How to Sign Off on a Study Submission as the PI

- Principal Investigators
- Department Chairs
- "Special Routing"
  - IDS Pharmacy
  - Radiology
  - Nursing
- Other authorizations
  - Co-investigators
  - Other departments involved in the research

Type "https://inspir.bu.edu" in the web browser's address bar and click "Enter"; or click on this link: https://inspir.bu.edu. **This will bring you to this INSPIR II log-in page**

Log In

BOSTON UNIVERSITY — BOSTON MEDICAL CENTER. *EXCEPTIONAL CARE. WITHOUT EXCEPTION.*

INSPIR II
Integrated Network for Subject Protection In Research

Username (not email):

Password:

Log In

- You can Login using your BU username (e.g. "jdoe" if your BU email is "jdoe@bu.edu") along with your BU Kerberos password

OR

- You can Login using your BMC username (first 2 letters of your first name followed by the first 5 or 6 letters of your last name, same one you use in EPIC) along with your BMC password.

Type in your username and password and then click on "Log In".

1

2

3

System/Browser Requirements

INSPIR II Home   INSPIR II Manual   IRB Review Times   User Satisfaction

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Version 11.02 Build 140 Updated 2019/08/15 11:39

It is a violation of Institutional policy to log in using someone else's username and password or to give your username and password to someone else

Search...

Hello Khaled Khattar, BA
your last login was
03/22/2023 10:40 AM EDT

Announcements 1   ? Help   Tutorial   My Profile ▼   Log out

My Workspaces ▾   Study Assistant

Featured Study Operations

Create a New Study

Start a Submission Form for one of My Studies

View the Current Approvals for one of My Studies

View the Submission History for one of My Studies

View and Manage My Studies

By the Numbers

Submissions in Process	Forms Pending Submission	Pending My Response	High
54	53	3	

Tasks

All Tasks	34
Study Tasks	32

Under **Study Assistant** tab,
Click on **"Study Tasks"**

The system will scroll your Home page down to the "Study Tasks" section.

You can use the "Search" box to locate the study or draft. Or you can just scroll down.

Once you locate the "Submission Routing Signoff" task for the study you want to sign off, click on the "Open" icon

PI clicks links below
to open and read all the documents related to this study submission
BEFORE signing off on this submission.

d Khattar, BA
MC/BUMC - *MED* - Institutional Review Board

Announcements   ? Help   My Profile ▾   Log out

Submission Routing Signoff

Back

Save Signoff

Study Title: Copy of Demo Protocol for Instructions
Submission Reference Number: 1162096

Create PDF Packet

Include in PDF Packet	Compare to Last Approved	View in Separate Window	omponent Name
☑			

Submission Form(s)

		↗	Initial Review Submission Form
Submission Form(s):	☐		

Application

	☐	↗	Study Application

Document(s)

Category : Reducing Implicit and Explicit Bias in Research Form

☐		↗	Reduction-of-Explicit-and-Implicit-Bias-in-Research-Form

Attestation Statement

By selecting "Approve" and providing my electronic signature on this cer

- **All information in this application is correct, including confirmatio**
- **I will comply with the following PI responsibilities:**

PI reads the Attestation Statement before signing off.

1. Understand what research activities are overseen by the HRPP and consult with HRPP staff if in doubt abo   ission to the IRB is required; and
2. Personally log into the electronic system using their individual username and password as an electronic sign
3. Provide information to the HRPP that is complete and accurate to the best of their knowledge; and
4. Design studies to protect individuals conducting the study, to adhere to ethical principles and standards appropriate to their discipline, to safeguard the rights and welfare o
   population selected to distribute the risks and benefits fairly, to employ additional safeguards necessary to protect vulnerable populations, to safeguard research data,
5. Determine that adequate resources will be available to carry out the study, including facilities, access to an appropriate population, medical and psychological resou
6. Ensure that prior to beginning work on the study, the Principal Investigator and all members of the research team meet all applicable Boston Medical Center and B
   credentials, and licenses; and are trained on and appropriately delegated responsibility for study procedures; and
7. Not initiate any human subjects research activities until an IRB final outcome letter has been received and all required institutional approvals have been obtaine
8. Be responsible for execution and management of the study, including oversight of all study personnel and any sub-awardees/subcontractors under their directi
9. Comply with all applicable terms, conditions, assurances and certifications referenced in the application, award (grant or contract), and protocol; and with all ap
   to IRB requirements, patient confidentiality, HIPAA, debarment, finances and record retention) related to this study; and
10. Follow the IRB-approved research plan by recruiting subjects in a fair and equitable manner; by adhering to the approved inclusion and exclusion criteria and m
    documenting informed consent; by meeting all applicable HIPAA and other data security requirements; by maintaining the privacy of subjects and protecting th
    members who request information or have concerns or complaints; and by providing aggregate and/or individual study results to subjects if promised; and
11. Maintain all required records and cooperate with any request for auditing by the HRPP, sponsor, or government agency; and
12. Comply with all requirements for identifying and reporting Unanticipated Problems, Adverse Events, deviations, and safety monitors' reports, and any other ne
13. Ensure that IRB approval is obtained prior to making any change to the approved study plan, consent form, or study personnel unless the change is im
    that a status check-in is provided before the due date for studies without expiration dates; and that a Final Report is submitted to close the study at th

To sign off on the submission is a
2 steps process for **the PI:**

Khaled Khattar, BA as Principal Investigator   ○ Approve ○ Deny
Do you Approve or Deny this submission?

1

Save Signoff

2

1. PI clicks **Approve** or **Deny**
2. Then clicks "Save Signoff" – this will
Submit this submission.