Non-Commercial IRB Cede Review and You: Policies, Processes, Tips, and Tricks

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Non-Commercial IRB Cede Review and You: Policies, Processes, Tips, and Tricks

Learning Objectives

- Discuss the different roles and responsibilities of reviewing IRBs and relying institutions
- Review tips and tricks for the initial non-commercial cede review process
- Learn about our BMC/BUMC HRPP Policies and Procedures for maintaining compliance when ceding
- Review case studies related to ceded responsibilities

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What is "cede review?"

- Ceding, or "relying" is when an institution agrees to use an IRB outside their institution to oversee a research study(ies)
  - "Relying" Institution cedes to the "Reviewing" Institution
- Different types of IRBs can be the Reviewing IRB
  - Other academic institutions involved in the study
  - Consortium "central" IRBs
  - Commercial IRBs

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What is “cede review?”

- Why would an institution want to cede review?
  - To increase efficiency of the IRB review process
    - Only one IRB needs to conduct ethical review of the protocol/consent
    - Relying site might only involved in certain aspects of the study
  - To obtain leverage in requesting protocol or consent changes
  - Because the Institution *has* to cede to a sIRB in order to participate

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What studies are most commonly ceded?

- Federally-supported (HHS), multi-site, non-exempt studies

Why?

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Single IRB Regulations

- NIH Single IRB Policy for Multi-Site or Cooperative Research
  - Applies to all NIH-funded multi-site non-exempt research
- Common Rule "Cooperative Research" 45 CFR 46.114
  - Federal Policy for the Protection of Human Subjects ("the Common Rule")
  - Applies to all HHS-supported research

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Retained and Ceded Responsibilities

- What responsibilities does the Relying Institution cede?

These will be discussed in detail, but broadly:

- The ethical review under 45 CFR 46 ("Common Rule") and, when applicable, 21 CFR 50 and 56 (FDA regulations)
- In certain cases, Privacy Board review (HIPAA)

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Retained Responsibilities

- Evaluation of requests to cede review (and associated activities, such as recruitment procedures and impact on local HRPP policies); and
- Determinations that the study meets the requirements for waivers of HIPAA authorization for research uses and disclosures of subjects' protected health information; and
- Conflict of interest reporting and evaluation; and
- Reviews performed by special routing; and
- Post-approval monitoring of research; and

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Retained Responsibilities

- Investigator qualifications:
  - The process for ceding review includes providing training for investigators and research staff and assuring that all study staff meet the qualifications and training requirements, including personnel added to the study after initial approval; and
- Organizational conflicts of interest: BMC and BU are responsible for notifying the external IRB of any organizational conflicts of interest

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Ceded Responsibilities

- Performing the scientific review of the protocol; and
- Ensuring concordance between any applicable grant and the protocol; and
- Reviewing potential noncompliance, including complaints, protocol deviations, and results of audits and making determinations of noncompliance according to the policies and procedures of the IRB of record; and
- Evaluating the protections provided by management plans for conflicts of interests and imposing additional requirements if necessary to protect the rights and welfare of subjects; and

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Ceded Responsibilities

- Obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners; and
- Reporting to regulatory agencies and sponsors concerning serious or continuing noncompliance, unanticipated problems, and suspensions or terminations of IRB approval.
  - The IRB of record is expected to provide the BMC and BUMC HRPP the opportunity to review and comment on the report before it is sent to regulatory agencies or sponsors.

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Commercial v Non-Commercial Cede

COMMERCIAL IRB

Criteria for Ceding:

- industry-sponsored, multi-site trial involving an IND or IDE held by the industry-sponsor; or
- federally-supported multi-center trial where the commercial IRB has been selected as the IRB of record.

