Ceding Review and SMART IRB

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BOSTON MEDICAL CENTER AND BOSTON UNIVERSITY MEDICAL CAMPUS

Ceding Review and SMART IRB

Learning Objectives

- Learn when research studies are most often ceded to an outside IRB
- Discuss the procedures involved in ceding review
- Understand how to complete the INSPIR cede review application

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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 (i.e. if the grant application due date is after 1/25/2018), 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 a site IRB that agrees to be the sIRB for the study

When are studies 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; or
    - Western IRB (WIRB) [if done through SMART IRB]; or
    - Hummingbird IRB (HIRB) [not 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).

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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…

- If through SMART IRB: If the sponsor/main site approves, email the c/sIRB's SMART IRB Point of Contact to confirm they will enter into a SMART IRB agreement for the review. This e-mail must be attached in INSPIR.
- 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 (Industry-Sponsored IND/IDE Study ***ONLY***)

Contact the appropriate grants office and attorney for your submission:

- OSP-MED (Attorney Bill Segarra; Phone: (617) 353-6151; email segarra@bu.edu);
- BMC-CTO (Attorney Cara Martinoli; Phone: (617) 414-5110; email cara.martinoli@bmc.org).

Send your attorney a copy of the sponsor's consent form template, and request that they add compensation for injury language which conforms with the Clinical Trial Agreement.

Cede Review Procedures

STEP THREE

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

- Basic Information (PI, H#, Study Phone #'s)
- If IND/IDE: Your attorney's compensation for injury language (from STEP TWO)
- Costs template language
- 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 FOUR

Obtain documentation of the sponsor/main site approval for the consent edits described in STEP THREE, and attach this documentation to your INSPIR application

Cede Review Procedures

STEP FIVE

Prepare and submit your INSPIR cede review application!

STEP SIX

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 SEVEN

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 EIGHT

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 NINE

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), 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.**

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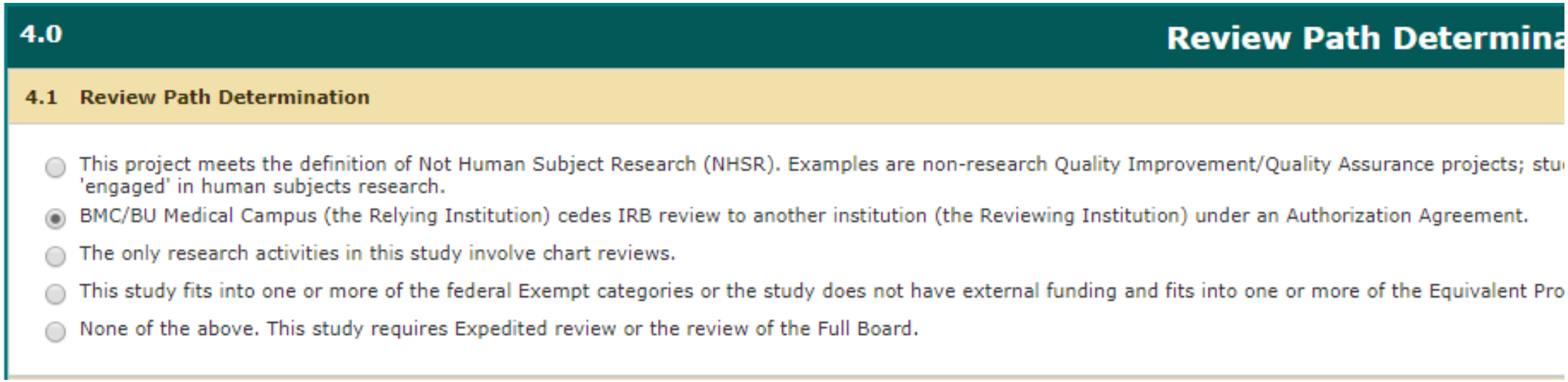
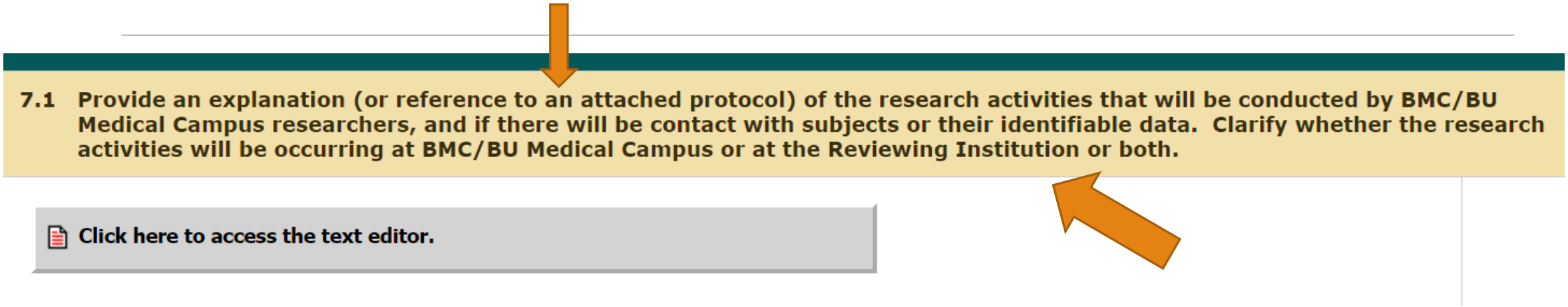
Cede Review in INSPIR



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

Cede Review in INSPIR



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]
- If the study is being ceded to a cIRB other than Hummingbird IRB, the email documenting the commercial IRB's willingness to use SMART IRB
- 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)

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

Other Items to Keep in Mind

- Most often, the Reviewing IRB will act as the HIPAA Privacy Board. Thus, there is no HIPAA section in INSPIR. The Reviewing IRB may ask you to complete their own HIPAA form (if a Waiver of Authorization is needed, for example).

- 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.

Other Items to Keep in Mind

4. Is your institution a covered entity under HIPAA for research activities? ○ Yes ○ No

5. If applicable, provide any institution-specific details regarding HIPAA activities that may be relevant to the Reviewing IRB.

6. If your institution and/or components are a covered entity, what are the HIPAA authorization/informed consent document requirements?

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

Cede Review in INSPIR

Thank you!

What questions do you have?