

# Institutional Review Board of the Cooper Union

## 2014 Annual Report

Prof. Robert Q. Topper, Chair

In keeping with Federal guidelines, this annual report encompasses IRB activity during the 2014 calendar year. The Institutional Review Board of the Cooper Union (IRB) is responsible for the review and supervision of all human subject research carried out by faculty, staff, administrators and students of the Cooper Union. Administrative support continues to be needed for the IRB to fulfill its mandate from the Federal government and the Cooper Union. It is extremely important for all academic deans and administrative department heads to communicate with their supervisees regarding the necessity for their human subject research work to be reviewed before its commencement.

The following individuals served on the IRB during 2014. Individuals whose names are marked with (\*) served as IRB secretary for one or more meetings.<sup>1</sup>

**Robert Q. Topper, Ph.D.; Professor of Chemistry; IRB Chair (\*)**

**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**

In part, the statement of purpose of the Cooper Union IRB reads 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.”***

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<sup>1</sup>All 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.

It should be noted that 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. Accordingly, the 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 population under Federal law and they receive special protections. Surveys of Cooper Union employees must be carried out in a manner that meets Federal, state and city law as well as contract law and the IRB of the Cooper Union is charged with handling these as well. The IRB has developed procedures to review internal surveys in a highly efficient manner that is unique and effective, as described on the following pages.

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. In 2013 one meetings was held and three were cancelled due to a lack of agenda items. All proposals that have been approved through Expedited review, or which have been reviewed and determined to lie in the Exempt category<sup>2</sup> since the last meeting, are discussed at IRB meetings. All IRB members have direct electronic access to the proposals on a continual basis.

In 2014, no proposals received Full review but five received Expedited review, and all were approved. 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 members 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.

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-

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<sup>2</sup> 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.

based surveys were allowed to use the streamlined process but in 2013, this process was modified to allow the use of electronic survey tools as long as certain criteria are satisfied. During the 2014 calendar year, six surveys were confirmed to lie in the Exempt category and approved via this process. It should be emphasized that all surveys, whether internal or external, and whether or not they are directly supported by Federal funding, must be reviewed and approved by the IRB. Furthermore, the IRB has authority to direct anyone carrying out unapproved human subject research of any kind to immediately cease and desist from that activity.

In 2014, the IRB continued to use three Moodle sites developed and maintained by Prof. Topper to facilitate and enhance the committee’s work. One is open and publically available, and explains the IRB’s role and activities;<sup>3</sup> one requires Moodle registration and contains all documents necessary for researchers to apply for IRB review and approval of projects;<sup>4</sup> 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.<sup>5</sup> Currently there are 44 students, faculty, administrators and staff registered for the use of the internal Moodle site.

**Table 1. Summary and Status of Applications - 2014** (*Principal researcher in italics*)

Research Proposals			
Application #	Researchers	Title	Status
01-2014	<i>C. Sable</i> , B. Schenker, A. Zielkowski, E. Lima	Motorized Cart User-Interface Evaluation for ACCIO	Approved 3/14/2014 (Expedited Review)
02-2014	<i>M. Baglione</i> , M. Pimpinella, G. Fava, G. Oliveria	Studying the Use of Smartphone SPL Apps in Speech-Language Pathology	Approved 4/7/2014 (Expedited Review)
03-2014	<i>M. Baglione</i> , Y. Guo, D. Moreno	Degree of Comfort: A Thermal Comfort Study of 41 Cooper Square	Approved 4/1/2014 (Expedited Review - Exempt)
04-2014	<i>A. Raja</i>	Advanced Machine Learning for Prediction of Preterm Birth	Approved 7/31/2014 (Expedited Review)
05-2014	<i>D. Wooton</i> , T. Andargachew	Image-Based Biomechanical Modeling of the Human Thorax	Approved 11/6/2014 (Expedited Review - Exempt)

<sup>3</sup> <https://moodle.cooper.edu/moodle/course/view.php?id=571> . Accessed 6/1/2015. Registration is required.  
<sup>4</sup> <https://moodle.cooper.edu/moodle/course/view.php?id=573>. Accessed 6/1/2015. All Cooper Union community members can register for this site.  
<sup>5</sup> <https://moodle.cooper.edu/moodle/course/view.php?id=572>. Accessed 6/1/2015. This site is for IRB members only.

<b>Self-Guided Reviews of Exempt Internal Surveys</b>			
<b>Application #</b>	<b>Researchers</b>	<b>Title</b>	<b>Status</b>
S01-2014	<i>Baglione, Moreno</i>	Degree of Comfort: 41 Cooper Square Thermal Comfort Survey Project	Approved - Exempt
S03-2014	<i>Engineering Student Council</i>	ESC Student Survey 2014	Approved – Exempt
S04-2014	<i>Lepek</i>	Student Questionnaire – ChE 141 (Final Evaluation)	Approved - Exempt
S05-2014	<i>Margherito, Delagrammatikas</i>	Study Abroad Program Questionnaire for Students	Approved – Exempt
S06-2014	<i>Margherito, Delagrammatikas</i>	Study Abroad Program – Course and Instructor Evaluation Form	Approved – Exempt
S07-2014	<i>Margherito, Delagrammatikas</i>	Study Abroad Program – Interest Survey	Approved – Exempt