

Local Responsibilities: Lessons Learned from Cede Review

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Overview

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 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

Additional Special Routing

- Department resources
 - Nursing
 - Perinatal
 - Ambulatory Pediatrics
 - Cancer/Oncology
 - Psychiatry/Behavioral Health
 - General Clinical Research Unit
 - Investigational Pharmacy
- Targeted recruitment
 - Students, Medical Residents
- Safety
 - Biomedical Engineering
 - Institutional Biosafety
 - Radiation Safety/Radiology
 - Lasers
 - Human Gene Therapy
- Clinical Trial Office
 - Medicare Cost Analysis
 - Compensation for Injury language in consent form

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

BMC/BU Medical Campus to Cede Review

the Principal Investigator will continue to be responsible to the BMC/BU Medical Campus IRB for the following:

1. Submitting INSPIR internal study personnel changes for research staff updates; and ensuring that all research staff meet BMC/BU Medical Campus requirements for training, and compliance with BMC/BU Conflict of Interest policies.

Responsibility: Standard I-7: The Organization has and follows written policies and procedures to ensure that the use of any investigational or unlicensed test article complies with all applicable legal and regulatory requirements.

7.2 Protocol Type (select the appropriate box)

Studies involving the use of drugs or biologicals

This protocol is a drug study.

This protocol is NOT a drug study.

Device trials

This protocol is a device study.

This protocol is NOT a device study.



The BMC/BUMC HRPP must be able to identify locally-used drugs/devices to be able to act on any information about new risks

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.

8.0 Special Populations

8.1 Enrollment of BMC/BU Medical Campus students or employees (faculty, staff, or trainees). BMC/BU Medical Campus policies requires that the appropriate Dean or Chief sign off on research where students or residents are targeted for recruitment. BMC/BU Medical Campus policies generally do not allow for enrollment of students or employees (faculty or staff) who report directly to one of the study investigators. Please check all that apply:

- Not Applicable.
- Students (graduate or medical/dental/SPH students) are targeted for enrollment.
- Recruitment targets medical/surgical/dental residents.
- This study will enroll BMC/BU Medical Campus employees, students or lab personnel but will NOT enroll any subjects who report directly to ANY of the investigators (as students, employees, trainees, or staff).
- We are requesting an exception to the BMC/BU Medical Campus policy. We would like to enroll subjects who report directly to one or more of the investigators. We have attached a detailed explanation as to why we are requesting an exception.

8.2 Wards

BMC/BU Medical Campus policies require that children who are wards of the Massachusetts Department of Children & Families may be enrolled in research only if either parental permission will be obtained for enrolling their children in research or the Department of Children & Families will obtain prior judicial approval for enrolling the children when the parents cannot be located, or when the children are in custody for surrender for adoption or for termination of parental rights. Please check one of the following:

- These policies will be followed for enrollment of wards
- We are requesting an exception to these policies. We have attached a detailed explanation as to why we are requesting an exception

8.3 Cognitively Impaired Subjects

BMC/BU Medical Campus policies specify who is an allowable Legally-Authorized Representative as follows:

- Court-appointed guardian and previously-designated research proxy for any category of research
- General healthcare proxy, only for research that holds out the prospect of direct benefit
- Next of kin, only for research that holds out the prospect of direct benefit or for research where consent of the subject could be waived under 46 CFR 116(d)

Please check one of the following:

- These policies will be followed for enrollment of decisionally-impaired subjects
- We are requesting an exception to these policies. We have attached a detailed explanation as to why we are requesting an exception

8.4 Non-English Speaking Subjects

BMC/BU Medical Campus policies do not allow minors to be interpreters when non-English speaking subjects are enrolled and allow adult family members to be interpreters only if the study does not require an interpreter with a medical background. Please check one of the following:

- These policies will be followed for enrollment of non-English speaking subjects
- We are requesting an exception to these policies. We have attached a detailed explanation as to why we are requesting an exception

8.5 Limited- and Non-readers

BMC/BU Medical Campus policies require that for greater than minimal risk research, either an impartial witness must be present throughout the consent process or an alternative method of ensuring comprehension is used if the consent form is read to a potential subject. Please check one of the following:

- These policies will be followed for enrollment of limited- and non-readers
- We are requesting an exception to these policies. We have attached a detailed explanation as to why we are requesting an exception

- This information above is collected in the initial cede review application
- The BMC/BUMC HRPP will allow exceptions if the rights and welfare of special populations are not adversely affected

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

6.7 Are you recruiting subjects from the BMC/BU Medical Campus location?

Yes

No

10.0 Recruitment Procedures/Materials

10.1 Recruitment Procedures

Describe in detail how the research population will be identified and your methods for contacting potential subjects and providing them with information about the study.

- The BMC/BUMC HRPP reviews the proposed recruitment methods to ensure that recruitment procedures comply with all BMC/BUMC policies, and are appropriate for our patient/participant population

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

BMC/BU Medical Campus to Cede Review

the Principal Investigator will continue to be responsible to the BMC/BU Medical Campus IRB for the following:

2. Submitting Unanticipated Problems in INSPIR that are internal, serious, unexpected, and related or possibly related to the research to the BMC/BU Medical Campus IRB as well as to the IRB of record.
3. Submitting a Change Request and Modification to notify the BMC/BU Medical Campus IRB before implementing the amendment if there is a modification to the study that affects the items the BMC/BU Medical Campus IRB originally reviewed (e.g., radiation safety, biosafety, pharmacy, departmental approvals, nursing review, Clinical Trials Office, recruitment, non-English speakers).

- 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

Responsibility: Element I.5.A. The Organization conducts audits or surveys or uses other methods to assess compliance

The BMC/BUMC HRPP includes all ceded studies in the auditing program:

- QA Reviews: not-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

Conclusions

- Institutions have myriad retained responsibilities for ceded studies
- The I-9 Standard can be used to systematically identify policies and procedures for effectively sharing IRB oversight
- The electronic IRB submission portal at BMC/BUMC was designed to track cede review studies and facilitate review of local responsibilities as part of the cede review process, both at the time of initial review and throughout the life of the study

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