CUNY SPH Human Research Protection Program (HRPP)
2018 Annual Report

The CUNY Graduate School of Public Health and Health Policy (CUNY SPH) Human Research Protection Program (HRPP) assists the University in promoting high quality, ethical research. It does so by providing regulatory and administrative oversight of human subjects research (HSR) conducted by SPH faculty, staff, and students across the School, including its programs and centers. The Office also provides educational support to SPH researchers and assists them in complying with federal, state, and University HSR policies.

This first annual report details SPH researcher engagement with the SPH HRPP Office and CUNY IRB during 2018, based on information gleaned from two SPH HRPP administrative databases (described below).
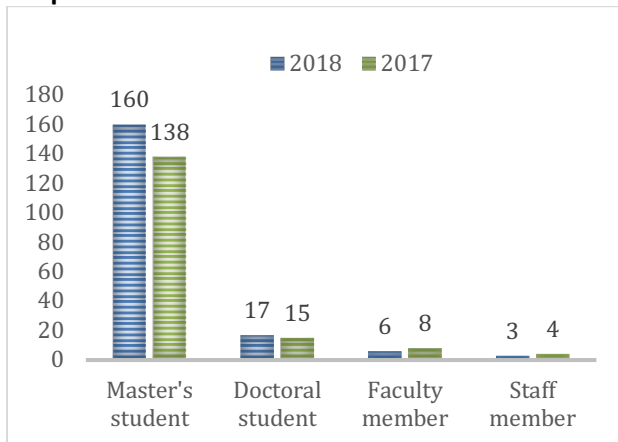
SPH HRPP Human Subjects Research (HSR) Assessment Form

The SPH HRPP HSR Assessment Form contains information obtained from SPH student, faculty, and staff entries to the HSR Assessment Form, a Qualtrics survey that queries researchers about their proposed projects. The SPH HRPP Office reviews entries and makes determinations about whether a project is HSR and IRB approval is needed. Completion of this form is required for all master's and doctoral fieldwork students.

Submission characteristics

In 2018, the SPH HRPP Office received **186** submissions, an increase of 13% (n=21) from 2017. The vast majority of submissions were from master's students. Graph 1 presents a breakdown of submissions by submitter type (e.g., faculty, staff, student).

Graph 1. Number of HSR Assessment Form Entries by Submitter Type, 2017-2018.

Among the 177 submissions received from students, the majority were those in the MPH program (n=148, 84%), with only 12 from the MS program and 17 from the DPH program. Departmental representation among student submissions was fairly uniform: 46 from students in the HPAM department, 44 from those in CHASS, 38 from EOHS, and 36 from EPI/BIOS. Relatively fewer (n=12) students from the PH NUTR program submitted entries, which corresponds to the fewer number of students enrolled in this program.

Among the 186 total submissions, 36 (19%) were determined to constitute human subjects research (HSR) by the SPH HRPP Office and require IRB approval. Researchers took varying actions to obtain IRB approval following receipt of a HSR decision. Most students developed a new CUNY IRB application (n=14, 39%) or were added to an existing CUNY IRB application (n=7, 19%), as opposed to establishing an IRB Authorization Agreement (IAA) with an external host site (n=3, 8%). As of December 31, 2018, action had not been taken on seven cases.
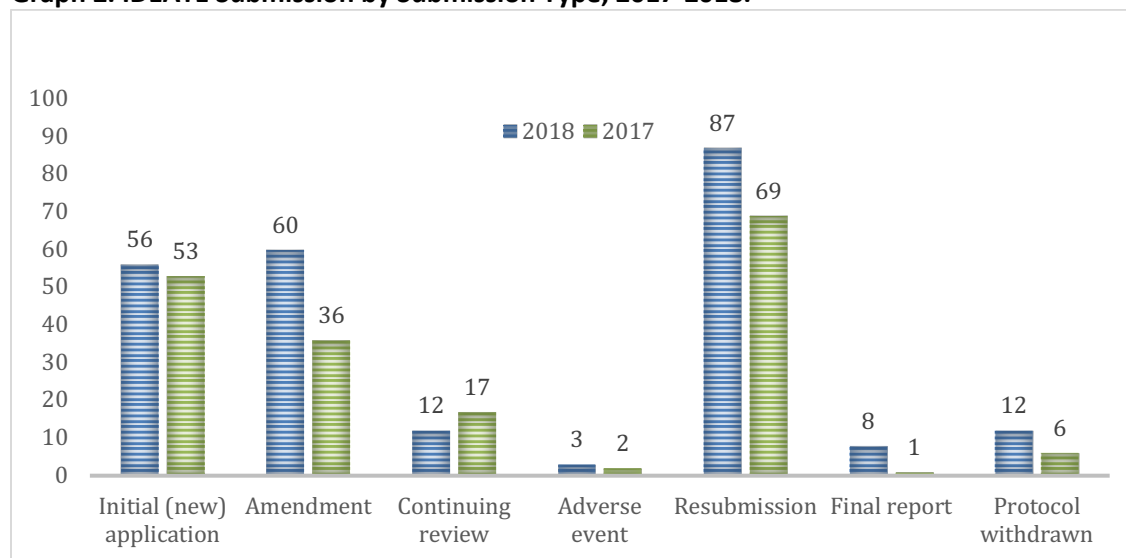
SPH IRB Protocol Submissions

