INSPIR: Don't EXpire, Get **INSPIRed**

CRRO Seminar: Wednesday, September 17, 2025

Lin Themelis, MA, CIP – IRB Administrator
Mark Testerman, MBA, CIP – Senior IRB Analyst II

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Important for how you approach today's seminar:

This is an ***ongoing conversation*** that the IRB wants to have with you, and we will do it ***AGAIN*** if you have an appetite for more INSPIR submission insights!

- You will have an opportunity to ask questions at the end of the presentation, and in the middle of it if something comes to mind!

- Send questions to Lin Themelis (lint@bu.edu) and/or Mark Testerman (marktes@bu.edu) for ***NEXT TIME*****!**

Yes, you *CAN* have a copy of these slides.

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TAKEAWAYS

MY TAKEAWAYS

Image: https://www.franchisewire.com/hamburglar-returns-touting-tweaks-to-mcdonalds-burgers/

1. Check INSPIR instructions online - Contact INSPIR Application Administrator when stumped
2. Finalize your routing list
3. Click "Save and Continue"
4. Know whose side has the submission
5. Know who to go to for INSPIR help

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TAKEAWAY 1: READ THE INSTRUCTIONS

WHY?

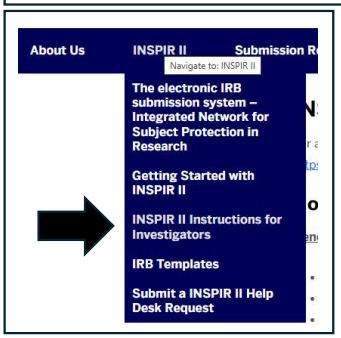
IRB Analysts do not see what you see in their version of INSPIR.

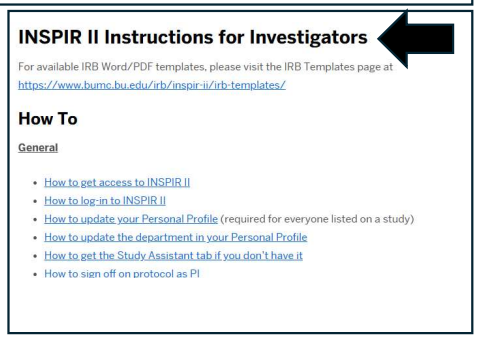
If you ask them, *how do I do XYZ in INSPIR?* they are likely to direct you here:

https://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/

HOW?

- Go to https://www.bumc.bu.edu/irb/
Hover over *INSPIR II* in the ribbon and select *INSPIR II Instructions for Investigators* from the dropdown.
Select the instructions appropriate to your question. It is a long list!
- If all else fails…then contact your analyst or *Khaled Khattar, INSPIR Application Administrator (kkhattar@bu.edu)*





