

Cede Review and You – How to Navigate this Evolving “New World” of IRB Review

MATTHEW OGRODNIK, MS, CIP

DIRECTOR INSTITUTIONAL REVIEW BOARD

BOSTON MEDICAL CENTER AND BOSTON UNIVERSITY
MEDICAL CAMPUS



Ceding Review and SMART IRB

Learning Objectives

- Discuss the procedures involved in ceding review
- List what changes have been made to the code review process at BMC/BUMC
- Explain tips and important items to keep in mind for the most efficient local code review submission

Coding Review and SMART IRB

Learning Objectives

- Discuss the procedures involved in coding review
- List what changes have been made to the code review process at BMC/BUMC
- Explain tips and important items to keep in mind for the most efficient local code review submission

What studies are most commonly ceded?

- NIH-funded, multi-site, non-exempt studies
 - If BMC/BU Medical Campus is *NOT* prime awardee, these studies will always be ceded going forward, due to the NIH Single IRB policy
 - If BMC/BU Medical Campus *IS* prime awardee of NIH grant, the study will usually be ceded to a designated Single IRB (sIRB)
 - This could be Commercial IRB (cIRB) or an academic site IRB that agrees to be the sIRB for the study

What studies are most commonly ceded?

- Industry-sponsored, multi-site, IND/IDE studies
 - The commercial IRB must be:
 - an AAHRP-accredited IRB that has agreed to execute the reliance agreement through SMART IRB
- You always have the option to have the BMC/BUMC IRB review these studies

When are studies most commonly ceded?

Quick note on SMART IRB:

SMART IRB is a *platform* (not an IRB) that enables IRB reliance among institutions who agree to collaborate under a pre-signed master SMART IRB global reliance agreement. A protocol-specific SMART IRB Agreement is then created for each study. (see www.smartirb.org).

Cede Review Procedures

STEP ONE

- Identify the chosen Commercial IRB (cIRB); if NIH-funded, this might be a non-commercial sIRB rather than cIRB (such as another site)
 - If cIRB for IND/IDE study, confirm the cIRB is AAHRPP-accredited and a SMART IRB participant

Cede Review Procedures

STEP ONE continued...

- cIRB: if eligible, inform the sponsor/main site that ceding will be permitted *if* agreement is through SMART IRB
- Non-commercial sIRB: Preference is through SMART IRB; otherwise, reliance agreement (IAA) will be reviewed by Office of the General Counsel

Cede Review Procedures

STEP ONE continued...

- Inform the sponsor/main site that you must now obtain approval from the BMC/BU Medical Campus IRB through an internal cede application **BEFORE** completing any of their additional forms or applications.

Cede Review Procedures

STEP TWO

Customize the main site/sponsor's consent template with BMC/BU Medical Campus language from [Adult Consent template](#):

- Basic Information (PI [name, address, email], H#, Study Phone #'s)
- Costs section template language
- Compensation for Injury template language (if non-industry funded)
- HIPAA language must reference BMC and/or BU (as applicable)
- Make sure the IRB contact info is the cIRB/sIRB, not BMC/BUMC

Cede Review Procedures

STEP THREE Create a Velos application (“Study Initiated” state) and upload the four required documents*:

- a. Budget
- b. Protocol
- c. The Consent Form that was modified in STEP TWO
- d. Clinical Trial Agreement

*Some of these may not apply to NIH-funded studies; provide what CTO asks for

Cede Review Procedures

STEP THREE continued...(Industry-Sponsored IND/IDE Study ***ONLY***)

1. In ICF, BMC CTO will review the Costs, and Compensation for Injury (if PI is BMC), and may contact you with changes based on documents in Velos.

2. If the PI's home institution is BU Medical Campus, also send your Consent Form to BU-OSP for review of the "Compensation for Injury" language:

OSP-MED (Attorney Bill Segarra; Phone: (617) 353-6151; email segarra@bu.edu)

Cede Review Procedures

STEP THREE continued...(Industry-Sponsored IND/IDE Study
ONLY)

Obtain sponsor/main site approval for the consent edits,
and attach the approved consent form to your INSPIR
application.

Cede Review Procedures

STEP FOUR

Prepare and submit your INSPIR cede review application!

STEP FIVE

After review of your INSPIR application is complete, the BMC/BUMC IRB will send the SMART IRB form to the cIRB for signature; or, if sIRB, the IAA will be sent for signature (if approved by OGC)

Cede Review Procedures

STEP SIX

Once the BMC/BUMC IRB has received the signed SMART IRB agreement from the cIRB (or signed IAA if used for sIRB), we will ask you to proceed with any processes that are required by the cIRB or sIRB (such as completing a separate application in their electronic system).

Cede Review Procedures

STEP SEVEN

Once you complete any processes required by the cIRB or sIRB, they should send you the following:

1. Approval documentation (usually a letter) that BMC/BUMC has been added as a site; and
2. Approved versions of the BMC/BUMC-specific consents.

Send these documents to the IRB Analyst assigned to your cede submission.