IRB Options:

- Any for-profit commercial IRB
  - Advarra, WCG IRB most common

NON-COMMERCIAL IRB

Criteria for Ceding:

- any study could be eligible

IRB Options:

- any non-commercial IRB (generally, another academic medical center/academic institution)

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Commercial v Non-Commercial Cede

For Ceding to both Commercial AND Non-Commercial IRBs:

Eligible IRBs:

> minimal risk = AAHRPP-accredited

< minimal risk =

- Participation in SMART IRB platform; or
- Judgment of IRB or HRPP Director (based on review of reviewing IRB policies and procedures and any letters or findings within the past five years from OHRP or FDA as a result of investigations or inspections of the IRB)

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Initial Cede Process

- Most institutions have an internal "cede review" process
  - For example, at BMC/BUMC, we have a special "cede application"
    - This helps institutions determine whether we agree to cede (or in some cases conduct the study at all)

Section 4.1

Review Path Determination

O This project meets the definition of Not Human Subject Research (NHSR). Examples are non-research Quality Improvement/Quality Assurance projects; studies that involve obtaining anonymous data/tissues or coded data; or BMC/BU Medical Campus is not 'engaged' in human subjects research.

O BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.

O The only research activities in this study involve chart reviews with no subject interaction.

O This study fits into one or more of the federal Exempt categories or the study does not have external funding and fits into one or more of the Equivalent Protections Exempt categories.

O None of the above. This study requires Expedited review or the review of the Full Board.

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Cede Application Tips

 # When is an INSPIR cede application needed?

An INSPIR cede application is needed:

- when Boston Medical Center or Boston University Medical Campus is being added as a Relying Site to an approved Reviewing Institution's non-Exempt study which has a designated single IRB; **AND**

- if BMC/BUMC meets **one or more** of the following criteria for being "engaged in research" for the Reviewing Institution's study to justify the need for an IRB Authorization Agreement to rely on the Reviewing Institution's single IRB:

  - Is the primary awardee of the grant; and/or
  - Will be consenting subjects; and/or
  - Will be interacting with subjects post-consent; and/or
  - Will be accessing subjects' identifiable data

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Cede Application Tips

 # What are requirements for the BMC/BUMC Principal Investigator?

The BMC/BUMC Principal Investigator for the INSPIR cede application must meet the following criteria:

- Have an active INSPIR account: How to get access to INSPIR II
- Have updated INSPIR profile fields: How to update your Personal Profile
  - Degree, Relationship to the Institution, Affiliation, Email Address, Primary Phone Number, Mailing Address (Building name and street address of Department); and Department
- Be current with CITI Medical Campus Training: https://www.bumc.bu.edu/ohra/required-training/
- Be current with Good Clinical Practice (GCP) training, if the study is a clinical trial
- Be listed in the PI Home Institution Finder Database: http://wwwapp.bumc.bu.edu/PI_Home_Institution/
- Must not have any expired INSPIR studies for which no continuing review or final report have been submitted in INSPIR
- If a Student/Resident/Fellow, must have a Supervising Principal Investigator

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Cede Application Tips

 # What documentation is needed from the Reviewing Institution?

Obtain the following documents from the Reviewing Institution study team. You will be copying information from these documents into your INSPIR cede application; and attaching these documents to your submission:

- Reviewing IRB initial approval letter
- Reviewing IRB renewal approval letter with a current expiration date (if applicable)
- Reviewing IRB amendment approval letter for the current approved protocol and consent
- Current approved protocol
- Current approved consent
- Recruitment materials (flyers, brochures, opt-out letters, etc) [can be submitted later as amendment]
- Clinicaltrials.gov 8-digit NCT number (if the study is a clinical trial)
- Name of Funding Agency, Award #, and name of grant PI

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Cede Application Tips

 # Who cannot be added as internal study personnel on INSPIR cede applications?

1-**BU Charles River Campus External Investigators.** When adding BU-CRC personnel to the application, there will be a "BU-CRC" notation after their name. The following BU Charles River Campus personnel are considered "BU-CRC External Investigators" who will require a reliance agreement directly with the Reviewing Institution IRB (if engaged in research):

- BU Charles River Campus students obtaining academic credit at CRC for their research activities
- BU Charles River Campus faculty and staff

2-**External Investigators.** The IRB must grant special approval exception for Reviewing Institution External Investigators to have INSPIR access as "Administrative Assistants" and/or "Study Contacts" to assist the BMC/BUMC PI with the INSPIR application.

