
CUNY SPH Human Research Protection Program (HRPP) 2020 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 2020, including SPH researcher engagement with our office and the CUNY IRB.

Research Continuity during the COVID-19 Pandemic

The COVID-19 pandemic has had far-reaching implications across functions and activities at CUNY, including research operations. In mid-March, the CUNY Central HRPP office issued guidance on conducting HSR in light of COVID-19 to ensure the ongoing protection of participants during the pandemic, which the SPH HRPP office immediately implemented. To protect the health and welfare of the SPH community and research participants, HSR involving direct interaction with study participants was suspended to minimize risk of contracting or spreading COVID-19, in accordance with CDC, CUNY, and SPH guidance, with the exception of research conferring a therapeutic benefit. The implications of this directive on research continuity have varied. In some cases, SPH researchers have transitioned in-person research to remote formats. In other cases, Principal Investigators have needed to cease or postpone their research activities when online substitutes were neither practical nor possible.

We recognize the disruption and hardship that this circumstance has created for many in our research community in regard to project completion deadlines, time sensitive research processes, and grant funding, in addition to potential implications on research participants. We appreciate the flexibility and adaptability researchers at the SPH have demonstrated as we have navigated uncharted HSR territory, and we commend our researchers for engaging in new research endeavors to better distill the myriad impacts of COVID-19 on the health and well-being of diverse communities.

Resuming In-Person Research

In December, the SPH received approval from the CUNY Vice Chancellor for our [Plan for Restarting Research](#), which allows researchers at the school to resume conducting in person research activities upon receiving the appropriate approvals. Researchers who are interested in doing so should follow guidelines in the research restart plan. This includes requesting permission from the Associate Dean for Research, Michele Kiely (Michele.Kiely@sph.cuny.edu), to initiate or resume in-person research at either an on-site (i.e., CUNY owned or leased property) or off-site location. Requests will be evaluated on a

case-by-case basis. Following approval, researchers are required to obtain IRB approval (new via submission of a new IRB application or a protocol Amendment) before beginning or resuming any in-person HSR activities. Additionally, the SPH HRPP Office and Office of Research encourage researchers to continue limiting research interactions with people to minimize risk of contracting or spreading COVID-19, in accordance with [CUNY Coronavirus Guidance](#), [CDC Guidance](#), and school guidance.

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 2020.

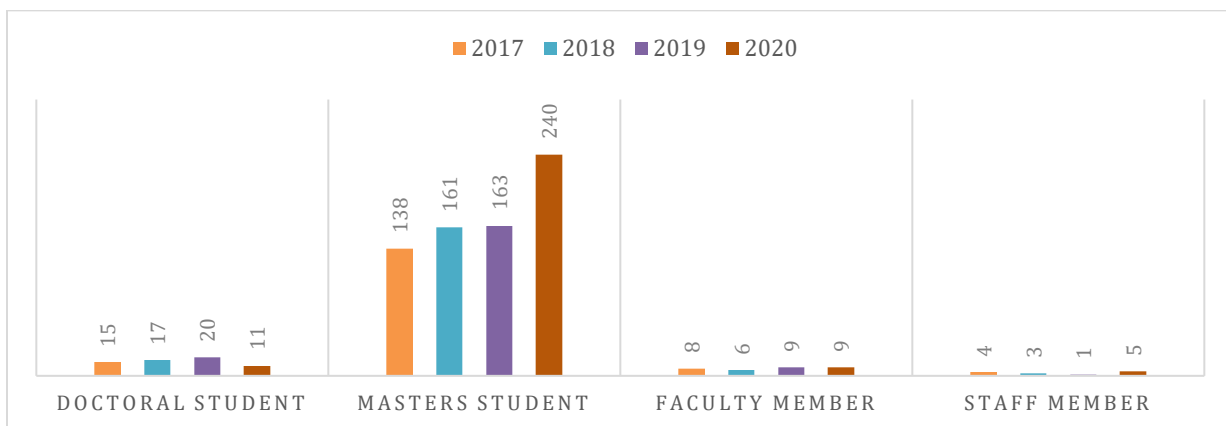
SPH HRPP Human Subjects Research (HSR) Assessment Form

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. Other SPH researchers are encouraged to submit an entry if they are uncertain whether their project qualifies as HSR or if they need formal HSR decision documentation.

Submission characteristics

In 2020, the SPH HRPP Office received **265** HSR Assessment Form submissions. The vast majority of submissions were from master’s students. Figure 1 depicts Assessment Form submissions by submitter type (e.g., faculty, staff, student) from 2017 (initial tracking year) to 2020.

Figure 1. Number of HSR Assessment Form Entries by Submitter Type, 2017-2020.



Among the 251 submissions received from doctoral and master’s students, the majority were from those in the MPH program (n=229, 91%), with 11 (4%) from the MS program, 9 (4%) from the PhD program, and 2 (1%) from the DPH program. In regard to departmental representation, 87 (35%) were from students in the HPAM department, 44 (18%) were from CHASS, 37 (15%) from EOGHS, 55 (22%) from EPI/BIOS, and 28 (11%) from the PH NUTR program.

As of December 31, 2020, HSR determinations had been made on all 251 submissions. Thirty-six (14%) were determined to constitute human subjects research (HSR) by the SPH HRPP Office and require IRB approval, and the remainder (n=229, 86%) were determined not to be HSR. Researchers took varying actions to obtain IRB approval following receipt of an HSR decision. Among the 31 HSR determinations issued to master’s students, most obtained IRB approval by being added to an existing CUNY faculty or staff member’s IRB application (n=16, 52%). Conversely, all doctoral students, faculty, and staff who received HSR determinations initiated new CUNY IRB applications on which they served as PI. As of December 31, 2020, IRB action was pending for nine researchers.

