

## **CUNY HRPP Procedures: HRPP Staff Responsibilities**

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### **1. Overview**

CUNY HRPP Staff (“Staff”) is responsible for facilitating and supporting the CUNY Human Research Protection Program (HRPP), including the IRB review process, through the implementation of the duties described herein.

### **2. Staff Responsibilities**

All HRPP staff is responsible for the following:

#### **2.1. Regulatory and Policy Expertise**

- Providing guidance to CUNY researchers and IRB members with regards to regulations and CUNY policy concerning human subject protection
- Assisting researchers in applying relevant regulations and CUNY policy when preparing their IRB applications
- Reviewing research submissions to evaluate whether they require CUNY HRPP or IRB review, and issuing related determinations
  - Goal: It is suggested that the determinations of whether an activity requires CUNY HRPP or IRB review be completed within 1-2 business days<sup>1</sup>.
- Performing administrative pre-review of research submissions to ensure that the submission is complete, consistent and addresses all regulatory and Policy requirements prior to review by IRB member(s) or the convened IRB
  - Goal: It is suggested that pre-reviews be completed within 2-3 business days of receipt<sup>2</sup>.
- Keeping current with changes in federal and State regulations and guidance to ensure best practices and to make recommendations regarding their implementation to the University Director for Research Compliance

#### **2.2. Communication**

- Serving as a liaison between the IRBs and the researchers
- Communicating the IRB’s concerns to the researchers in a clear and concise manner, including references when appropriate
  - Goal: It is suggested that IRB communications to the researchers during the expedited review process be relayed within 2-3 business days of review completion<sup>3</sup>.
  - IRB communications to the researchers regarding reviews conducted at a convened IRB meeting shall be relayed within 5 business days.

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<sup>1</sup> This may vary by College depending on workload and other duties assigned at the College level.

<sup>2</sup> This may vary by College depending on workload and other duties assigned at the College level.

<sup>3</sup> This may vary by College depending on workload and other duties assigned at the College level.

- Notifying researchers and CUNY Administrators, when relevant, in writing of the IRB's decisions to approve, disapprove, require modifications to, terminate or suspend human subject research activities.
- Maintaining active communication with IRB members to ensure timely completion of reviews

### **2.3. Administrative Duties**

- Promptly responding to investigators' inquiries by telephone or e-mail
- Assigning research submissions to appropriate reviewer(s), identifying the need for additional reviewer(s) or consultant(s), when appropriate
- Supporting IRB members in their responsibility to conduct a timely review of all applications for the use of human subjects in research
- Ensuring compliance with HRPP Procedures
- Maintaining adequate IRB records, as delineated in federal regulations and CUNY Policy
- Reporting to the University Director for Research Compliance on all matters related to HRPP

### **2.4. HRPP Coordinators**

HRPP Coordinators have the following additional responsibility:

- Reviewing research submissions that meet the criteria for exemption from IRB review, and issuing related determinations
  - Goal: It is suggested that exempt reviews be completed and determination sent to the researcher within 1-2 days of submission<sup>4</sup>.

### **2.5. IRB Administrators**

IRB Administrators have the following additional responsibilities:

- Scheduling IRB meetings, maintaining meeting attendance and ensuring quorum at IRB meetings
- Preparing and distributing meeting agendas, meeting minutes and lists of approvals granted via the expedited review procedures
  - Meeting agendas and related materials shall be provided to the IRB members a minimum of one week in advance of the meeting
- Attending IRB meetings, providing regulatory and Policy guidance to facilitate convened IRB discussions, and documenting convened IRB deliberations by taking meeting minutes and recording any controverted issues
  - Meeting minutes shall be completed no later than 5 business days after the meeting
- Ensuring review of draft correspondence to researchers by the IRB Chair, Vice Chair or designee prior to researcher notification

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<sup>4</sup> This may vary by College depending on workload and other duties assigned at the College level.

- Correspondence resulting from convened IRB meetings shall be completed and delivered to the Chair, Vice Chair or designee no later than 2-3 business days after the meeting
- Identifying IRB member training and education needs, devising plans to address these needs and implementing these plans