First Looks
– the new INSPIR Application

CRRO Seminar Series

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Outline

- History of INSPIR versions
- Changes being made
  - Eliminations
  - Modifications
  - Additions
- Process for migration
- Feedback

History of IRB Submission

- Introduction of electronic system
  - Integrated Network for Subject Protection In Research - Launched March 15, 2004
  - Based upon a platform developed at Baylor College of Medicine
  - Went out of business in 2008.
  - Because of lack of ongoing support, replaced March 15, 2011 with INSPIR II

History of IRB Submission (cont.)

- The transition from paper in 2004 was painful
  - Required submission of conversion modification
- To avoid a repeat, the conversion from INSPIR I to INSPIR II was automated
  - Imposed limitations on changes
    - Remnants of INSPIR I remain in current application
    - Overall structure remains the same

History of IRB Submission (cont.)

- The conversion from I to II was not pain-free
- Up to 27 section “saves” required
- Avoided requiring multiple “saves” again by making no more changes to INSPIR II application (until now)
- The vendor (ImedRIS) has reduced the requirement for “saves” in the new platform installed during last Intersession.

Changes in INSPIR

- Elimination of some questions and elimination of duplicates
- Review Path question at earliest point possible
- Common pathway for all cede reviews
- More straight-forward process for external investigators whose participation is our responsibility
- No more HIPAA forms

Elimination

4.0 External non-BU/BMC Investigators

4.1 In this section, only list non-BU/BMC investigators (not a full-time or permanent part-time employee of BMC, BU, BPHC, etc.). Any BU/BMC personnel should be listed in the KSP section (3rd section)

List here all non-BU/BMC persons working on the protocol who will be *engaged in the research on behalf of BU/BMC*. This includes all persons who are conducting research *under an Authorization Agreement (IAA) with BU/BMC IRB*.

Add External Personnel to the study

Delete	Edit	Name	Institution	Telephone	E-mail	Role
No External Personnel has been added to this Study						

4.2 Does this study involve participation of non-BUMC investigators who are determined to be "not-engaged" in the research?

