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, 2019 through August 31, 2020. This report covers a non-standard year as students were sent home in March 2020 due to the COVID-19 pandemic.
1. Compliance Committee: Institutional Animal Care and Use Committee (IACUC) – Research with Vertebrate Animals

1.1 Responsible Individuals

<table>
<thead>
<tr>
<th>Role</th>
<th>Individual</th>
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<tbody>
<tr>
<td>Institutional Official</td>
<td>Pat Manley, PhD/Rick Bunt, PhD</td>
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<tr>
<td>Chair</td>
<td>Catherine Combelles, PhD</td>
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<tr>
<td>Attending Veterinarian</td>
<td>Joanne Huyler, DVM</td>
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1.2 Committee Membership

The members of the 2019-2020 Middlebury IACUC were: Rev. Molly Bidwell (non-affiliated member), Pete Brooks (non-affiliated member), Clint Cave (scientist, Neuroscience) Catherine Combelles (scientist, Biology), Mike Dash (scientist, Psychology), Joanne Huyler (veterinarian), Clarissa Parker (scientist, Psychology), and Bill Waldron (non-scientist, Religion). Pat Manley was the Institutional Official for the animal program through June 30th, 2020. Rick Bunt took over as IO on July 1st, 2020.

1.3 Workflow Summary

Meetings

The Middlebury IACUC met five times during the academic year and approved: four new protocols, two third-year renewals, and one significant amendment. 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 9th, 2019 and the second inspection and program review took place on June 9th, 2020.

Administration and Reporting

During the academic year, IACUC staff processed and approved: 2 amendments, 12 annual reviews, and five personnel amendments. On October 15, 2019, Dr. Sara Savage from USDA conducted the annual inspection. Dr. Savage 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 2019. IACUC staff also prepared and submitted an annual report to the Public Health Service’s Office of Laboratory Animal Welfare (OLAW) in January 2020. The assurance renewal was submitted to OLAW in July 2020. The AAALAC accreditation site inspection originally scheduled for March 30th, 2020 was cancelled due to the pandemic.

Training

During the 2019-2020 academic year, 88 students and 12 faculty or staff completed or renewed animal welfare training through the Collaborative Institutional Training Institute (CITI) online modules. The Vivarium Manager trained 91 students and one faculty/staff member on safe work practices in the Animal Facility. The Associate Director for Research Compliance trained four new IACUC members, one new PI, and the new IO. 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 six 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 for the IACUC during this time period.
2. Compliance Committee: Institutional Biosafety Committee (IBC) – Research with Recombinant DNA

2.1 Responsible Individuals

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<tr>
<td>Responsible Official</td>
<td>Pat Manley, PhD/Rick Bunt, PhD</td>
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<tr>
<td>Chair</td>
<td>Grace Spatafora, PhD</td>
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2.2 Committee Membership

The members of the 2019-2020 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 was the responsible official for the biosafety program through June 30th, 2020; Rick Bunt took over July 1, 2020.

2.3 Workflow 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 2020.

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

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<tr>
<td>Signatory Official</td>
<td>Jeffrey Cason, PhD</td>
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<tr>
<td>Chair</td>
<td>Andrea Robbett, PhD</td>
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<tr>
<td>Administrator</td>
<td>Katie Gillespie</td>
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3.2 Committee Membership

The members of the 2019-2020 Middlebury IRB were: Sayaka Abe (scientist, Japanese Studies), 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), Jennifer Ortegren (non-scientist, Religion), Jim Ralph (Academic Affairs), Andrea Robbett (scientist/Chair, Economics), Michael Sheridan (scientist, Sociology/Anthropology), Martin Seehuus (scientist, Psychology), and Bonnie Stevens (Community Member).
3.3 Workflow Summary

Meetings
The Middlebury IRB met five times during the academic year and reviewed and approved 9 full board proposals (see Appendix A for a list of full board proposals approved in 2019-20).

Administration and Reporting
During the academic year, IRB staff reviewed: 28 proposals that were deemed not to be human subjects research (NHSR) and 93 proposals that were deemed exempt from the federal regulations. IRB staff and committee members reviewed and approved 11 proposals at the expedited level. In total, the IRB received and processed 141 submissions. Figure 1 depicts the number of projects reviewed (and the review category) for the past five years. During that period, the average number of projects reviewed was 165.6. In 2019-2020, the number of projects reviewed fell under that average. This downward trend is somewhat expected given the disruption of the COVID-19 pandemic.

Figure 1: Number of IRB Submissions Reviewed Per Academic Year

Figure 2 shows that the majority of submissions (N=80; 70%) came from students and faculty on the Vermont campus, 20 submissions came from Monterey, and the remaining submissions came from Language Schools (N=7), the Schools Abroad (N=5), and external researchers (N=1). This breakup changed slightly from previous years, with more submissions coming from the Vermont campus.
Figure 3 shows that the majority of IRB submissions came from students (N=73;), 39 submissions came from faculty or staff, and 1 submission came from an external researcher. This trend is consistent with previous years where students submitted the majority of IRB proposals.

IRB staff prepared and submitted an updated IRB registration to the Department of Health and Human Services (HHS) in September 2019.

**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, 165 students and 17 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

In October 2019, the first ever IRB user satisfaction survey was distributed in order to identify areas for improvement and establish baseline metrics to track quality and satisfaction over time. Results indicated that 75% of users (N=46) were extremely satisfied with the timeliness of protocol review, IRB staff responsiveness, and IRB staff helpfulness/respectfulness. While overall results were quite positive, some minor areas of improvement were identified, including minor reorganization of the IRB website, which was implemented immediately. Respondents also noted that the online ethics training can be quite time consuming. As a result, the required CITI modules were edited down, and an option was added to allow users to customize their training. Several respondents also requested more examples of student work/completed IRB applications. This idea was discussed with the IRB and while the committee felt that posting example proposals may interfere with pedagogy/advising, it was decided that a more interactive consent form tool would be helpful for students putting together proposals for the first time. This idea is under development. The user satisfaction survey will be repeated in future years to track changes as improvements are implemented.
Appendix A: Full Board Proposals Approved by the IRB in 2019-20

1. Durning, Anna (student) - Sense of place and access to resources among migrant dairy workers in Addison County; approval finalized 11/8/19
2. Hyman, Mikayla (student) - LGBTQIA+ youth health: A comparative study of a community support center and primary health care; approval finalized 10/11/19
3. Kimble, Matthew (faculty) - ERP and eye tracking studies of expectancies in trauma survivors; approval finalized 10/18/19
4. Landis, Annika (student) - Negotiating cultures of speech and discourse in relation to contemporary left-right politics; approval finalized 10/23/19
5. Nakano, Miki (student) - What's for Lunch? Examination of the National School Lunch Program's influence on elementary students' understanding of class; approval finalized 10/30/19
6. Nguyen, Hoang Minh Hieu (student) - Bridging the attainment gap: Online education in rural Vietnam; approval finalized 8/12/20
7. Sayre, Margaret (student) - Building a child-friendly island for the Vashon Latino/a/x community; approval finalized 12/20/19
8. Seehuus, Martin & Rodriguez, Elsa (faculty) - Child sexual abuse study; approval finalized 12/3/19
9. Trotman, Natalie (student) – The influence of early bilingualism on third language acquisition: An analysis of cross-linguistic transfer among Latino students in a high school world languages French class; approval finalized 9/19/19