



Middlebury

**RESEARCH COMPLIANCE REPORT**  
**2018-2019**

---

## 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 Associate Director for Research Compliance 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, 2018 through August 31, 2019.

# 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                  | Steve Trombulak, PhD |
| Attending Veterinarian | Joanne Huyler, DVM   |

## 1.2 Committee Membership

The members of the 2018-2019 Middlebury IACUC were: Rev. Molly Bidwell (non-affiliated member), Catherine Combelles (scientist, Biology), Susan DeSimone (scientist, Biology), Joanne Huyler (veterinarian), Clarissa Parker (scientist, Psychology), Len Rowell (non-affiliated member), Steve Trombulak (scientist/Chair, Biology), and Steve Viner (non-scientist, Philosophy). Pat Manley is the Institutional Official for the animal program.

## 1.3 Work Flow Summary

### *Meetings*

The Middlebury IACUC met seven times during the academic year and approved: three new protocols, three third-year renewals, and four significant amendments. Volunteers from the full committee also conducted two animal facility inspections and two program reviews, which were presented to the full committee and submitted to Institutional Official Pat Manley. One facility inspection and program review took place on December 13<sup>th</sup>, 2018 and the second inspection and program review took place on June 26<sup>th</sup>, 2019.

### *Administration and Reporting*

During the academic year, IACUC staff processed and approved: 10 minor amendments, 11 annual reviews, and seven personnel amendments. On October 24, 2018, Dr. Paula Gladue from USDA conducted the annual inspection. Dr. Gladue inspected the IACUC records and the vivarium; no non-compliant items were found. IACUC staff prepared and submitted an annual report to the United States Department of Agriculture (USDA) in November 2018. IACUC staff also prepared and submitted an annual report to the Public Health Services Office of Laboratory Animal Welfare in January 2019.

### *Training*

During the 2018-2019 academic year, 89 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 Associate Director for Research Compliance trained 89 students and four 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 15 students and five 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

New training presentations were created for new faculty and new IACUC members. The presentations will be implemented in the upcoming academic year.

## 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 2018-2019 Middlebury IBC were: Tim Allen (laboratory staff, Science Technical Support Services), Nick Artim (non-affiliated member), Kim Cronise (scientist, Psychology), Glen Ernstrom (scientist, Biology/Neuroscience), Katie Gillespie (NIH contact, Academic Affairs), Tom Scanlon (non-affiliated member), and Grace Spatafora (chair, Biology). Pat Manley is the responsible official for the biosafety program.

### 2.3 Work Flow Summary

#### *Meetings*

The IBC did not have any proposals to review during the academic year. Committee members provided feedback on a training presentation designed for students working with recombinant DNA.

#### *Administration and Reporting*

IBC staff prepared and submitted an annual report to the NIH Office of Science Policy in March 2019.

### 2.4 Policy Changes/Updates

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

## 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              | Andrea Robbett, PhD (September, 2018 – March, 2019; August 2019)/Michael Sheridan, PhD (April 2019 – July 2019) |
| Administrator      | Katie Gillespie   |

### 3.2 Committee Membership

The members of the 2018-2019 Middlebury IRB were: Katie Gillespie (non-scientist Academic Affairs), Julie Johnson (MIIS GSTILE, Translation and Interpretation), Sharad Joshi (MIIS GSIPM, Nonproliferation and Terrorism Studies), Michael Linderman (scientist, Computer Science), Amy Morsman (Academic Affairs), Jennifer Ortegren (non-scientist, Religion), Andrea Robbett (scientist/Chair, Economics), Michael Sheridan (scientist, Sociology/Anthropology), Martin Seehuus (scientist, Psychology), and Bonnie Stevens (Community Member). Dr. Robbett was on leave from April through July so Dr. Sheridan filled in as interim chair during that period.

### 3.3 Work Flow Summary

#### Meetings

The Middlebury IRB met five times during the academic year and reviewed 9 full board proposals. Of those, five proposals were eventually approved (see Appendix A for a list of full board proposals approved in 2018-19); the others were either rejected or withdrawn.