The SPH IRB Protocol Submissions database was developed by the SPH HRPP office to track itemized IRB submissions received via IDEATE, CUNY's IRB submission platform. Each entry contains protocol-specific information, such as the submission date, protocol number, PI name, PI role, submission type (e.g., initial application, amendment, continuing review, resubmission, final report, adverse event), HRPP action (e.g., returned for modifications, under HRPP review, under Expedited IRB review, under Convened IRB review), IRB type (e.g., Exempt, Expedited, Convened), and HRPP processing time.

Submission characteristics

In 2018, the SPH HRPP Office received **238 I**DEATE submissions, an increase of 29% (n=54) from 2017. Graph 2 presents a breakdown of IDEATE submissions by type (e.g., initial (new) application, amendment, continuing review, adverse event, resubmission (following requested modifications), final report, and protocol withdrawn). There was an increase in all IRB application submission types between 2017 and 2018, except for continuing review applications—a trend that corresponds with the nearly 50% research portfolio increase across SPH departments, centers, and institutes in 2018.

Graph 2. IDEATE Submission by Submission Type, 2017-2018.

The majority of submissions were from SPH faculty (n=143, 60%). Table 1 provides an overview of IDEATE submissions by Principal Investigator (PI) type.

Table 1. IDEATE Submission by PI Type, 2018.

Submission Type	Faculty	Doctoral student	Master's student	Staff	Total
Initial (new)	27	8	17	4	56
Amendment	48	11	1		60
Continuing review	7	5			12
Adverse event	3				3
Resubmission	50	19	14	4	87
Final report	3	2	3		8
Protocol withdrawn	5	1	6		12
Total	143	46	41	8	**238**

Last year, 124 received IRB applications were subject to HRPP or IRB review. The vast majority (n=94, 76%) of these applications underwent Expedited review by a single IRB member, 29 (23%) underwent Exempt review by the SPH HRPP Office, and one (1%) underwent review by the Convened (full-board) IRB.

Non-compliance
Our office is pleased to report that in 2018, the SPH did not have any instances of non-compliance.

Looking Ahead to 2019
The SPH HRPP Office is committed to supporting HSR among the SPH research community. In 2019, we plan to continue developing educational supports and resources for researchers to facilitate high-quality, ethical research.

With the anticipated January 21, 2019 implementation of the new Federal Common Rule, the CUNY IRB and HRPP will undergo significant changes to meet new regulations. Specifically, revisions will be made to CUNY HRPP policies and procedures, as well as the CUNY IRB application. An overview of Common Rule changes can be found on our website. These regulatory changes will largely benefit SPH researchers by streamlining and simplifying IRB processes. Our office will be educating SPH faculty, students, and staff on Common Rule revisions and their implications for researchers in the months ahead, however, please contact us at any time with questions.

Contact Us
The SPH HRPP Office is here to assist and support you! Contact us at hrpp@sph.cuny.edu with questions, concerns, or feedback. We also encourage you to check out HRPP/IRB resources for faculty, staff, and students on our website: https://sphhrpp.commons.gc.cuny.edu/