CUNY HRPP Procedures: HRPP Staff Responsibilities

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
  o Goal: It is suggested that the determinations of whether an activity requires CUNY HRPP or IRB review be completed within 1-2 business days.
• 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
  o Goal: It is suggested that pre-reviews be completed within 2-3 business days of receipt.
• 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
  o 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.
  o IRB communications to the researchers regarding reviews conducted at a convened IRB meeting shall be relayed within 5 business days.

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• 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
  o **Goal:** It is suggested that exempt reviews be completed and determination sent to the researcher within 1-2 days of submission.

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
  o 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
  o 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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• 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