

Institutional Review Board of the Cooper Union

2015 Annual Report¹

The statement of purpose of the Cooper Union IRB reads (in part) as follows:

“The Institutional Review Board of the Cooper Union for the Advancement of Science and Art (IRB) has the responsibility for the oversight of all research involving human subjects conducted or supported through research activities which are conducted by faculty, students and/or staff associated with the Cooper Union. The goal of this oversight is to protect the rights, privacy and welfare of all human participants in research while respecting, supporting and enhancing the responsible and ethical scholarship activities of the faculty, students and staff.

To achieve this goal, the IRB has the authority to review, approve, modify or disapprove research protocols submitted by faculty, staff and student investigators which involve human subjects as well as to monitor and review their progress. The review and monitoring processes are to be guided by federal rules and regulations, and are based on the Protection of Human Subject Code of Federal Regulations, the Belmont Report and provisions of 45CFR46 – Protection of Human Subjects. These regulations require institutions receiving federal funds to have all research involving human participants be approved by an IRB.”²

The following individuals served on the IRB during 2015.³

Melody Baglione, Ph.D; Associate Professor of Mechanical Engineering

Julie Castelluzzo, M.S.; Librarian

Toby Cumberbatch, Ph.D.; Professor of Electrical Engineering

Benjamin Davis, Ph.D.; Assistant Professor of Chemical Engineering

Christina Ho, M.Eng.; External IRB Member; Con Edison

Yashodan C. Risbud, M.Eng.; Director, C.V. Starr Research Foundation and Adjunct Professor

Robert Q. Topper, Ph.D.; Professor of Chemistry; IRB Chair

Administrative support continues to be needed for the IRB to fulfill its mandate. In particular, it is extremely important for the college’s leadership to communicate annually with their supervisees regarding the necessity for all human subject research work to be reviewed before its commencement.

As has been emphasized in previous reports, Federal guidelines do not exempt survey-based human subject research from IRB oversight. The technical definition of what the Federal government considers to be “research” specifically encompasses surveys carried out of students, faculty, staff and alumni. Our IRB is responsible for ensuring that this sort of research is carried out in a manner which is legal, ethical, and in accordance with institutional obligations. In particular, students are considered to be a vulnerable

¹ Submitted by Prof. Robert Q. Topper, Chair; June 2016.

² From the Cooper Union Institutional Review Board by-laws; adopted April 2011.

³All members have completed the NIH Office of Extramural Research’s online training program entitled “Protecting Human Research Participants.” <https://phrp.nihtraining.com/users/login.php> . Accessed 6/1/2015.

population under Federal law and they receive special protections. Although they are less vulnerable under the law, surveys of Cooper Union employees (including faculty) must be carried out in a manner that meets Federal, state and city law as well as contract law and the IRB is charged with handling the approval processes for these surveys as well. In order to facilitate matters, the IRB has developed procedures to review **low-risk** internal surveys in an efficient manner, through a self-guided affirmation process.

Any human subject research which involves physical experimentation of any kind must first be approved by the Faculty Safety Coordinator as well as the Dean(s) of the school or faculty within which the Principle Investigator is affiliated. However, some experimental work is permitted by Federal law to be reviewed within the Expedited category while other projects require Full review, which occurs during a regular IRB meeting. In addition to the review work that IRB members complete throughout the year, the IRB schedules four regular meetings each year, typically twice each academic semester. A meeting is cancelled if there are no proposals pending for Full review or other business pending. All proposals that have been approved through Expedited review, or which have been reviewed and determined to lie in the Exempt category⁴ since the last meeting, are discussed at IRB meetings. All IRB members have direct electronic access to the proposals on a continual basis. In 2015 one meetings was held and three were cancelled due to a lack of agenda items.

In 2015, no proposals received Full review but five received Expedited review, and all were approved (with one being found to lie in the Exempt category following review). It should be noted that before a proposal is accepted for Expedited review, the IRB Chair typically must work with the Principal Investigator to ensure that their application is complete and correct before review can actually begin. When proposals receive Expedited review status, the review work is done online by the IRB Chair and IRB members online, separately from the regular meetings.

Researchers whose work which is deemed to fall within the Exempt category need not file an annual report, but in all other cases Federal regulations require the submission of annual reports. Failure to submit an annual or closure report minimally results in non-consideration of any future proposals until the report is submitted and may cause the IRB to order a project to be summarily ended. In 2015, an internal audit was initiated of all proposals and a process initiated to bring all investigators into compliance with this requirement. This process should be completed in 2016.

Some human subject research only involves a relatively straightforward use of surveys that pose minimal risks. Many (but not all) of these surveys fall into the Exempt category. For this sort of human subject research a streamlined process, unique to Cooper Union, has been established. The process is only used for those kinds of survey-based studies which can claim Exempt status. Applicants follow a self-guided process without the need to fill out or submit a form (but the survey questions must be submitted so that the IRB Chair can confirm the Exempt status of the survey). Previously only paper-based surveys were allowed to use the streamlined process but in 2013, this process was modified to

⁴ Some human subject research lies in the Exempt category but Federal funding agencies still require the IRB to review the proposal before they will consider it for funding review. The IRB of the Cooper Union handles these requests via the Expedited review process, which is a common practice.

allow the use of electronic survey tools as long as certain criteria are satisfied. During the 2015 calendar year, no surveys were submitted for approval through this process. This contrasts notably with 2014, during which time six surveys were thus approved.

In 2015, the IRB continued to use three Moodle sites to facilitate and enhance the committee's work. One is open and publically available, and explains the IRB's role and activities;⁵ one requires Moodle registration and contains all documents necessary for researchers to apply for IRB review and approval of projects;⁶ and one is used solely by IRB members for agendas, minutes, annual reports, and information which must be kept on file in case of audit, such as resumes and NIH training certificates for IRB members.⁷ Currently there are 62 students, faculty, administrators and staff registered to use the internal Moodle site.

Table 1. Summary and Status of Applications - 2015 (*Principal researcher in italics*)

Research Proposals			
Application #	Researchers	Title	Status
01-2015	<i>G. del Cerro</i>	2015 Admitted Applicants Survey	Approved 5/5/2015 (Expedited Review)
02-2015	<i>C. Gunning, K. Blumenkrantz, J. Castelluzzo, T. Micchelli, C. Salomon</i>	Library Information Resources Instruction Assessment	Approved 4/20/2015 (EXEMPT)
03-2015	<i>A. Wolf, E. Lima</i>	Creativity and Anxiety in Invention Factory SM Participants	Approved 10/7/2015 (Expedited Review)
04-2015	<i>M. Lay, S. Kulm, M. Abdallah</i>	Comparison of Melatonin Levels in College Students Against Literature Values	Approved 11/19/2015 (Expedited Review)
05-2015	<i>C. Sable, J. Herzberg, A. Landman, E. Sofer</i>	S.L.E.E.V.E.: Sign-Language-Evaluating Expression Vocalization Engine	Approved 1/4/2016 (Expedited Review)

⁵ <https://moodle.cooper.edu/moodle/course/view.php?id=571> . Accessed 6/1/2015. Registration is not required.

⁶ <https://moodle.cooper.edu/moodle/course/view.php?id=573>. Accessed 6/1/2015. All Cooper Union community members can register for this site.

⁷ <https://moodle.cooper.edu/moodle/course/view.php?id=572>. Accessed 6/1/2015. This site is for IRB members only.