3-**Internal BMC/BUMC personnel who do not have the required current CITI / GCP training or who have inactive INSPIR accounts.**

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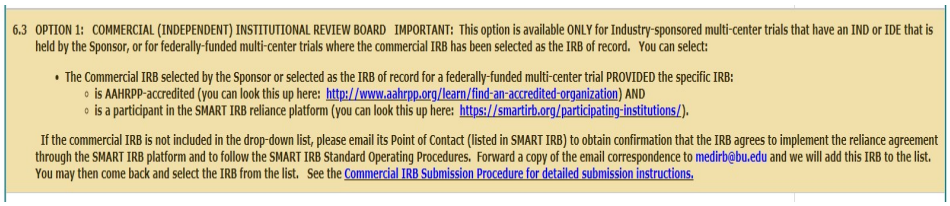
Cede Application Tips

 # How do I create the INSPIR non-Commercial IRB cede application?

- Create the draft application, and complete up to Section 4.1: How to create a new protocol draft in INSPIR II. The INSPIR study title should be identical to the Reviewing Institution's study title.
- Select the 2nd option in Section 4.1 Review Path Determination, then complete up to Section 6.3:
- Answer NO to Section 6.3 for Commercial IRB



6.3 OPTION 1: COMMERCIAL (INDEPENDENT) INSTITUTIONAL REVIEW BOARD IMPORTANT: This option is available ONLY for Industry-sponsored multi-center trials that have an IND or IDE that is held by the Sponsor, or for federally-funded multi-center trials where the commercial IRB has been selected as the IRB of record. You can select:

- The Commercial IRB selected by the Sponsor or selected as the IRB of record for a federally-funded multi-center trial PROVIDED the specific IRB:
  - is AAHRPP-accredited (you can look this up here: http://www.aahrpp.org/learn/find-an-accredited-organization) AND
  - is a participant in the SMART IRB reliance platform (you can look this up here: https://smartirb.org/participating-institutions/).

If the commercial IRB is not included in the drop-down list, please email its Point of Contact (listed in SMART IRB) to obtain confirmation that the IRB agrees to implement the reliance agreement through the SMART IRB platform and to follow the SMART IRB Standard Operating Procedures. Forward a copy of the email correspondence to medirb@bu.edu and we will add this IRB to the list. You may then come back and select the IRB from the list. See the Commercial IRB Submission Procedure for detailed submission instructions.

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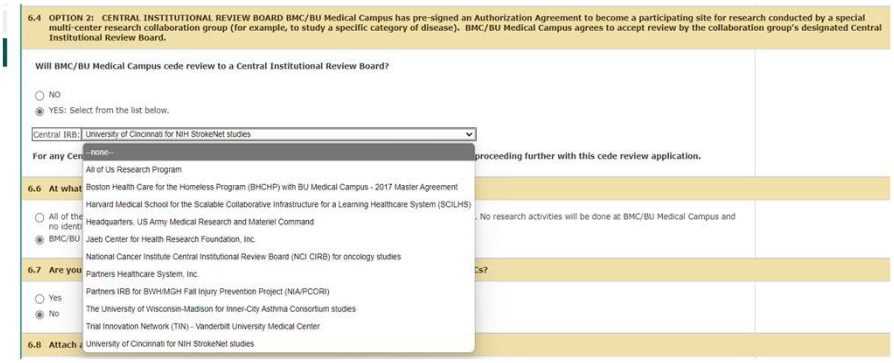
Cede Application Tips

How do I create the INSPIR non-Commercial IRB cede application?

- Answer YES to Section 6.4 if your Reviewing Institution IRB is listed in the Central IRB list. Then complete the rest of the application.



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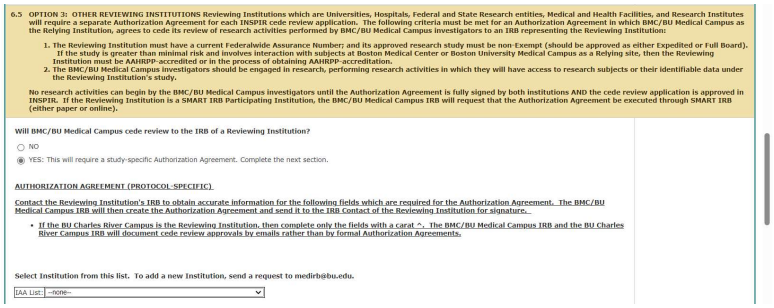
Cede Application Tips

How do I create the INSPIR non-Commercial IRB cede application?

