



Middlebury

RESEARCH COMPLIANCE REPORT
2017-2018

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 in order to promote the responsible conduct of research.

This report covers the time period from September 1, 2017 through August 31, 2018.

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 | Pat Manley, PhD |
| Chair | Tom Root, PhD |
| Attending Veterinarian | Joanne Huyler, DVM |

1.2 Committee Membership

The members of the 2017-2018 Middlebury IACUC were: Rev. Molly Bidwell (non-affiliated member), Catherine Combelles (scientist, Biology), Amanda Crocker (scientist, Neuroscience), Shalom Goldman (non-scientist, Religion), Joanne Huyler (veterinarian), Clarissa Parker (scientist, Psychology), Tom Root (chair, Biology), and Len Rowell (non-affiliated member). Pat Manley is Institutional Official for the animal program.

1.3 Work Flow Summary

Meetings

The Middlebury IACUC met seven times during the academic year and approved: eight new protocols, five third-year renewals, and ten significant amendments. 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 Pat Manley. One facility inspection and program review took place on December 14th and the second inspection and program review took place on June 5th.

Administration and Reporting

During the academic year, IACUC staff processed and approved: two minor amendments, 6 annual reviews, and eight personnel amendments. IACUC staff prepared and submitted an annual report to the United States Department of Agriculture (USDA) in November 2017. IACUC staff also prepared and submitted an annual report to the Public Health Services Office of Laboratory Animal Welfare in January 2018. On March 28, 2018, Dr. Jessica Gowins from USDA conducted the annual inspection. Dr. Gowins inspected the IACUC records and the vivarium; no non-compliant items were found.

Training

During the 2017-2018 academic year, 119 students and eight faculty or staff completed or renewed animal welfare training through the Collaborative Institutional Training Institute (CITI) online modules. Animal facility staff and/or the Research Compliance Manager trained 97 students and three faculty/staff members on safe work practices in the Animal Facility. The Middlebury IACUC has an Occupational Health & Safety (OH&S) Program in order to protect employees and students working with animals. This year 20 students and seven faculty/staff members submitted risk assessment forms and were cleared for work with animals by a medical professional. Annual reminders were also sent to all participants enrolled in the OH&S program in order to ensure that all user information is current/accurate.

1.4 Policy Changes/Updates

There were no significant policy changes or updates for the IACUC during this time period.

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

2.1 Responsible Individuals

| <u>Role</u> | <u>Individual</u> |
|----------------------|----------------------|
| Responsible Official | Pat Manley PhD |
| Chair | Grace Spatafora, PhD |

2.2 Committee Membership

The members of the 2017-2018 Middlebury IBC were: Tim Allen (laboratory staff, Science Technical Support Services), Nick Artim (non-affiliated member), Kim Cronise (scientist, Psychology), Katie Gillespie (NIH contact, Academic Affairs), Tom Scanlon (non-affiliated member), Grace Spatafora (chair, Biology), Jeremy Ward (scientist, Biology). Pat Manley is the responsible official for the biosafety program.

2.3 Work Flow Summary

Meetings

The IBC met on April 17, 2018 to review three faculty submissions. One submission was approved as is and the other two submissions were approved pending clarification of waste disposal practices.

Administration and Reporting

IBC staff prepared and submitted an annual report to the NIH Office of Science Policy in March 2018.

2.4 Policy Changes/Updates

During the April 2018 meeting, the IBC decided that low risk proposals would be approved for a five-year period (barring any amendments altering the risk determination). The IBC also recommended that a safety presentation be developed for students working with recombinant DNA. The Research Compliance Manager created an rDNA safety presentation (reviewed by the Middlebury Sciences Environmental Health & Safety Working Group and IBC members) that will be ready for implementation during the upcoming 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 | Jeffrey Cason, PhD |
| Chair | Carlos Velez, PhD (September, 2017 – January, 2018)/Michael Sheridan, PhD (February 2018 – August 2018) |
| Administrator | Katie Gillespie |

3.2 Committee Membership

The members of the 2017-2018 Middlebury IRB were: Tsuneo Akaha (MIIS GSIPM, Development, Practice, and Policy), Katie Gillespie (non-scientist Academic Affairs), Julie Johnson (MIIS GSTILE,

Translation and Interpretation), Michael Linderman (scientist, Computer Science), Jennifer Ortegren (non-scientist, Religion), Jim Ralph (Academic Affairs), Andrea Robbett (scientist, Economics), Michael Sheridan (scientist, Sociology/Anthropology), Bonnie Stevens (Community Member), and Carlos Velez (Chair, Psychology). Due to a new academic appointment, Dr. Velez stepped down from the committee in January 2018 and Michael Sheridan took over as chair. Martin Seehuus became the new faculty representative for the Psychology Department for the Spring 2018 semester.

3.3 Work Flow Summary

Meetings

The Middlebury IRB met eight times during the academic year and reviewed 11 full board proposals; eight proposals were approved outright, approval was tabled/deferred for three proposals, and one proposal was rejected.

Administration and Reporting

During the academic year, IRB staff reviewed: 35 proposals that were deemed not to be human subjects research (NHSR) and 99 proposals that were deemed exempt from the federal regulations. IRB staff and committee members reviewed and approved 29 proposals at the expedited level. In total, the IRB received and processed 174 submissions. Figure 1 depicts the number of projects reviewed (and the review category) for the past three years; submissions have remained relatively consistent over the three academic years this report has been issued.