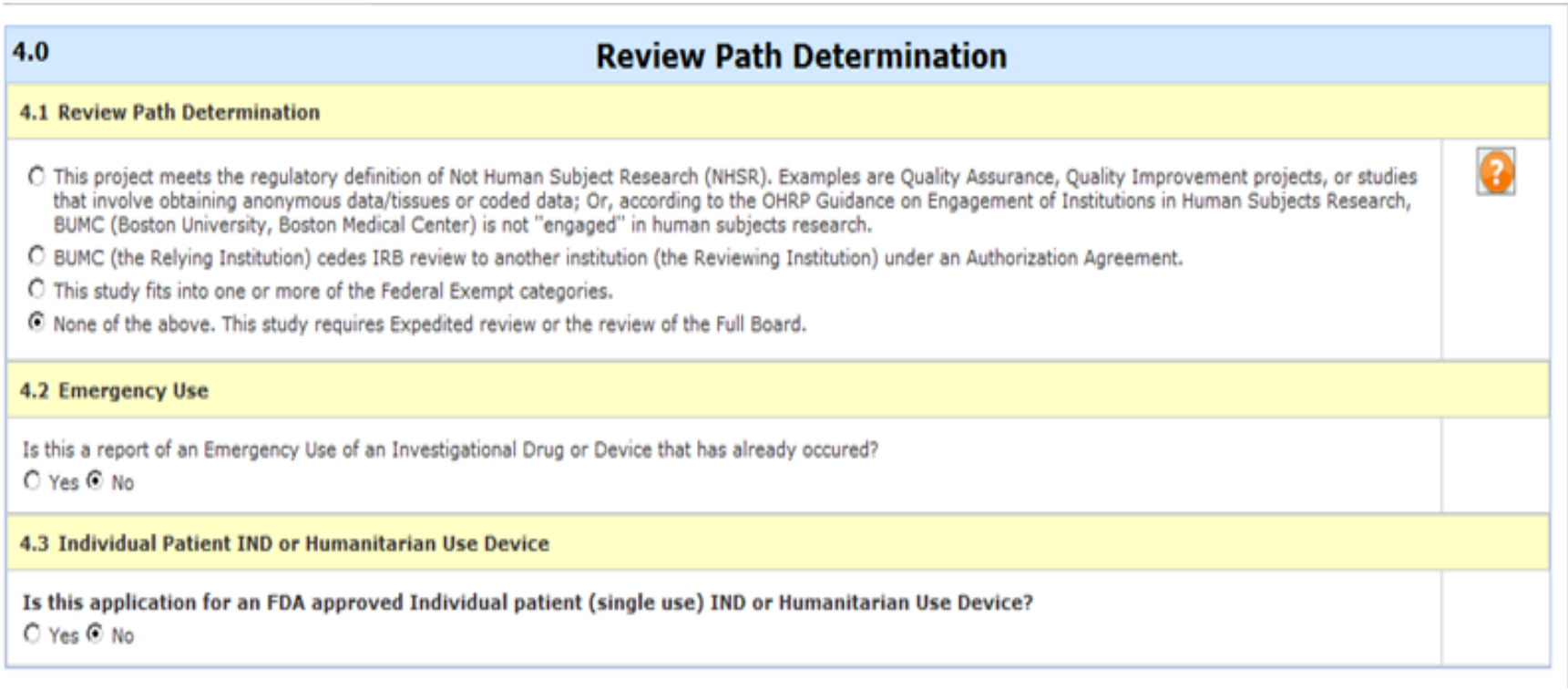
Yes No

If you answered Yes above, indicate in the text box below; the names of the non-BUMC investigators, all study activities they will be performing, the names of their institutions, and why they are determined to be NOT-Engaged in the research (based on the OHRP engagement guidance).

Click here to access the text editor.

4.3 Study Attachments

Earlier Review path



4.0 Review Path Determination

4.1 Review Path Determination

- ○ This project meets the regulatory definition of Not Human Subject Research (NHSR). Examples are Quality Assurance, Quality Improvement projects, or studies that involve obtaining anonymous data/tissues or coded data; Or, according to the OHRP Guidance on Engagement of Institutions in Human Subjects Research, BUMC (Boston University, Boston Medical Center) is not "engaged" in human subjects research.
- ○ BUMC (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.
- ○ This study fits into one or more of the Federal Exempt categories.
- ◉ None of the above. This study requires Expedited review or the review of the Full Board.

4.2 Emergency Use

Is this a report of an Emergency Use of an Investigational Drug or Device that has already occured?

○ Yes ◉ No

4.3 Individual Patient IND or Humanitarian Use Device

Is this application for an FDA approved Individual patient (single use) IND or Humanitarian Use Device?

○ Yes ◉ No

Cede Review

6.0 BUMC to Cede Review

The INSPIR cede review application is a shortened version with questions relevant to the cede review process. An Authorization Agreement is required whereby the BUMC IRB as the Relying Institution, agrees to cede review to another IRB representing the Reviewing Institution as the IRB of record. The INSPIR cede review approval letter will name the Reviewing Institution as the IRB of record for the cede review application.

6.1 Is the Reviewing Institution's protocol approved as Expedited or Full Board?

- ○ NO - If NO, then do not continue with this cede review application. Contact the BUMC IRB at medirb@bu.edu or at Phone 617-638-7207 for further assistance.
- ◉ YES - Continue with Question 6.2.

6.2 Will all BUMC investigators in Section 3.0 be engaged in research by having access to research subjects or their identifiable data under the Reviewing Institution's protocol?

- ○ NO: If NO, then do not continue with this cede review application. Contact the BUMC IRB at medirb@bu.edu or at Phone 617-638-7207 for further assistance.
- ◉ YES: Select only one option from the following three options described below:

Cede Review – Option 1

6.3 OPTION 1: INDEPENDENT INSTITUTIONAL REVIEW BOARD

BUMC has pre-signed an Authorization Agreement to delegate its review of selected research studies to an Independent Institutional Review Board. In this capacity, the Independent IRB functions as an internal Full Board review panel of the BUMC IRB and follows BUMC policies and procedures. INSPIR cede applications will be administratively pre-reviewed by BUMC to ensure that the research study meets the criteria set forth in the Authorization Agreement and BUMC institutional requirements.