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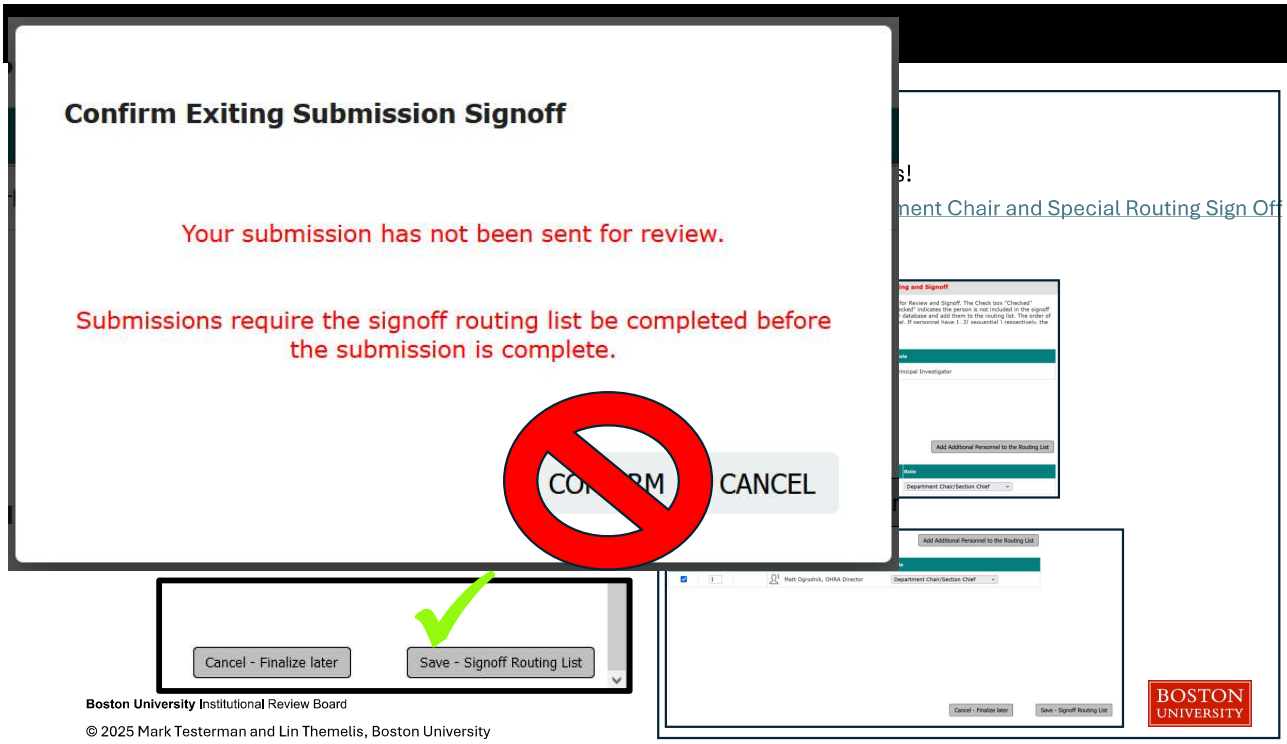

TAKEAWAY 3: CLICK SAVE AND CONTINUE

WHY?

If you do not, the section you just worked on will not save, and the application form will not attach correctly for IRB review.

HOW?

There is a button to save only the section, but that will not guarantee you have saved all sections.

Clicking ***Save and Continue to Next Section*** through to the end is the way to make sure your application form is submitted the way you want it.

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TAKEAWAY 4: WHOSE SIDE IS IT ON?

When you click "Submit" or the IRB clicks "Complete" the study goes to the other party.

ON YOUR SIDE:

We do not have the same "view" of INSPIR that you do.

We may not know what you are looking at or how it functions.

Certain functions are not available to us when a study is not on our "side."

ON THE IRB'S SIDE:

You cannot attach documents to your submission when it is on the IRB's side.

You cannot edit your application.

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TAKEAWAY 5: KNOW WHO TO GO TO FOR INSPIR HELP

Whom do I ask?

Do you have questions about the content of your submission?

Do you want to know how to respond to IRB stipulations?

Did you just return a submission but forgot something?

YES?

Contact your Analyst

Do you have questions about how to ***USE*** INSPIR?

For example, attaching documents, making revisions, trouble with getting a submission out of your side and to the IRB's?

YES?

Contact Khaled Khattar, INSPIR Application Administrator: kkhattar@bu.edu

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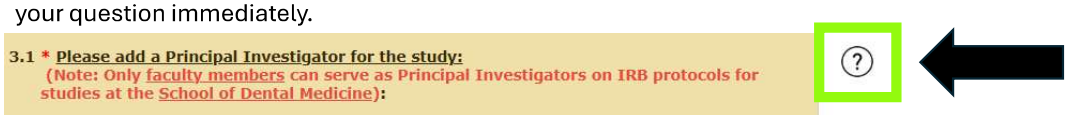
INITIAL SUBMISSIONS - General

The little things you always wanted to know…

1) PIs cannot be listed as Department Chair on their own studies and cannot sign off as Department Chair.