- Answer YES to Section 6.5 (Other Reviewing Institution) if 6.4 does not apply (this is most common). Then complete the rest of the application.



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Cede Application Tips

 # How do I create the INSPIR non-Commercial IRB cede application?

- Select the Reviewing Institution from the IAA List. If you do not see the Reviewing Institution in the IAA List, then send an email to medirb@bu.edu to request the Institution to be added to the IAA list.
  - Select "Mass General Brigham Incorporated" when the MGB IRB is the IRB of Record for any of their affiliated institutions.
  - Look up the Reviewing Institution at the Smart IRB website to obtain their Federalwide Assurance Number, and the Reviewing Institution Smart IRB contact at https://smartirb.org/participating-institutions/.

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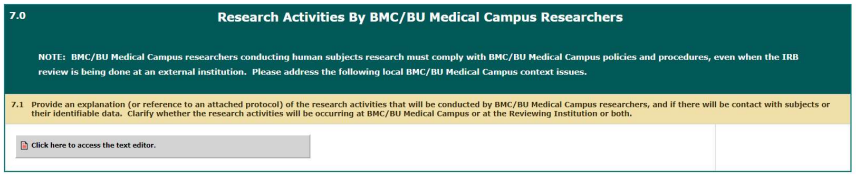
Cede Application Tips

 # Tips for Section 7.1 - Research Activities by BMC/BUMC

(Going forward, Section numbering may vary depending on how you answer questions in the INSPIR application)

- The IRB needs to specifically know what research activities will be conducted by BMC/BUMC regarding these categories:
  - Is the primary awardee of the grant; and/or
  - Will be consenting subjects; and/or
  - Will be interacting with subjects post-consent; and/or
  - Will be accessing subjects' identifiable data
- VERY IMPORTANT: BE SPECIFIC ABOUT BMC/BUMC ACTIVITIES IF WE ARE NOT CONDUCTING THE FULL PROTOCOL HERE. IF CONDUCTING FULL PROTOCOL, MAY REFERENCE THE PROTOCOL.



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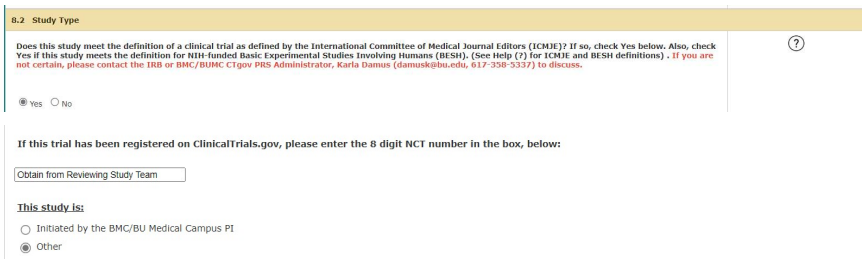
Cede Application Tips

 # Tips for Section 9.2 - Funding Source: Study Type

- If the Reviewing Institution study is a clinical trial, then answer YES; and request the ClinicalTrials.gov number from the Reviewing study team (if not yet available, enter PENDING).
- ***This study is***: Always answer OTHER for a cede application.



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Cede Application Tips

 # Tips for Section 9.4 - Funding Source: Grants Office

- Select the Grants Office that matches the Principal Investigator's Home Institution in the PI Home Institution Finder Database:
  - If the Home Institution is Boston University Medical Campus, then select BU Office of Sponsored Programs (OSP-MED).
  - If the Home Institution is Boston Medical Center, then obtain confirmation of the correct BMC grants office: either the BMC Research Finance (RF) Office, or the BMC Clinical Trial Office (CTO) – see https://www.bmc.org/research-operations/portfolio-assignments-directory

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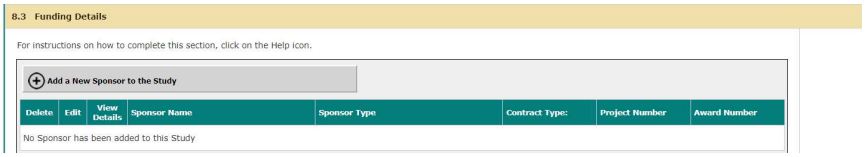
Cede Application Tips

Tips for Section 9.3 - Funding Source: Funding Details

- Sponsor Name: Send an email to medirb@bu.edu if you cannot find the name of the sponsor.
- Award Number: Enter the grant award number. This number gets transferred to all the INSPIR outcome letters. Enter PENDING if not yet available.
- Project Number: This is the internal identification number used by the grants office for the award. Enter PENDING if not yet available.
- The Principal Investigator will be required to submit a cede amendment to update the INSPIR application with the Award Number and Project Number when they become available.