The Principal Investigator will then submit amendments, renewals, protocol deviations, and adverse events directly to the Independent IRB according to its submission processes and forms. However, the Principal Investigator will continue to be responsible to the BUMC IRB for the following:

1. **Submitting INSPIR internal study personnel changes for research staff updates; and ensuring that all research staff meet BUMC requirements for human subjects certification and recertification, and compliance with BUMC Conflict of Interest policies.**
2. **Submitting Unanticipated Problems in INSPIR that are internal, serious, unexpected, and related or possibly related to the BUMC IRB as well as to the IRB of record.**

Will BUMC cede review to an Independent Institutional Review Board?

- ○ NO
- ○ YES: Select from the list below.

null: --none--

(Click on the (?) Help icon to learn more about each Independent IRB listed above and what are the requirements).

For any independent institutional review boards not listed above, send an inquiry to medirb@bu.edu before proceeding with this cede review application.

Cede Review – Option 2

6.4 OPTION 2: CENTRAL INSTITUTIONAL REVIEW BOARD

BUMC has pre-signed an Authorization Agreement to become a participating site for research protocols conducted by a special multi-center research collaboration group (for example, to study a specific category of disease). BUMC agrees to accept review by the collaboration group's designated Central Institutional Review Board. INSPIR cede review applications will be administratively pre-reviewed by BUMC to ensure that the research study meets the criteria set forth in the Authorization Agreement and BUMC institutional requirements.
The Principal Investigator will then submit amendments, renewals, protocol deviations, and adverse events directly to the Central IRB according to its submission processes and forms. However, the Principal Investigator will continue to be responsible to the BUMC IRB for the following:

1. **Submitting INSPIR internal study personnel for research staff updates; and ensuring that all research staff meet BUMC requirements for human subjects certification and recertification, and compliance with BUMC Conflict of Interest policies.**
2. **Submitting Unanticipated Problems that are internal, serious, unexpected, and related or possibly related to the BUMC IRB in INSPIR as well as to the IRB of record.**

Will BUMC cede review to a Central Institutional Review Board?

- ○ NO
- ◉ YES: Select from the list below.

null: National Cancer Institute Central Institutional Review Board (NCI CIRB) for oncology studies

For any Central Institutional Review Boards not listed above, send an inquiry to medirb@bu.edu before proceeding further with this cede review application.

Cede Review – Option 3

Will BUMC cede review to the IRB of a Reviewing Institution?

- ○ NO
- ◉ YES: This will require a protocol-specific Authorization Agreement. Complete the next section.

AUTHORIZATION AGREEMENT (PROTOCOL-SPECIFIC)
Contact the Reviewing Institution's IRB to obtain accurate information for the following fields which are required for t Authorization Agreement. The BUMC IRB will then create the Authorization Agreement and send it to the IRB Contact Reviewing Institution for signature.

- **If the BU Charles River Campus is the Reviewing Institution, then complete only the fields with an asterisk *. T IRB and the BU Charles River Campus IRB will document cede review approvals by emails rather than by forma Authorization Agreements.**

Select Institution from this list. To add a new Institution, send a request to medirb@bu.edu.

IAA List:	Brandeis University

Reviewing Institution Federalwide Assurance Number:

FWAxxxxxxx

Reviewing Institution Protocol Title:

xxxxxxx

Reviewing Institution Protocol Number:

xxxxxxx

Reviewing Institution Principal Investigator Last Name:

xxxxxxx

Reviewing Institution Principal Investigator First Name:

xxxxxxxx

Reviewing Institution IRB Contact Name:

xxxxxxxx

Reviewing Institution IRB Contact Phone Number:

xxxxxxxx

Reviewing Institution IRB Email Address:

xxxxxxxxx

External Investigators

10.0 IRB Authorization Agreement - BUMC is the Reviewing Institution

10.1 Identify the category which best describes the External Investigators. The BUMC IRB will be their IRB of Record (the Reviewing Institution) through an appropriate Authorization Agreement.

