



Middlebury

**RESEARCH COMPLIANCE REPORT**  
**2016-2017**

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## 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, 2016 through August 31, 2017.

# 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/Pat Manley, PhD
Chair	Bob Cluss, PhD
Attending Veterinarian	Joanne Huyler, DVM

## 1.2 Committee Membership

The members of the 2016-2017 Middlebury IACUC were: Rev. Molly Bidwell (non-affiliated member), Bob Cluss (chair, Chemistry), Catherine Combelles (scientist, Biology), Amanda Crocker (scientist, Neuroscience), Joanne Huyler (veterinarian), Clarissa Parker (scientist, Psychology), Len Rowell (non-affiliated member), John Spackman (non-scientist, Philosophy). As of July 1<sup>st</sup>, 2017, Pat Manley was appointed the new Institutional Official for the animal program by Middlebury President Laurie Patton.

## 1.3 Work Flow Summary

### *Meetings*

The Middlebury IACUC met six times during the academic year and approved: three new protocols, two third-year renewals, and five 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 Steve Trombulak. One facility inspection and program review took place on December 15<sup>th</sup> and the second inspection and program review took place on June 6<sup>th</sup>.

### *Administration and Reporting*

During the academic year, IACUC staff processed and approved: two minor amendments, 15 annual reviews, and seven personnel amendments. IACUC staff prepared and submitted an annual report to the United States Department of Agriculture (USDA) in November 2016. IACUC staff also prepared and submitted an annual report to the Public Health Services Office of Laboratory Animal Welfare in January 2017. In the fall of 2016, Middlebury went through a program review and inspection as part of the re-accreditation process through AAALAC International; full accreditation was granted for another three years. On June 7, 2017, Dr. Jessica Gowins from USDA conducted the annual inspection. Since no registered species were in the facility at the time of the inspection, Dr. Gowins only inspected the IACUC records; no non-compliant items were found.

### *Training*

During the 2016-2017 academic year, 77 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 61 students and ten 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 17 students and three 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

Middlebury's Animal Welfare Assurance was updated with the Public Health Service in October 2016 and will be valid through October 2020.

## 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/Pat Manley PhD
Chair	Grace Spatafora, PhD

### 2.2 Committee Membership

The members of the 2016-2017 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). As of July 1<sup>st</sup>, 2017, Pat Manley became the responsible official for the biosafety program.

### 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 2017.

### 2.4 Policy Changes/Updates

The new rDNA registration application was implemented this year. Three faculty members submitted registration forms, which were reviewed and forwarded to the Chemical Hygiene Officer and Environmental Health & Safety Coordinator to be used during lab compliance assistance visits. All three were found to be within the NIH Guidelines exempt categories.

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

### 3.1 Responsible Individuals

<u>Role</u>	<u>Individual</u>
Signatory Official	Susan Baldrige, PhD
Chair	Matt Kimble, PhD
Administrator	Katie Gillespie

### 3.2 Committee Membership

The members of the 2016-2017 Middlebury IRB were: Tsuneo Akaha (MIIS GSIPM, Development, Practice, and Policy), Lorraine Besser (Philosophy), Katie Gillespie (non-scientist Academic Affairs), Emiliano Huet-Vaughn (scientist, Economics), Matthew Kimble (chair, Psychology), Pablo Oliva (MIIS GSTILE, Language Studies, Spanish), Jim Ralph (Academic Affairs), Ira Schiffer (non-scientist,

Chaplain's Office), Michael Sheridan (scientist, Sociology/Anthropology), Bonnie Stevens (community member).

### 3.3 Work Flow Summary

#### *Meetings*

The Middlebury IRB met seven times during the academic year and reviewed 12 full board proposals; 11 proposals were approved and one was withdrawn from consideration.

#### *Administration and Reporting*

During the academic year, IRB staff reviewed: 46 proposals that were deemed not to be human subjects research and 120 proposals that were deemed exempt from the federal regulations. IRB staff and committee members reviewed and approved 13 proposals at the expedited level. In total, the IRB received and processed 191 proposals, up from 171 in 2015-16. The increase is attributed both to more research occurring and also to improved communication about the IRB process.

IRB staff prepared and submitted an updated IRB registration and Federalwide Assurance to the Department of Health and Human Services (HHS) in September 2016.

#### *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, 80 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. The new two-page application for minimal risk studies was implemented in Fall 2016 along with an interactive survey-tool to help users determine what level of review their project might qualify for; the survey tool was utilized 152 times during the academic year. Ninety-six applications were submitted using the new online minimal risk application. No problems were reported with the application, which streamlines the process for investigators and also relieves some administrative burden on the IRB.

A new option for human subjects ethics training was made available to investigators via the Collaborative Institutional Training Institute (CITI) online module for Social/Behavioral Research. This module was part of Middlebury's existing CITI subscription (used for animal welfare) and provides investigators with training targeted specifically to social/behavioral research (rather than biomedical research). Use of the CITI module also reduces administrative burden in terms of tracking investigator training and ensures continuity across compliance areas.

The IRB also increased outreach and education efforts this year. The IRB held its first open house on September 20<sup>th</sup>, 2016 in the Center for Teaching and Learning. Matt Kimble, Jim Ralph, and Katie Gillespie attended on behalf of the IRB. Four students came to the open house and received guidance about the IRB proposals. Additionally, a 1-page Quick Guide to the IRB was made available to investigators in order to better explain the review process and requirements.