committee: Institutional Review Board (IRB) – Research with Human Subjects

3.1 Responsible Individuals

<u>Role</u>	<u>Individual</u>
Signatory Official	Jim Ralph, PhD
Chair	Mike Sheridan, PhD
Administrator	Katie Gillespie

3.2 Committee Membership

The members of the 2015-2016 Middlebury IRB were: Lorraine Besser (Philosophy), Katie Gillespie (non-scientist Academic Affairs), Emiliano Huet-Vaughn (scientist, Economics), Matthew Kimble (scientist,

Psychology), Robert McCleery (MIIS GSIPM, Development, Practice, and Policy), Pablo Oliva (MIIS GSTILE, Language Studies, Spanish), Jim Ralph (Academic Affairs), Ira Schiffer (non-scientist, Chaplain's Office), Michael Sheridan (chair, Sociology/Anthropology), Bonnie Stevens (community member).

3.3 Work Flow Summary

Meetings

The Middlebury IRB met six times during the academic year and approved 11 full board proposals.

Administration and Reporting

During the academic year, IRB staff reviewed: 25 proposals that were deemed not to be human subjects research and 117 proposals that were deemed exempt from the federal regulations. IRB staff and committee members reviewed and approved 18 proposals at the expedited level. In total, the IRB received and processed 171 proposals.

IRB staff prepared and submitted an updated IRB registration and Federalwide Assurance to the Department of Health and Human Services (HHS) in September 2015.

Training

All investigators conducting research with human subjects are required to complete training in the ethical conduct of research as part of their IRB application. In the last academic year, 50 students and 16 faculty or staff underwent or renewed their human subjects ethics training via the National Institutions of Health online course.

3.4 Policy Changes/Updates

There were several major changes to the Middlebury IRB policies/procedures. First, it was recommended that the IRB Signatory Official be changed from Jim Ralph to Provost Susan Baldrige in order to follow guidance from the HHS Office for Human Research Protections. Second, it was recommended that the box applying federal regulations 45 CFR 46 (The Common Rule) to all research, regardless of funding source, be unchecked in order to maximize flexibility in the regulations for minimal risk research. Both changes were approved by Provost Susan Baldrige. These changes will be made to Middlebury's Federalwide Assurance when it is updated in the next academic year.

IRB staff worked with Information Technology Services to add language on data security to the IRB policy and to create a website with data storage best practices for investigators. Final revisions to both the policy and website will be finalized in the next academic year.

The IRB also approved a new application form for exempt determinations. The two-page application was designed to streamline the submission process for minimal risk studies and will be implemented in Fall 2016.

4. Compliance Area: Middlebury Sciences Environmental Health and Safety Working Group

4.1 Composition

The Middlebury Sciences Environmental Health and Safety Working Group is an informal, volunteer working group was created in November 2015 at the invitation of Cathy Ekstrom in order to formalize a laboratory safety program for the Middlebury Sciences. The working group consisted of: Cathy Ekstrom, Beth Eliason, Katie Gillespie, Jen Kazmierczak, Jody Smith, and Jonathan Kemp.

4.2 Work Flow Summary

Meetings

The working group met approximately 30 times during the academic year in order to outline a vision for a strong safety culture and laboratory safety program in the Middlebury Sciences. A key part of this effort

included giving presentations about the vision for the lab safety program to Middlebury's Senior Leadership, Science Department Chairs, and the Board of Trustees Risk Group. The working group prepared revisions to several plans (Chemical Hygiene Plan, Laboratory Management Plan) and created safety programs and trainings.

Training

In June, training sessions were held for faculty and staff on how to implement and ensure compliance with the updated Chemical Hygiene Plan and Laboratory Management Plan; 52 faculty and staff in Bicentennial Hall attended these trainings and additional sessions will be held in the upcoming academic year to ensure full compliance. Over the summer, 95 research students participated in a pilot laboratory safety training program. Based on this pilot program, a laboratory safety training program for students will be implemented in the upcoming academic year.

4.3 Policy Changes/Updates

Beth Eliason oversaw significant updates to the Chemical Hygiene Plan and the creation of a Laboratory Management Plan; Beth was also appointed as Chemical Hygiene Officer for the institution. Key components of the plan revisions included: the creation of an online chemical inventory, the establishment of a new procedure for labeling of laboratory waste containers and cleanout of unwanted materials, and the reestablishment of the Chemical Safety Committee. An interim Chemical Safety Committee met in May 2016 and formal faculty appointments were made for the upcoming academic year. The working group will assist the faculty committee with future planned portions of the laboratory safety program, such as a compliance assistance program with periodic laboratory inspections. The working group also created a new laboratory safety website (go/labsafety) to provide safety information and resources for faculty, staff, and students.