Cede Review Procedures

STEP EIGHT

The Analyst will upload the cIRB/sIRB's approval documents from STEP EIGHT to your INSPIR cede application, and confirm that the compensation for injury language matches the attorney language. If so, you will receive the cede approval outcome letter.

You may now begin research activities!

Cede Review Procedures

POST-APPROVAL PROCESS:

1. Adding Internal Personnel: Submit an Internal Study Personnel Change form in INSPIR before submitting the change to the external IRB, so that we can comply with our agreement by ensuring training certifications and COI disclosures are completed.
2. Ancillary Review Changes: If there is an amendment to the study that affects the items we originally reviewed (e.g., radiation safety, biosafety, pharmacy, departmental approvals, nursing review, Clinical Trials Office, recruitment), involves a new ancillary review office, or requires adding a new Special Population (Cognitively Impaired, Part 2, etc) submit a Change Request and Amendment form in INSPIR to notify us before implementing the amendment.

Cede Review Procedures

POST-APPROVAL PROCESS:

3. Reportable Events: If an Unanticipated Problem occurs at BMC/BUMC that involves potential harm to a local subject, submit a RENI to report the incident to us, as well as reporting to the reviewing IRB. This is so we have an opportunity to help mitigate the harm without delay.

4. Study Closure: When the study is closed by the Commercial IRB, submit a Final Report for your INSPIR cede application. (This Final Report is a very short form to close the ceded study in INSPIR.)

Cede Review Procedures

POST-APPROVAL PROCESS:

MAKE SURE THAT REQUIRED TRAINING IS UP TO DATE

Internal study personnel must be current with CITI Medical Campus certification/recertification.

- See [Human Subjects Protection training](#).

Internal study personnel must be current with GCP Medical Campus training for clinical trials.

See [Good Clinical Practice \(GCP\) training](#).

Cede Review in INSPIR

4.0

Review Path Determination

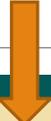
4.1 Review Path Determination

- This project meets the definition of Not Human Subject Research (NHSR). Examples are non-research Quality Improvement/Quality Assurance projects; studies 'engaged' in human subjects research.
- BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.
- The only research activities in this study involve chart reviews.
- 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 Pro
- None of the above. This study requires Expedited review or the review of the Full Board.



Choose the above option in the Review Path section to create the Cede Review application

Cede Review in INSPIR



7.1 Provide an explanation (or reference to an attached protocol) of the research activities that will be conducted by BMC/BU Medical Campus researchers, and if there will be contact with subjects or their identifiable data. Clarify whether the research activities will be occurring at BMC/BU Medical Campus or at the Reviewing Institution or both.



 [Click here to access the text editor.](#)

Please note that if there is an attached protocol, you may reference the protocol (such as “See attached industry protocol”) rather than copy/pasting the study procedures into the textbox.

However, if BMC/BU Medical Campus researchers will only be conducting certain components of the study, the role of BMC/BU Medical Campus researchers needs to be delineated here.

Cede Review in INSPIR

7.2 Protocol Type (select the appropriate box)

This section asks the following Yes/No questions:

Are BU Medical Campus Students being targeted for recruitment?

Are BMC/BU Medical Campus Employees (faculty, staff, or trainees) being recruited?

Wards

Will any (even one) minor who is a ward of the State be recruited?

Cognitively Impaired Subjects

Will any (even one) adult subject be recruited who will require the use of a Legally-Authorized Representative for consent?

Non-English speaking subjects

Will any (even one) subject be recruited who does not speak English?

Limited- and non-readers

Will any (even one) subject be recruited who is a limited- or non-reader (will need to have the consent form read to him/her)?

Cede Review in INSPIR

Please answer these carefully, as they drive follow-up questions that relate to our internal HRPP Policies and Procedures. Our internal P&P still need to be followed when ceding (unless an exception(s) is approved by the BMC/BU Medical Campus IRB)

For example:

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

Cede Review in INSPIR

Or, for example:

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

Cede Review in INSPIR

Other cede sections mirror the standard INSPIR application:

1. Recruitment: If you are recruiting local participants on-site at BMC/BU Medical Campus, you must fill out the recruitment section (do not reference the protocol!)
2. Drug or Biological Agents (if applicable)
3. Devices (if applicable)

Cede Review in INSPIR

Documents to attach to Initial Review Submission Form:

- Protocol
- Template consent (updated to be BMC/BU Medical Campus-specific) [prior to STEP SIX]
- Approval letter of Reviewing IRB (once obtained)*
- BMC/BU Medical Campus-specific consent approved by Reviewing IRB (once obtained)*
- Any form(s) from the commercial IRB that require signature from either BMC or the BMC/BU Medical Campus IRB*

*You may just email these to IRB analyst to attach once received (see STEP EIGHT)

Ceding Review and SMART IRB

Learning Objectives

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Cede Review Changes

- We no longer require email documentation that the commercial IRB will use SMART IRB
 - In practice, there has been 100% usage
- The ICF review by BMC CTO is performed in conjunction with setting up the Velos account
 - Very important to set up this account prior to cede submission if study uses BMC clinical services

Cede Review Changes

- No more special agreements with Hummingbird IRB or Western IRB (WIRB)
 - Now, for cede, any commercial IRB is ok if they are AAHRPP-accredited and will use SMART IRB

Cede Review Changes

- We have added important new questions about local activities/policies:

Patients of Substance Use Disorder Clinic(s)

Will you obtain any information that would identify someone as a patient of a federally-assisted substance use disorder clinic (Project RESPECT, Office-Based Addiction Clinic, CATALYST Clinic, or others - see (?) Help Icon for full list)?