☐ A. External Investigators from a Relying Institution

If you checked the check box above, please list the relying institution's information in the table below:

Institution Information	Contact for IRB Authorization Agreement
Institution Name: IAA List: BIDMC Does this institution have an FWA: ◉ Yes ○ No FWA Number (if any):	Contact Name: Contact Phone: Contact Email:

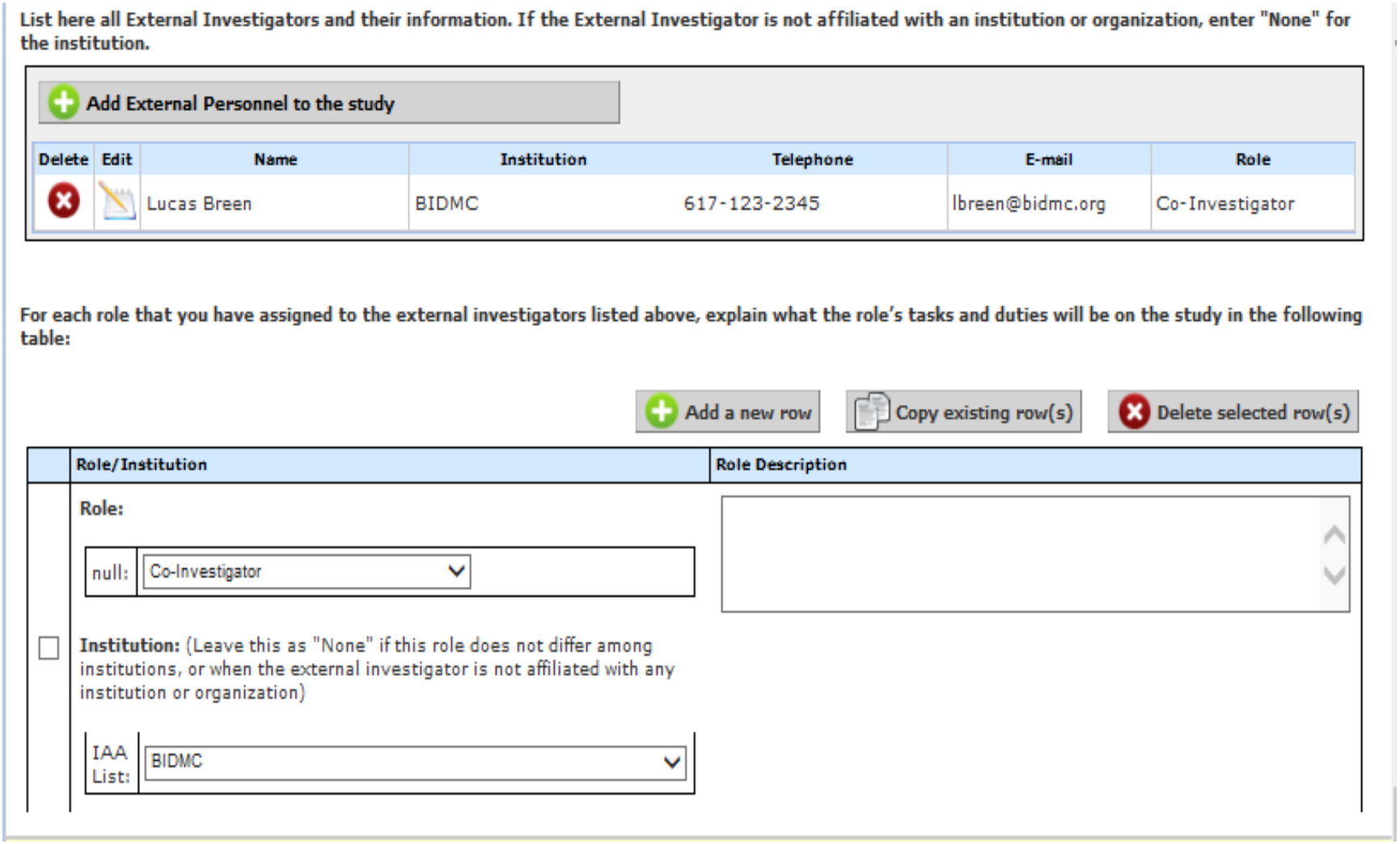
Note: **List the External Investigators in Section 10.2 - Table of External Investigators.**

☐ B. External Investigators who are independent and not affiliated with any institution or organization.