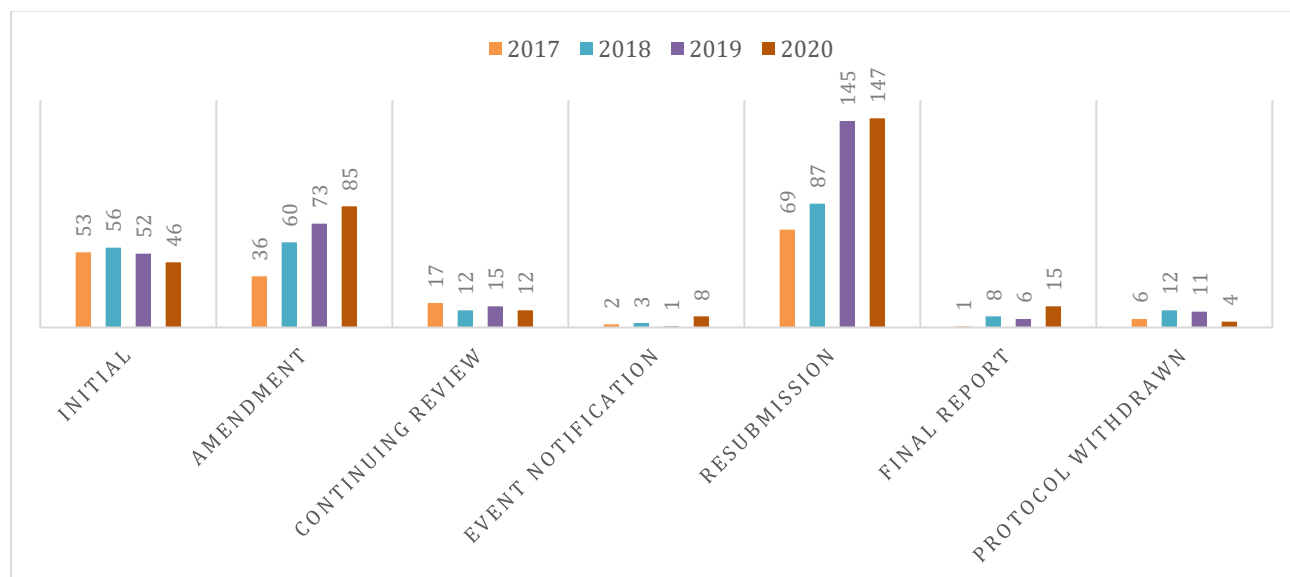
SPH IRB Protocol Submissions

The SPH IRB Protocol Submissions database was developed by the SPH HRPP office to track itemized IRB submissions to 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 (following requested modifications), final report, event/notification, protocol withdrawn), 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 2020, the SPH HRPP Office received **317** IDEATE submissions, an increase of 4% (n=14) from 2019. Figure 2 presents a breakdown of IDEATE submissions by type. The number of initial submissions declined slightly in 2020 and was the lowest (n=46) among the four years this data has been recorded, which is likely a reflection of the significant disruption COVID-19 has caused to research activities.

Figure 2. IDEATE Submissions by Submission Type, 2017-2020.



Among the 317 IDEATE submissions, the majority were from SPH faculty (n=235, 74%). Table 1 provides an overview of IDEATE submissions by PI type.

Table 1. IDEATE Submission by PI Type, 2020.

<i>Submission Type</i>	<i>Faculty</i>	<i>Doctoral students</i>	<i>Master's students</i>	<i>Staff</i>	<i>Other</i>	<i>Total</i>
<i>Initial (new)</i>	24	10	5	6	1	46
<i>Amendment</i>	73	6	0	6	0	85
<i>Continuing review</i>	11	1	0	0	0	12
<i>Event notification</i>	8	0	0	0	0	8
<i>Resubmission</i>	108	21	6	12	0	147
<i>Final report</i>	9	3	1	1	1	15
<i>Protocol withdrawn</i>	2	0	2	0	0	4
<i>Total</i>	235	41	14	25	2	317

Last year, 151 submissions received were subject to HRPP/IRB review, including initial IRB applications, protocol amendments, and continuing review applications. The vast majority (n=119, 79%) of these applications underwent Expedited review by a single IRB member, 9 (6%) underwent Exempt with Limited Review, which are also reviewed by a single IRB member. Twenty-three (15%) were reviewed at the Exempt level by the SPH HRPP Office. No applications were reviewed by the full board.

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 2020, three IAAs were executed between CUNY and other institutional IRBs related to faculty-initiated research.

Non-compliance

In 2020, the SPH had one instance of non-compliance. The issue was promptly reported to the HRPP, and subsequently, to the IRB, in accordance CUNY policy. Following convened review, the IRB issued corrective actions, which were taken by the PI to address the issue.

2021: Looking Ahead

The SPH HRPP Office remains committed to supporting the SPH research community during this unprecedented time while ensuring adherence to ethical principles of research and the protection of participants. We will continue to provide timely guidance around policies and protocols related to conducting research during the COVID-19 pandemic from University, government, and public health authorities and encourage researchers to regularly visit our website for up-to-date information.

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://sph.cuny.edu/research/human-research-protection-program/>