CUNY SPH Human Research Protection Program (HRPP)
2019 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 annual report provides an overview of key SPH HRPP activities during 2019, including SPH researcher engagement with our office and the CUNY IRB.

2018 Common Rule

On January 21, 2019, revised Federal Common Rule regulations (i.e., the "2018 Common Rule") issued by the U.S. Department of Health and Human Services' (HHS) went into effect. The Common Rule regulates research involving human subjects and resulted in a number of changes to CUNY HRPP policies and procedures.

The SPH HRPP Office developed myriad resources to educate SPH researchers about the new Common Rule and its impact on their research, in addition to regularly providing one-on-one support. 2018 Common Rule resources can be found on our website.

We appreciate our research community's understanding and patience as the updated CUNY IRB application template was rolled out and other HRPP policies were implemented. Overall, the transition to compliance with the 2018 Common Rule has gone smoothly.

Cooperative Research Projects

Implementation of one provision of the 2018 Common Rule regarding cooperative (i.e., multi-site) research projects was delayed and will go into effect on **January 20, 2020**.

In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects; however, this stipulation results in the engagement of multiple IRBs and duplicates efforts. In an effort to streamline the IRB approval process, the use of one IRB for cooperative research will be required (e.g., "Single IRB" or "sIRB") as of January 20, 2020. However, there are certain restrictions on this requirement:

1) A Federal department or agency must be supporting or conducting the research;
2) The institutions that are involved must be located in the U.S.; and
3) The research sites must be located in the U.S.

In November 2019, the HHS' Office for Human Research Protections (OHRP) announced its determination of exception for two categories of research from the required use of a sIRB. These include:

(1) Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB initially approved the research before January 20, 2020.
(2) Cooperative research conducted or supported by NIH if either:
  a. the NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or
  b. NIH excepted the research from its single IRB policy before January 20, 2020.

Note that this determination is only made for purposes of section 46.114(b)(2)(ii) – namely, for determining whether certain cooperative research may be excepted from the single IRB mandate. This determination does not prevent, nor should it be viewed as discouraging, the voluntary use of a single IRB in cooperative research subject to the 2018 Requirements that would fall within the above two categories. Further, note that category (2)(b), above, applies for the duration of NIH's exception from its policy for the particular research study; categories (1) and (2)(a) apply for the duration of the research.

Of important note, while implementation of the sIRB requirement will occur on January 20, 2020, the NIH also imposed a sIRB requirement, which was implemented on September 15, 2017, for NIH funded multi-site clinical trials. All SPH researchers must abide by OHRP and NIH regulations surrounding IRB approval for cooperative research.

SPH Researcher Engagement

The SPH HRPP Office tracks researcher engagement based on information gleaned from two SPH HRPP administrative databases. The below sections describe these databases and key findings from 2019.

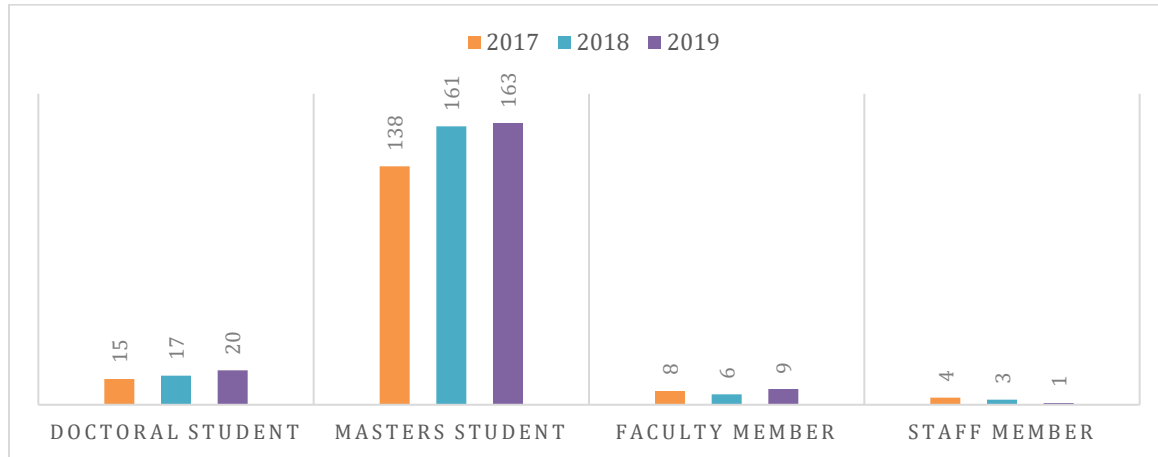**SPH HRPP Human Subjects Research (HSR) Assessment Form**
The SPH HRPP HSR Assessment Form was developed by our SPH HRPP office to aid us in making HSR determinations to facilitate regulatory compliance and ethical research conduct. The Assessment Form captures information from SPH student, faculty, and staff, via a Qualtrics survey, about their proposed research projects. Our HRPP Office reviews form entries and makes determinations about whether a project is HSR and CUNY IRB approval is needed.