#### Administration and Reporting

During the academic year, IRB staff reviewed: 29 proposals that were deemed not to be human subjects research (NHSR) and 91 proposals that were deemed exempt from the federal regulations. IRB staff and committee members reviewed and approved 22 proposals at the expedited level. In total, the IRB received and processed 151 submissions. Figure 1 depicts the number of projects reviewed (and the review category) for the past four years. During that period, the average number of projects reviewed was 171.75. In 2018-2019, the number of projects reviewed fell under that average. This downward trend may be natural (e.g. fewer students choosing thesis projects that involve research with human subjects), but it will continue to be monitored and is one of the primary motivations behind launching an IRB user satisfaction survey in the upcoming academic year in order to determine whether more outreach/education efforts are needed.

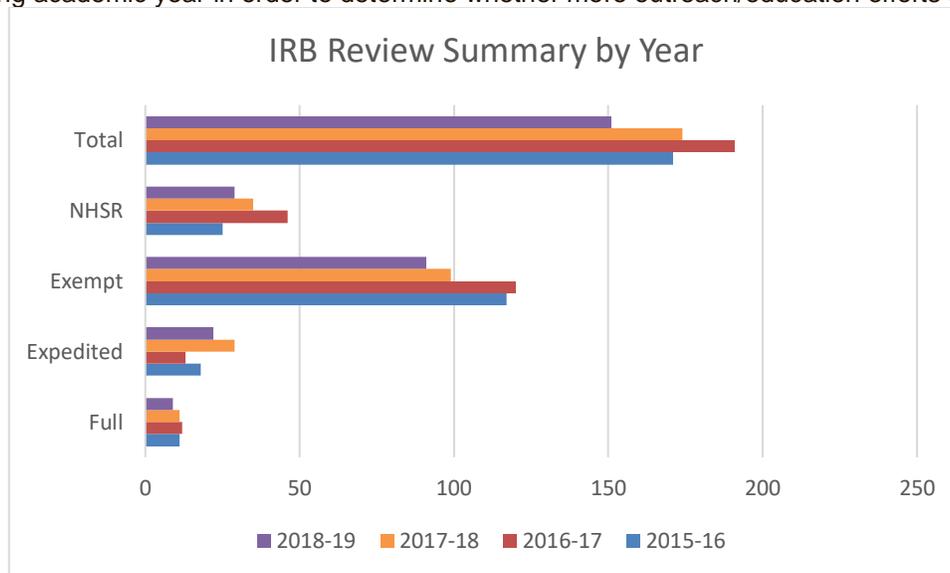


Figure 1: Number of IRB Submissions Reviewed Per Academic Year

Figure 2 shows that the majority of submissions (N=79; 67%) came from students and faculty on the Vermont campus, 22 submissions came from Monterey, and the remaining submissions came from Language Schools (N=9), the Schools Abroad (N=3), and external researchers (N=5). This breakup changed slightly from 2017-18, with more submissions coming from the Vermont campus. In the upcoming academic year, PIs will receive an IRB user satisfaction to help determine whether the needs of users at all campuses are being met.

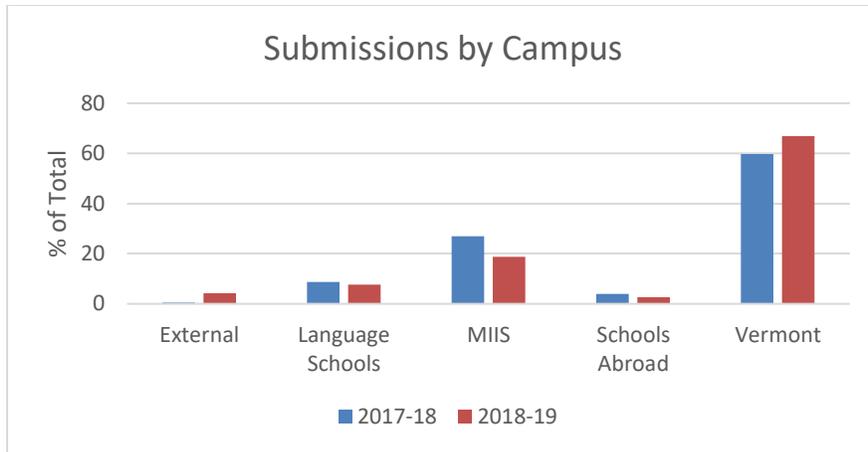


Figure 2: IRB Submissions by Campus

Figure 3 shows that the majority of IRB submissions came from students (N=64; 64%), 49 submissions came from faculty or staff, and 5 submissions came from external researchers (Middle grades who received Fulbright awards). This trend is consistent with previous years where students submitted the majority of IRB proposals.