Note:

- If the BUMC IRB agrees to accept review for the Independent External Investigator(s), then the Principal Investigator will be provided with an Individual Investigator Agreement (IIA) template. The Principal Investigator will be responsible for customizing an IIA to forward to each independent External Investigator for completion; and then forwarding the signed IIAs to IRB Coordinator Roz Schomer at roz@bu.edu. for processing.
- In Section 10.2 - Table of External Investigators, list this External Investigator's information and enter "None" for the Institution.

External Investigators (cont.)



List here all External Investigators and their information. If the External Investigator is not affiliated with an institution or organization, enter "None" for the institution.

Add External Personnel to the study

Delete	Edit	Name	Institution	Telephone	E-mail	Role
		Lucas Breen	BIDMC	617-123-2345	lbreen@bidmc.org	Co-Investigator

For each role that you have assigned to the external investigators listed above, explain what the role's tasks and duties will be on the study in the following table:

Add a new row | Copy existing row(s) | Delete selected row(s)

	Role/Institution	Role Description
	Role: null: Co-Investigator	
☐	**Institution:** (Leave this as "None" if this role does not differ among institutions, or when the external investigator is not affiliated with any institution or organization) IAA List: BIDMC	

No more HIPAA forms

1.0 HIPAA Compliance

1.1 Do you need access to protected health information (PHI) without signed authorization from the individual whose information you need?

- (•) Yes (Please answer the rest of the questions in this section)
- ( ) No (Please skip the rest of the questions in this section)

1.2 Do you only need PHI (without authorization) to identify subjects for recruitment?

- ( ) Yes
- ( ) No

1.3 Please indicate your selection criteria for the records: (e.g. all Type 2 diabetics prescribed metformin, all men aged 50-75 with diagnosis of BPH)

Click here to access the text editor.

1.4 Indicate what date range is needed for the records: (e.g. 11/14/98-12/1/13)

Click here to access the text editor.

1.5 Please list all data fields that are needed from the medical record or attach below the file containing the data elements:

Click here to access the text editor.

Select or Revise Existing | Add a New Document | Add Multiple Documents

Detach	Version	Title	Category	Expiration Date	Review Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

No more HIPAA forms (cont.)

1.6 Will you be using the Clinical Data Warehouse (CDW) or will study staff be accessing the records?

- ○ CDW
- ○ Study staff will access records
- ○ Both

1.7 Does your research require access to any of the HIPAA identifiers?

- ○ Yes
- ○ No (skip to the attestation at the end of this section)

If Yes, what identifiers will you be collecting?

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1.8 Please describe why the research cannot be conducted without access to protected health information:

Click here to access the text editor.

1.9 Why is it not practical to obtain authorization from the participants?

Click here to access the text editor.

1.10 What is your plan to protect any identifiable information from use and disclosure by unauthorized parties?

Click here to access the text editor.

1.11 When and how will you destroy any identifiers linked to the data?

(Please note: identifiers should be destroyed at the earliest opportunity as consistent with the design of the research study)

Click here to access the text editor.

1.12 Please affirm the items below:

- ☐ I agree that the protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Regulation (45 CFR 164.512)
- ☐ I declare that the requested information constitutes the minimum necessary data to accomplish the goals of the research.

Other Changes

- New Process for use of short form consent
- Changes to continuing review
  - Keep track of approved enrollment
  - Keep track of number of enrolled at last CR
  - Elimination of demographic table (still required in final report)
  - If using short form, number of usages by language

Additions

- Determine if study meets the NIH definition of clinical trial
- Need to capture which trials are required to be registered on clinicaltrials.gov by BU/BMC
  - Final IRB approval will not be issued until registered
- Added question if additional radiation (not standard of care) is used

Migration

- Will occur when you need to modify an existing protocol
  - Will NOT be necessary for continuing review

- Almost, but not entirely, painless.

Feedback

- We will be asking for volunteers to test and provide feedback prior to launch
  - Need both experienced and inexperienced users
- We also need on-going feedback
  - Let us know what parts you find confusing so that we can provide help text that actually helps.

THANK YOU