If Yes: You will be asked to fill out special Part 2 documentation

HIV Testing Status

Will you need to obtain information on HIV testing status prior to consent being obtained (e.g., for recruitment purposes)?

If Yes: You will be asked to describe how you will ensure this info is not shared outside of BMC prior to consent.

Cede Review Changes

- We have added important new questions about local activities/policies:

Data sharing

Do you plan to share data with a third-party vendor or software application or program?
Note: sponsors are not considered third parties.

If Yes:

For BMC research, reach out to privacyofficer@bmc.org

For BU research, reach out to bumcinfosec@bu.edu

They will need to review their privacy and security practices, and obtain a BMC and/or BU HIPAA Business Associate Agreement before HIPAA data is shared with the third party/vendor or application.

You need to make this contact promptly because this process can require significant information gathering and analysis.

In the textbox below, please enter the date on which you contacted the BMC Privacy Officer and/or BU Information Security to initiate this privacy and security review process: []

Cede Review Changes

- The BMC/BUMC now retains the responsibility to grant waivers of HIPAA authorization for recruitment
 - Therefore, if you will access PHI without signed authorization for pre-screening purposes, you must complete the HIPAA compliance section

Cede Review Changes

Ceded studies are also subject to the Promotion Materials review process:

- You must work with the BMC Communications and Marketing Department or applicable BUMC Communications Office on the development of research recruitment materials and/or on the review of sponsor-supplied materials
- You may submit new/revised materials using the 'Recruitment Materials Submission Form'

Ceding Review and SMART IRB

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Tips and Other Items to Keep in Mind

- Do not assume the BMC/BU Medical Campus IRB can be the Single IRB – contact us during grant preparation!
- As with studies reviewed locally, all ancillary routing sign-offs (IPS, IBC, CTO, etc) must be obtained in INSPIR before the Cede application reaches us. See here for list of sign-offs if you want to reach out to them:
 - https://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/dept_sign_off/

Tips and Other Items to Keep in Mind

- Please be sure to finalize the Compensation for Injury language with BMC CTO or BU-OSP and study sponsor prior to submission!
- Requiring revisions to this language can take time and it is best done prior to IRB submission, or even during the ancillary sign-off process (then email medirb@bu.edu final version to attach)

Tips and Other Items to Keep in Mind

- If the Single IRB/Main Site (most often for NIH) asks you to submit an online SMART IRB request, do NOT do this until you have submitted your cede application
 - We need the cede application to process these, and it is more efficient for us to help you with this online request
- If you are requesting use of short form consent process, reach out to IRB to discuss which languages you will use
 - Often, Spanish and Haitian Creole will not be permitted as they are “anticipated”

Tips and Other Items to Keep in Mind

- Please reach out to the IRB at medirb@bu.edu *prior* to submitting a cece amendment if you have any questions about whether it is needed
 - We do not require submission of most types of protocol/consent form changes, only those listed in the following slides:
 - Slides 18-19 (POST-APPROVAL)
 - Local Consent sections (Slide 10)
 - Other exceptions: study personnel changes and new/revised recruitment materials

Other Items to Keep in Mind

- The Reviewing IRB may ask you to complete site-specific “local context forms.” Please feel free to reach out to the IRB for assistance in completing these.
 - Please note, however, that these cannot be finalized until the cede review application is at least submitted to the IRB.
 - This is because we need site-specific local information (such as recruitment methods) to complete these

Other Items to Keep in Mind

- i* 4. Is your institution a covered entity under HIPAA for research activities? Yes No
- i* 5. If applicable, provide any institution-specific details regarding HIPAA activities that may be relevant to the Reviewing IRB.
- i* 6. If your institution and/or components are a covered entity, what are the HIPAA authorization/informed consent document requirements?
- i* 7. What is your institution policy on use of short form consents for non-English speaking individuals?
- 8. What is the age of majority in your state?

These are some examples of questions on the local context form



Other Items to Keep in Mind

- Please also be sure to communicate *all* information in the INSPIR application to the Reviewing IRB.
- This information (recruitment methods, whether or not you are approved for short form consent, etc) must be incorporated into your IRB approval from sIRB.
- Cede studies do undergo QA reviews from our local team and study procedures must match what is in INSPIR application

Cede Review in INSPIR

Some Helpful Links:

- Ceding Review: <https://www.bumc.bu.edu/irb/submission-requirements/when-to-submit/ceding-review/>
- October 2019 CR TIMES Feature Article, SMART IRB and You: <https://wwwapp.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=760>
- HRPP Policies and Procedures, Section 2.5 [Multi-Site Research](#):

<https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#2.5>

Cede Review in INSPIR

Thank you!

What questions do you have?