Local Responsibilities: Lessons Learned from Cede Review

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Overview

- The BMC/BUMC HRPP used Standard I-9 to systematically identify all local responsibilities.
- We use INSPIR II, our electronic system, to capture needed information on ceded studies.

Responsibility: Ancillary reviews relevant to the HRPP

INSPIR II automatically routes for ancillary reviews:
- Department resources
  - Nursing
  - Perinatal
  - Ambulatory Pediatrics
  - Cancer/Oncology
  - Psychiatry/Behavioral Health
  - General Clinical Research Unit
  - Investigational Pharmacy
- Targeted recruitment
  - Students, Medical Residents

Additional Special Routing

- Safety
  - Biomedical Engineering
  - Institutional Biosafety
  - Radiation Safety/Radiology
  - Lasers

Responsibility: Element III.2.A. Ensuring researchers and research staff have appropriate qualifications and expertise to conduct the research

The BMC/BUMC HRPP reviews study personnel for duration of study:
- All individuals who will be engaged in the research must be listed on the initial INSPIR II application submission.
- The BMC/BUMC HRPP checks for qualifications, training, and Conflict of Interest disclosures according to BMC/BUMC policies.
- Investigators are notified of BMC/BUMC requirement to submit change forms to add or remove local study personnel.

Responsibility: Standard I-9: The Organization has written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected

- The BMC/BUMC HRPP includes all ceded studies in the auditing program:
  - The BMC/BUMC HRPP reviews the proposed recruitment methods to ensure that recruitment procedures comply with all BMC/BUMC policies.
  - Local Unanticipated Problems must be reported to the BMC/BUMC HRPP in addition to the IRB of record to minimize delays in necessary responses for harm mitigation.

Responsibility: Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.

- The BMC/BUMC HRPP reviews the initial cede review application submission:
  - If the rights and welfare of research participants are not protected, the application will not be approved.

Responsibility: Standard II-10: The Organization conducts audits or surveys and uses other methods to assess compliance

- The BMC/BUMC HRPP includes all ceded studies in the auditing program:
  - QA Reviews: for-cause audits after the first few subjects are enrolled.
  - For-Cause Audits: as-requested by the BMC/BUMC IRB or the IRB of record.

Responsibility: Element III.1.E. Researchers and Research Staff recruit participants in a fair and equitable manner.

- The BMC/BUMC HRPP will allow exceptions if the rights and welfare of research participants are not appropriately protected.

Responsibility: Element III.2.D. Researchers and Research Staff follow all applicable reporting requirements

- Local Unanticipated Problems must be reported to the BMC/BUMC HRPP in addition to the IRB of record to minimize delays in necessary responses for harm mitigation.
- Protocol changes that affect BMC/BUMC retained responsibilities must be reported to allow local review for continuing compliance with BMC/BUMC policies.

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