2) Pay attention to the "**?" icons** In the INSPIR application form – they may answer your question immediately.



3) Enter the correct funding information – do some digging if necessary. This may determine the review pathway, whether or not BU or BMC is engaged, and whether your study has BU or BMC as a home institution. These are all levers which can alter the regulations you need to follow.

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INITIAL SUBMISSIONS - Exempt

Figure out whether your study meets the requirements for EXEMPT review:

The HRPP policies provide guidance. If you submit a study as exempt instead of expedited, and vice versa, you add extra rounds of stipulations and a longer review time to your study's lifecycle

Certain types of human research studies can be designated as exempt if all of the study activities fit into one or more specific categories and the study is minimal risk.

Prisoners: Research on prisoners (incarcerated subjects) qualifies for Exempt categories (4.1), (4.2), (9), (10), and (11), but only if the research is aimed at involving a broader subject population and only incidentally includes prisoners.

Drugs/Devices: Research on drugs/devices does NOT qualify for any exempt category.

Substance Use Disorder Programs: Research with external funding and research involving interaction with or data from subjects identified as patients at a BMC federally-assisted substance use disorder clinic(s) [see the (?) Help icon for the list of such clinics) does NOT qualify for categories (9), (10), (11), (12), or (13).

Retention of Data and Samples for Extra Use: Research involving the retention of biological samples or data for extra use by the study investigator(s) or by other investigators qualifies for categories (9), (10), (12), and (13). Extra use means any analysis that is in addition to that required for the study endpoints. Research with the sole purpose of establishing a repository does NOT qualify for any exempt category.

For more information, click **here**.

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Special Populations – These subject categories involve additional signoffs/paperwork/attestations

- ☐ Individuals whose HIV testing status is provided to the study team prior to consent being obtained (e.g., for recruitment)
- ☐ Individuals identified 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)

- ☐ BMC Residents or Fellows
- ☐ BU Medical Students and/or Graduate Medical Sciences Students
- ☐ BU Dental Students
- ☐ BU School of Public Health Students

NOTE: These are legal, institutional or regulatory requirements.
The IRB cannot waive or alter them, and satisfying them are the responsibility of the PI.

Section 6.4 Prospective Recruitment and Consent of Eligible Subjects
If you will be interacting with subjects you need a consent statement even if your research is exempt. This is where you will find instructions on how to do that:

Describe plans for screening and recruiting potential subjects. Describe how you will obtain abbreviated consent (see Exempt Information Sheet Template) from subjects prior to participation. (Note that if your consent process includes obtaining an authorization for use of Protected Health Information, you must use the Use and Disclosure of Your Health Information language in the template. If the research is in Exempt category 3.1 or 3.2 and involves deceiving the subjects regarding the nature or purposes of the research, the abbreviated consent must include informing subjects that they will be unaware of or misled regarding the nature or purposes of the research.)

If other sites are engaged – they will need to obtain IRB approval. For exempt studies the default is to obtain it from their own institution

- (•) Single site research - conducted by BMC/BU Medical Campus investigator(s)
- ( ) Multi-site research project - BMC/BU Medical Campus is a research site but is NOT the main study site
- ( ) Multi-site research - BMC/BU Medical Campus is the main research site and/or the BMC/BU Medical Campus Principal Investigator is the overall PI of the entire study or the FDA sponsor

Does this study have or require an Authorization Agreement for External (non-BMC/BU Medical Campus) investigators who will rely on BMC/BU Medical Campus IRB review? ***

( ) Yes (•) No

Navigation Menu: Separate Protocol

8.1 Separate Protocol

Is this a submission with a separate protocol? This protocol must be from the sponsor or cooperative group or be based on the **protocol template** found on the IRB website, and must include the purpose, inclusion/exclusion criteria, design/procedure, and data safety and monitoring plan. A separate protocol is REQUIRED for all initial submissions of medical or surgical clinical trials, multi-site clinical trials of any type, and NIH-funded clinical trials of any type. Depending on the complexity of the study, the IRB Director or Chair may require a separate protocol for other types of initial submissions. Please contact **medirb@bu.edu** if you have questions about whether a separate protocol is needed. A GRANT APPLICATION IS NOT A PROTOCOL.