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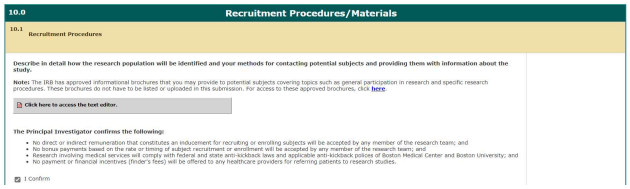
Cede Application Tips

Tips for Section 10.0 - Recruitment Procedures/Materials

- **Section 10.1**: If you attach flyers or other recruitment materials to the submission, then you must describe their use in this section.
- Printed materials such as flyers, brochures, and postcards that are only physically disseminated at Boston Medical Center or on the Medical Campus do not require Mar/Comm approval.
- Promotional materials that are external-facing (i.e., distributed beyond the physical BMC hospital or Medical Campus sites) will still require the Mar/Comm approval documentation, which needs to be attached to the submission. See Recruitment Help Update: When is Marketing/Communications Review Now Required? - Dec 2023



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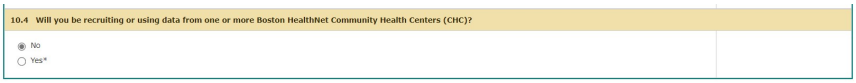
Cede Application Tips

Tips for Section 10.0 - Recruitment Procedures/Materials

Section 10.4: Boston HealthNet has a mandatory pre-approval process for studies involving any of its Community Health Centers – see Partnering with BHN Community Health Centers to Support Research Engagement - Feb 2022

If you do not have any signed Letters of Approval from the Boston HealthNet Community Health Centers, then answer NO; and send an email to medirb@bu.edu to request instructions regarding the Boston HealthNet pre-approval process. The approved Community Health Centers can be added through a cede amendment after initial cede approval.

If you do have signed Letters of Approval from any of the Boston HealthNet Community Health Centers, then answer YES; list the names of the CHCs, and enter a description of research activities to be conducted at the CHCs.



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Cede Application Tips

Tips for creating attachments to the INSPIR cede application

- Use the approved **Reviewing Institution approved consent template** for creating the BMC/BUMC-specific consent, and attach to the submission.
- Attach all the Reviewing Institution IRB study documents.

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Cede Application Tips

 # I submitted my INSPIR cede application – what's next?

- Allow 2-3 weeks for the IRB to complete its first review of your initial cede application. It will be returned to you with any stipulations to address.
- The Reviewing IRB may have forms which need to be completed for the BMC/BUMC Relying Site. Our IRB will complete these forms at the time it reviews your INSPIR cede application.
- When the cede application and the BMC-specific documents are finalized, then the IRB will notify you to PROCEED with obtaining the Reviewing Institution's approval for the BMC/BUMC Relying Site, and will provide the documents which you should forward to the Reviewing study team.
- Our IRB will need the following documents from the Reviewing IRB: (1) the Reviewing IRB approval letter for the BMC/BUMC Relying Site; (2) the fully executed Smart IRB reliance agreement (or other reliance agreement): and (3) the BMC-specific consent stamped by the Reviewing IRB (if applicable).

(continued)

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Cede Application Tips

 # I submitted my INSPIR cede application – what's next?

- Our IRB will confirm its acceptance of the Reviewing IRB approval documents for the BMC/BUMC Relying Site. If there are no issues, then the IRB will process the approval of the cede application; and then will send a confirmation of when the BMC/BUMC Relying Site can begin research activities.
- The INSPIR cede approval outcome letter will list research scenarios of when an INSPIR submission will be required, even though the Reviewing Institution is now the IRB of Record.
- The Principal Investigator will be required to submit a cede amendment to update the INSPIR application with the Award Number and Project Number when they become available.