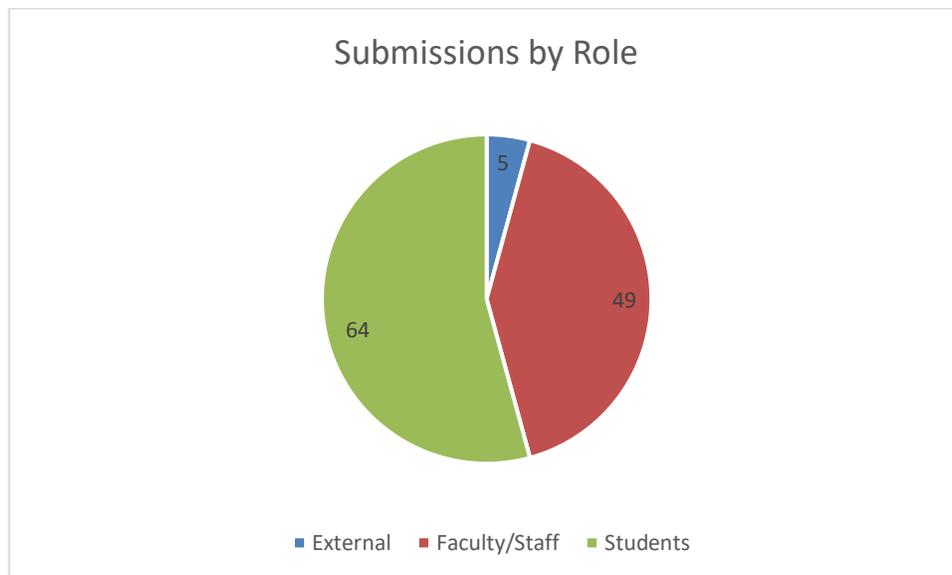


Figure 3: IRB Submissions by PI Role

IRB staff prepared and submitted an updated IRB registration and Federalwide Assurance to the Department of Health and Human Services (HHS) in September 2018. The IRB registration was also updated with each change in chair.

### 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, 150 students and 27 faculty or staff completed or renewed their human subjects' ethics training via the National Institutes of Health online course or the CITI Social & Behavioral Research module.

### 3.4 Policy Changes/Updates

[Changes to the Common Rule](#) went into effect on January 21, 2019. This resulted in one major change to investigators: minimal risk projects reviewed under the new rule no longer need to be renewed annually. This reduces some administrative burden to investigators (i.e. no annual report is required), but does introduce additional work for the IRB administrator. In order to remain in communication with investigators, the IRB administrator will send an annual check-in email to all investigators to: determine whether the project is active, ensure that no changes have been made to the project, and that no problems or adverse events occurred. Additionally, one new exemption category was added for benign behavioral interventions (e.g. playing an online game, allocating a nominal amount of cash among participants in an economics game, etc.). These changes were communicated to investigators via email and a [special section on the IRB website](#).

The IRB administrator designed a new relational database to manage IRB records. The previous “database” contained only one-to-one relationships, which resulted in redundant data entry and made compiling reports and pulling data tedious. The new database streamlines this process, though the homegrown system (with separate applications in Qualtrics and Drupal) is still time consuming.

## Appendix A: Full Board Proposals Approved by the IRB in 2018-19

1. Aguilar, Annie (student) – The Healthy Brain!; approval finalized 2/7/19
2. Benti, Meron (student) – “Mainstreaming” education of people with Albinism in East Africa; approval finalized 11/2/18
3. Gelker, Ivy (student) – Summer Camp: Age in the summer; approval finalized 7/22/19
4. Kennedy, Helen (student) – Language acquisition in primary school interactions; approval finalized 5/22/19
5. Kimble, Matthew (faculty) – ERP and eye tracking studies of expectancies in trauma survivors (renewal); approved 10/12/18