(•) Yes
( ) No

See here for our protocol template:
https://www.bumc.bu.edu/irb/inspir-ii/irb-templates/

Protocol Template

Is it a medical or surgical CT?

Is it a multisite clinical trial?

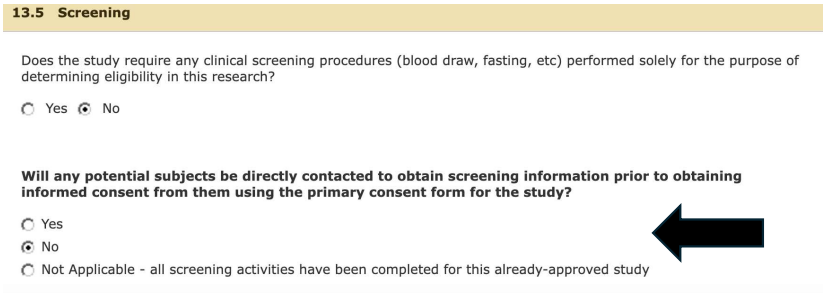
Is it a NIH funded clinical trial?

NO
?

NO PROTOCOL!

INITIAL SUBMISSIONS - Expedited

Screening in Person



Are you confirming eligibility in person?

Are you confirming eligibility BEFORE full consent?

Are you confirming eligibility with subjects who reach out to you?

YES

Check "Yes" to the second question and complete the next section

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AMENDMENTS

1) **Amendment Descriptions** ***are*** ***Not Optional***. They tell us what to look for in your materials. Your description also maps to your approval letter and will show the changes for which you have been approved.

2) Not stating the reasons for your amendment request in the amendment description adds a round of stipulations to your submission. This "Why" should encompass both what you plan to do and the underlying reason you are doing it. For example, do not say, "We need to draw an extra tube of blood." Rather, you should say, "We need to draw an extra tube of blood because we would like to run an additional assay for these reasons… It is relevant to our study because…"

3) When revising an existing document, attach a ***revision*** of an existing document. ***DO NOT*** start a new document thread. (More about this later…)

How to revise an existing Study Document

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AMENDMENTS

Amendment Description:

Please summarize the proposed changes for this amendment below. Make sure to explain:

- Describe why each change proposed is necessary (scientific or operational rationale); and
- Identify the materials (INSPIR application, data collection forms, etc.) that are affected by the changes and describe the changes made (e.g., "application Section 16.2 Confidentiality was updated...." or "Focus Group Guide Version 1.0 was modified...."); and
- If the study has an exempt information sheet(s), outline the revisions made to the exempt information sheet(s) to reflect the changes, or explain why revisions to the information sheet(s) are not needed.

WHY
We are revising our recruitment strategy as recruitment has been slow

WHAT
We have described the use of recruitment flyers in Section 6.4 and attach a flyer with study details. We also attach the BU Comms approval stamp

CONTENT
No changes to the consent form/consent statement were needed

...This applies to Consent Forms and Parental Permission Forms as well...

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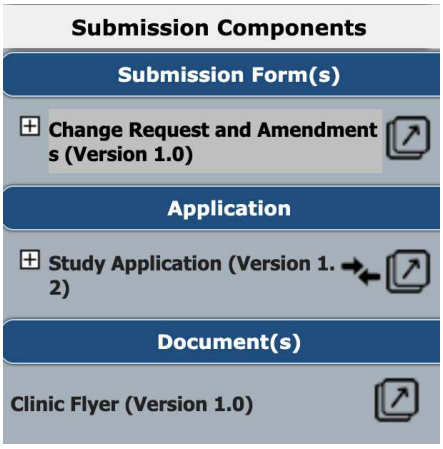
AMENDMENTS

What should my amendment look like?