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Requirements After Initial Cede Approval

- Once the initial request to cede review has been granted, you may begin research activities.
- When the BMC and BUMC IRB has entered into a reliance agreement with another IRB that acts as the IRB of record, the Principal Investigator (PI) must comply with all reporting requirements of the IRB of record.
  - For example: deviations, AEs/SAEs, Unanticipated Problems (UPs), enrollment numbers
  - However, you are still responsible for certain reporting requirements to the relying BMC/BUMC IRB.

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Reporting to relying BMC/BUMC IRB

- Submit Internal Study Personnel Changes to the BMC/BUMC IRB for administrative approval
  - The reviewing IRB may or may not wish to be informed about non-PI personnel changes; check with them!
- Submit Reportable Events and New Information (RENI) forms to report changes made to eliminate an apparent immediate hazard to subjects that occur at the BMC or BUMC site ("internal immediate apparent hazards to subjects").
  - This requirement is in addition to required reporting to the IRB of record according to its reporting requirements for changes made to eliminate an apparent immediate hazard to subjects

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Reporting to relying BMC/BUMC IRB

- Submit RENI forms to report any **serious and/or continuing noncompliance determinations made by the reviewing IRB** OR **Unanticipated Problem determinations** in relation to event(s) that occur at the BMC or BUMC site.
  - This form must be submitted to the IRB **within 7 days** of the investigator or research staff becoming aware of the reviewing IRB determination; and
- Submit a Status Check-In Report form prior to the status check-in due date
- Submit a Final Report after the IRB of record closes the study

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Reporting to relying BMC/BUMC IRB

- Submit Change Request and Amendment forms if the proposed changes:

Affect compliance with local policies or seek to modify previously-granted policy exception requests for enrollment of:

- Decisionally-impaired subjects who require the use of Legally Authorized Representatives (see Section 9.5)
  - Policy: Who is an allowable Legally-Authorized Representative?
- Non-English speaking subjects (see Section 8.4.5)
  - Policy: minors may not be interpreters; adult family members may only be interpreters if the study does not require an interpreter with a medical background; use of the short form consent process is not allowed with prior approval by BMC/BUMC IRB
- Wards of the State (see Section 9.2.3); and
  - Policy: When may wards be enrolled? Limited- and non-readers (see Section 8.4.6); and

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Reporting to relying BMC/BUMC IRB

- Submit Change Request and Amendment forms if the proposed changes:

Affect compliance with local policies or seek to modify previously-granted policy exception requests for enrollment of:

  - Students, trainees, and employees (see Section 9.6) and
    - Policy: adding new targeted recruitment of these groups or enrolling those who report directly to any of the investigators
  - Limited- and non-readers (see Section 8.4.6) and
    - Policy: adding new targeted recruitment of these groups or enrolling those who report directly to any of the investigators
  - Patients of Substance Use Disorder Clinic(s) (see Section 7.2.2.10); or
    - Policy: Use of data under 42 CFR Part 2

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Reporting to relying BMC/BUMC IRB

- Submit Change Request and Amendment forms if the proposed changes:
  - Affect compliance with local policies or seek to modify previously-granted policy exception requests for individuals involved the consent discussion for studies involving drugs, devices, or surgical procedures
    - For these studies, a Licensed Independent Professional (LIP, for example, physician, dentist, physician assistant, nurse practitioner) must discuss the purpose, risks, benefits, and alternatives with potential subjects.

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Reporting to relying BMC/BUMC IRB

- Submit Change Request and Amendment forms if the proposed changes:

Affect information provided regarding:

- the plan to prevent disclosure of HIV testing status to any non-Boston Medical Center research staff prior to written consent being obtained; or
- the plan to share data with a third-party vendor or software application or program; or
- recruitment procedures;

Or if the changes involve:

- adding new or modify existing recruitment materials; or
- adding a new or modifying an existing waiver of authorization for use and disclosure of Protected Health Information (see Section 8.5.2.2); or

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Reporting to relying BMC/BUMC IRB

- Submit Change Request and Amendment forms if the proposed changes:

- Require review by a special routing individual or entity that was not involved during initial the review process (see Section 7.2.2.2); or
- Add new or modify existing investigator or research staff Financial Conflicts of Interest as determined by Boston Medical Center/Boston University Faculty Review Committee on Research Financial Conflicts of Interest; or
- Affect information provided regarding organizational conflicts of interest review
- Add new study cohorts and/or new consent forms

As noted earlier, Status Check-In Reports for ceded studies will be evaluated to determine whether any information was not reported as required and whether any follow-up actions are required. A revised cede letter with the new status check-in due date will be provided via the electronic system.