Completion of this form and receipt of an HSR determination from our office is required of SPH master's and doctoral fieldwork students before they can enroll in the Fieldwork course. All other SPH researchers are encouraged to submit Assessment Form entries if they are uncertain whether their projects qualify as HSR or if they need formal HSR decision documentation.

Submission characteristics
In 2019, the SPH HRPP Office received **193** HSR Assessment Form submissions. The vast majority of submissions were from master's students. Graph 1 depicts Assessment Form submissions by submitter type (e.g., faculty, staff, student) from 2017 (initial tracking year) to 2019.

Graph 1. Number of HSR Assessment Form Entries by Submitter Type, 2017-2019.

Legend: ■ 2017 ■ 2018 ■ 2019

Doctoral Student: 15, 17, 20
Masters Student: 138, 161, 163
Faculty Member: 8, 6, 9
Staff Member: 4, 3, 1

Among the 183 submissions received from doctoral and master's students, the majority were from those in the MPH program (n=151, 83%), with only 12 (6.5%) from the MS program, 19 (10%) from the DPH program, and 1 (0.5%) from the PhD program. In regard to departmental representation, 57 (31%) were from students in the HPAM department, 42 (23%) were from CHASS, 34 (19%) from EOGHS, 41 (22%) from EPI/BIOS, and 9 (5%) from the PH NUTR program.

As of December 31, 2019, HSR determinations had been made on all 193 submissions but one. Among the 192 issued HSR decisions, 55 (29%) were determined to constitute human subjects research (HSR) by the SPH HRPP Office and require IRB approval, and the remainder (n=137, 71%) were determined not to be HSR. Researchers took varying actions to obtain IRB approval following receipt of an HSR decision. Most master's students were added to an existing CUNY IRB application (n=23, 42%) or developed a new CUNY IRB application on which they were the Principal Investigator (PI) (n=8, 15%), as opposed to establishing an IRB Authorization Agreement (IAA) with an external host site (n=2, 4%), among other options. Conversely, all doctoral students and faculty developed new CUNY IRB applications on which they were the PI. As of December 31, 2019, seven students had not yet taken action to fulfill IRB requirements.

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, Exempt with Limited Review, Expedited, Convened), and HRPP processing time.

Submission characteristics
In 2019, the SPH HRPP Office received **303 I**DEATE application submissions, an increase of 27% (n=65) from 2018. Graph 2 presents a breakdown of IDEATE submissions by type (e.g., initial (new) application, amendment, continuing review, event notification, resubmission (following requested modifications), final report, and protocol withdrawn). The number of initial submissions has remained fairly constant across the past three years, while the number of amendments and resubmissions have increased

significantly. Of note, with the implementation of the 2018 Common Rule, most non-exempt protocol will no longer require continuing review, so we anticipate that the number of continuing review applications we receive moving forward will decline.