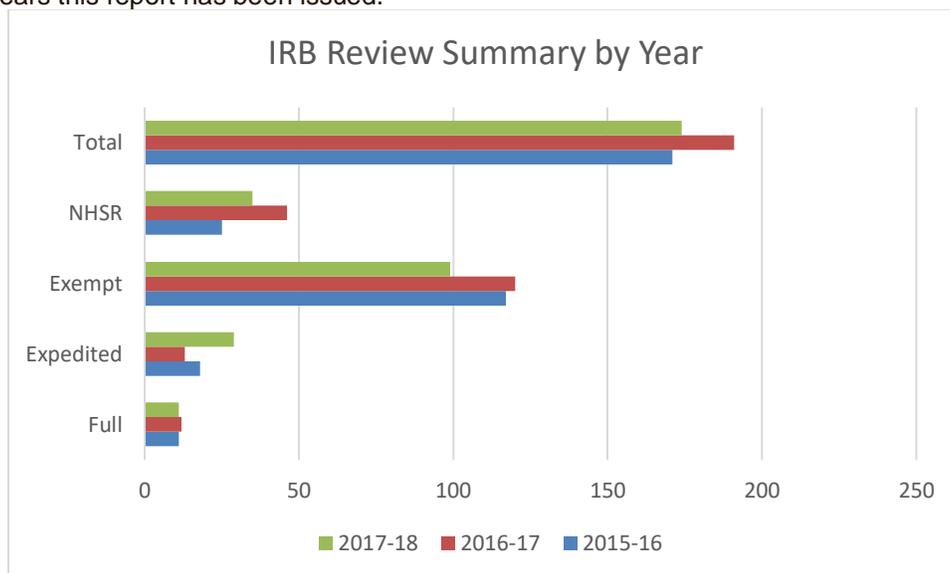


Figure 1: Number of IRB Submissions Reviewed Per Academic Year

Figure 2 shows that the majority of submissions (N=104; 60%) came from students and faculty on the Vermont campus, 47 submissions came from Monterey, and the remaining submissions came from Language Schools (N=15), the Schools Abroad (N=7), and an external researcher (N=1). The majority of IRB submissions came from students (N=104; 60%) and 70 submissions came from faculty or staff.

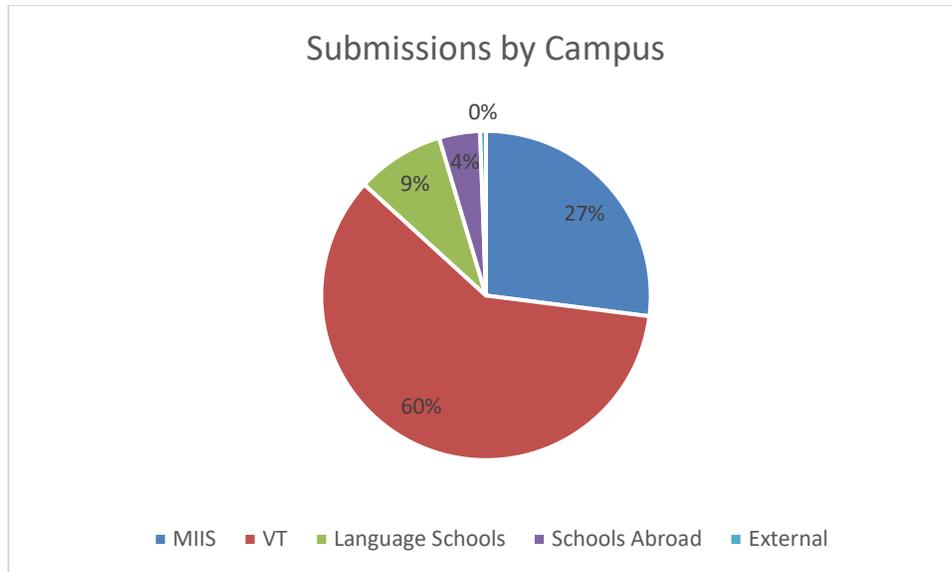


Figure 2: IRB Submissions by Campus

IRB staff prepared and submitted an updated IRB registration and Federalwide Assurance to the Department of Health and Human Services (HHS) in September 2017.

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, 72 students and 18 faculty or staff completed or renewed their human subjects' ethics training via the National Institutions of Health online course or the CITI Social & Behavioral Research module.

3.4 Policy Changes/Updates

There were several major changes to the Middlebury IRB policies/procedures. Beginning in Spring 2018, the IRB started holding office hours in order to provide better customer service. During the spring semester, 20 students and faculty took advantage of office hours, which will continued to be offered.

In March 2018, the IRB Administrator took over review of exempt proposals in order to reduce the workload of the IRB Chair. Thus far the change has provided relief for the chair without overly burdening the administrator; the workload distribution will continue to be monitored.

In April 2018, the IRB Administrator traveled to Monterey to meet with IRB members located at MIIS and key MIIS faculty and staff. A public presentation was also offered and recorded for posterity. The presentation is [available on the IRB website](#) and included a FAQ segment with questions specific to MIIS faculty and students.