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CASE STUDIES/POLLS

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Your local PI has recently retired, and a new local PI has been identified.

Which IRB needs notification of the Change?

A. The external REVIEWING IRB

B. The local RELYING IRB

C. Both IRB's

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Which IRB needs notification of the Change?

A. The external REVIEWING IRB

B. The local RELYING IRB

C. Both IRB's

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You are working on a study that is ceded to NYU. Your BMC PI has a new BU-CRC faculty collaborator who is joining the study. The CRC investigator will conduct the consent process with subjects and lead focus group discussions.

Should you add the CRC investigator as an internal investigator so that BU-CRC can also cede review to NYU?

A. Yes

B. No

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You are working on a study that is ceded to NYU. Your BMC PI has a new BU-CRC faculty collaborator who is joining the study. The CRC investigator will conduct the consent process with subjects and lead focus group discussions.

Should you add the CRC investigator as an internal investigator so that BU-CRC can also cede review to NYU?

A. Yes

B. No

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Enrollment into the study has been slow, and you wish to add a new recruitment method – posting flyers in the BMC clinic.

Which IRB needs to review the proposed change?

A. The external REVIEWING IRB

B. The local RELYING IRB

C. Both IRBs

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Enrollment into the study has been slow, and you wish to add a new recruitment method – posting flyers in the BMC clinic.

Which IRB needs to review the proposed change?

A. The external REVIEWING IRB

B. The local RELYING IRB

C. Both IRBs

53

53

As you prepare to submit this new recruitment method (posting flyers in the BMC clinic) as part of a cede amendment, your colleague asks if the flyer needs to be reviewed by BMC Marketing and Communications.

Is this required?

A. Yes

B. No

54

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Is this required?

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Your study undergoes a Quality Assurance review, which identifies 2 major deviations, and 1 Important Finding that might meet criteria for an Unanticipated Problem.

Which IRB needs to review these findings?

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B. The local RELYING IRB

C. Both IRBs

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After reviewing the 2 major deviations, the reviewing IRB determines that that the Important Finding does qualify as an Unanticipated Problem (UP).

Do you need to report this to the local relying IRB?

A. Yes

B. No

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58

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Do you need to report this to the local relying IRB?

A. Yes

B. No

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59

The eligibility criteria for the study are revised to increase the upper age limit. Previously, the age range was 18-50 years old, but an amendment proposes to change this to 18-60 years old.

Which IRB needs to review this proposed change?

A. The external REVIEWING IRB

B. The local RELYING IRB

C. Both IRBs

60

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61

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The study protocol is being revised to add a research-only CT scan. Previously, the only imaging data used as part of the study were images of existing CT scans that were taken as part of standard of care and could be pulled from medical records.

Which IRB needs to review this proposed change?

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C. Both IRBs

62

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C. Both IRBs

63

63

A BU SPH investigator is joining a new multi-site NIH-funded study under a subaward. The single IRB will be Duke University. His activities are helping to design the statistical plan for the protocol, and analyzing de-identified data.

Does BUMC need to cede review to Duke?

A. Yes

B. No

64

64

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Does BUMC need to cede review to Duke?

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66

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A BMC study that is ceded to BIDMC wishes to expand recruitment to Codman Square Health Center. The proposal involves posting flyers and asking providers to hand out business cards.

Which IRB needs to review this proposed change?

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Cede Review in INSPIR

Some Helpful Links:

- Ceding Review: https://www.bumc.bu.edu/irb/submission-requirements/when-to-submit/ceding-review/
- Cede Review Resources: https://www.bumc.bu.edu/irb/submission-requirements/when-to-submit/ceding-review/cede-review-resources/

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Cede Review

Thank you!

What questions do you have?

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