Graph 2. IDEATE Submission by Submission Type, 2017-2019.
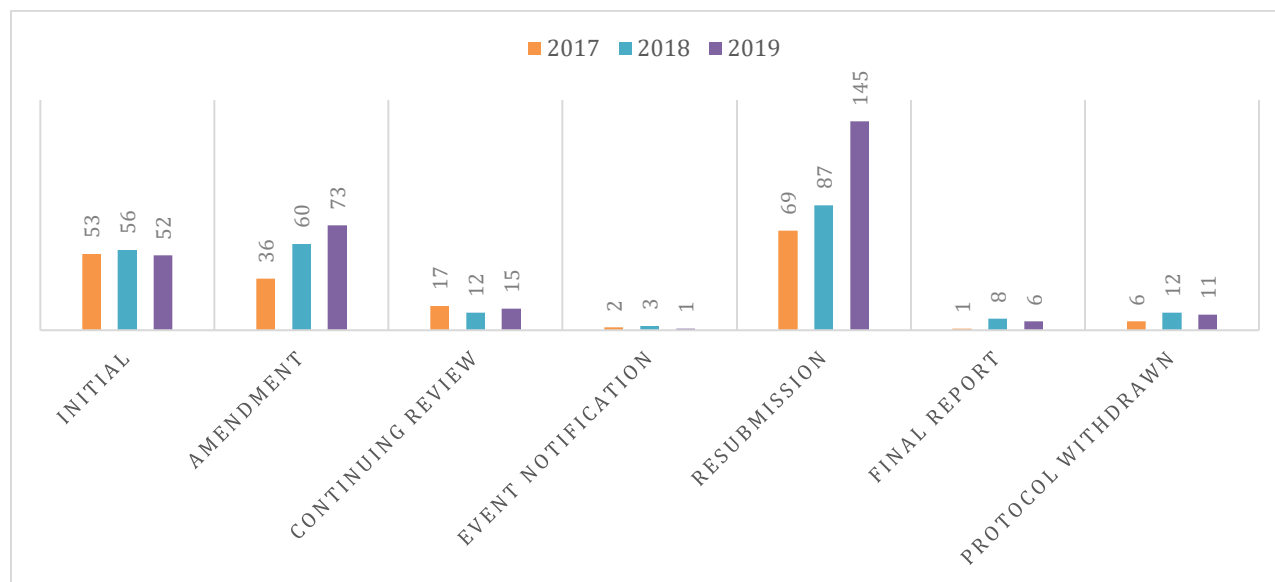
Among the 303 IDEATE submission, the majority were from SPH faculty (n=164, 54%). Table 1 provides an overview of IDEATE submissions by PI type.

Table 1. IDEATE Submission by PI Type, 2019.

Submission Type	Faculty	Doctoral student	Master's student	Staff	Total
Initial (new)	19	15	14	4	52
Amendment	52	14	2	5	73
Continuing review	8	5	1	1	15
Event notification	1	0	0	0	1
Resubmission	78	32	12	12	145
Final report	4	2	0	0	6
Protocol withdrawn	2	3	6	1	11
Total	145	56	31	19	**303**

Last year, 130 received IRB applications were subject to HRPP/IRB review. The vast majority (n=100, 77%) of these applications underwent Expedited review by a single IRB member, 9 (7%) underwent a new type of Exempt review established by the 2018 Common Rule—Exempt with Limited Review—which are also reviewed by a single IRB member. Twenty-one (16%) were reviewed at the Exempt level by the SPH HRPP Office. One application initially underwent review by the Convened (full-board) IRB but was ultimately recommended for processing at the Expedited level.

IRB Authorization Agreements (IAAs)

SPH researchers working collaboratively on non-exempt research studies with researchers at external institutions may choose to pursue an IRB Authorization Agreement (IAA) between the CUNY IRB and the external IRBs, establishing one institution's IRB as the IRB of Record for the study and therefore eliminating the need for duplicate IRB applications across institutions.

In 2019, nine IAAs were established between CUNY and other institutional IRBs, primarily for faculty research. As earlier mentioned, the use of a sIRB will be required under the 2018 Common Rule for many collaborative research studies beginning January 20, 2020.

Non-compliance

Our office is pleased to report that in 2019, the SPH did not have any instances of non-compliance with Federal or institutional HSR regulations.

2020: Looking Ahead

The SPH HRPP Office is committed to supporting HSR among the SPH research community. In 2020, we plan to continue developing educational supports and resources for researchers to facilitate high-quality, ethical research. With the upcoming implementation of the sIRB requirement, our Office will be providing support to researchers to facilitate compliance with the new policy. We also intend to continue strengthening coordination and collaboration with other SPH departments and offices, including the Office of Sponsored Programs and Research (SPaR) and Office of Experiential Learning (OEL).

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/