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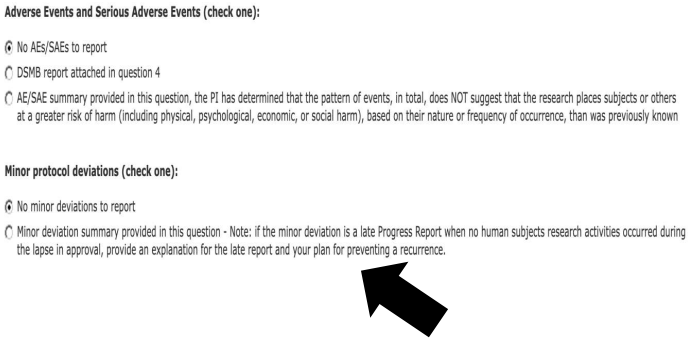
CONTINUING REVIEW

KEEP TRACK OF YOUR AEs/SAEs AND DEVIATIONS

The continuing review/status check-in template will ask you if you have any – if you are not sure, contact the analyst.

Do not immediately default to "No". Please evaluate what has transpired over the previous approval period. Missing these items can lead to non-compliance.



Adverse Events and Serious Adverse Events (check one):

- (•) No AEs/SAEs to report
- ( ) DSMB report attached in question 4
- ( ) AE/SAE summary provided in this question, the PI has determined that the pattern of events, in total, does NOT suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm), based on their nature or frequency of occurrence, than was previously known

Minor protocol deviations (check one):

- (•) No minor deviations to report
- ( ) Minor deviation summary provided in this question - Note: if the minor deviation is a late Progress Report when no human subjects research activities occurred during the lapse in approval, provide an explanation for the late report and your plan for preventing a recurrence.

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CONTINUING REVIEW – Full Board

A small request at continuing review time from a Full Board Panel Analyst:

Know Your Enrollment:

The Board approves a specific number of subjects for a reason: It believes that number has a satisfactory risk-benefit ratio within the context of the study.

If, at continuing review, you provide incorrect enrollment numbers, or are unsure about your enrollment numbers, you are inviting both questions from the Board and potential non-compliance. Both things cost time and may have serious consequences.

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GENERAL - Attaching and Revising Documents

- **UPLOAD DOCUMENTS IN .DOCX (WORD) FORMAT** for all your documents. Other formats (PPT, PNG, PDF) can be difficult for the IRB to stamp and evaluate side by side
- Add revised documents as revisions of previously approved or uploaded documents NOT new documents
- Use the same document file format for all your revisions. I.E., do not submit a revised document as a PDF when the original document was submitted as a Word Document

Please Note: Neglecting document control can lead to serious compliance issues. It is the team's responsibility to know which are the approved versions of documents and to use the correct versions.

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Contact Information:

IRB Director:
Jamie Merrill: jcm57@bu.edu

INSPIR Questions:
Khaled Khattar: kkhattar@bu.edu

Reliance (IAA/IIA) Agreements:
Roz Schomer: roz@bu.edu

Study Planning, Study Team Education/Training:
Clinical Research Resource Office: crro@bu.edu

https://www.bumc.bu.edu/crro/meet-the-team/contact-us/

Study Specific Questions:
Contact the analyst assigned to your study or medirb@bu.edu

Your humble presenters who also review your studies:
Lin Themelis: lint@bu.edu
Mark Testerman: marktes@bu.edu

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Q&A

This is an ***ongoing conversation*** that the IRB wants to have with you, and we will do it ***AGAIN*** if you have an appetite for more INSPIR submission insights!

- Send questions to Lin Themelis (lint@bu.edu) and/or Mark Testerman (marktes@bu.edu) for ***NEXT TIME***!

Boston University Institutional Review Board
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Thank you for joining us today!

The IRB is privileged to work with such a fantastic group of researchers.

Stay in touch,

Lin Themelis and Mark Testerman
lint@bu.edu; marktes@bu.edu