

# How to Sign Off on a Protocol

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



This is your homepage.  
It is the first screen you see when you log in.

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

Account: Khaled Khattar, BA  
Department: BMC/BUMC - MED - Institutional Review Board

Home Logout Help

My Assistant  
Study Assistant

**Study Assistant**

Add a New Study My Studies Submit a Form My Current Approvals Upcoming Renewals My Appointments

**Below are your incomplete Study tasks:**

Waiting Submission	10
Submission Routing Signoff	1

**Below are your incomplete IRB tasks:**

Continuing Review Due	12
Submission Response	2

**Click on the folder icon to view tasks**

In the middle of the screen you can see all your "Incomplete Tasks" tucked away in folders including sign-off tasks in "Submission Routing Signoff" folder

The “Submission Routing Signoff” folder will extend to reveal all incomplete signoff tasks that are still waiting.

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Account: **Khaled Khattar, BA**  
Department: **BMC/BUMC - MED - Institutional Review Board**

Home Logout Help

Welcome Khaled Khattar, BA ( Last Login: 04/13/2017 10:34 AM EDT )

**My Assistant**  
**Study Assistant**


**Study Assistant**

Add a New Study My Studies Submit a

**Below are your incomplete Study tasks:**

- Waiting Submission
- Submission Routing Signoff

1 task(s) found...

Open	Principal Investigator	IRB Number	Study Alias	Study Status	Ref Number	Submission Form Name	Expiration	Received
	Khaled Khattar, BA	H-35016	Demo	<b>Draft</b>	832436	Initial Review Submission Form		2017-04-13 10:57:21.0

**Below are your incomplete IRB tasks:**

- Continuing Review Due **12**
- Submission Response **2**

Click on the Open icon

Here is where Principal Investigators will find details about studies awaiting sign-off

PI must sign off on submissions before they go to the IRB

Submission Routing Signoff

Study Title: [ ]  
Number: [ ]  
Submission Form(s): [ ]

PI sign-off page

PI clicks links below to open and read all the documents related to the protocol BEFORE signing off on the protocol waiting.

Include in PDF Packet	Submission Component Name
<input type="checkbox"/>	Submission Form(s)
<input type="checkbox"/>	Initial Review Submission Form
<b>Application</b>	
<input type="checkbox"/>	Study Application

Back Save Signoff Create PDF Packet

Attestation Statement

PI reads the Attestation Statement before signing off.

By selecting "Approve" and providing my electronic signature, I attest that I:

1. Understand what research activities are overseen by the HRPP and consult with HRPP staff if in doubt about whether submission to the IRB is required; and
2. Personally log into the electronic system using his or her individual username and password as an electronic signature; and
3. Provide information to the HRPP that is complete and accurate to the best of his or her knowledge; and
4. Design studies to protect individuals conducting the study to adhere to ethical principles and standards appropriate to his or her discipline, to safeguard the rights and welfare of all human subjects, to minimize risks, to have adequate provisions to monitor the data for safety, to draw subjects from a population selected to distribute the risks and benefits fairly, to employ additional safeguards necessary to protect vulnerable populations, to safeguard research data, and to meet all applicable HIPAA requirements; and
5. Determine that adequate resources will be available to carry out the study, including facilities, access to an appropriate population, medical and psychological resources for subjects, and sufficient time from himself or herself and staff to conduct the research; and
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 Boston University requirements for the disclosure and management of conflicts of interest; have all required training, qualifications, 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 is received; and
8. Be responsible for execution and management of the study, including oversight and monitoring; and
9. Comply with all applicable terms, conditions, assurances and certifications (federal, and local laws, rules, regulations, policies, and guidelines, as well as 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 employing the approved process for obtaining and documenting informed consent; by maintaining the privacy of subjects and protecting the confidentiality of subjects; and by providing information to subjects, family members, and other interested parties as requested; and
11. Maintain all required records and cooperate with any request for auditing by the HRPP; and
12. Comply with all requirements for identifying and reporting Unanticipated Problems that might impact a subject's safety or willingness to continue in the study; and
13. Ensure that IRB approval is obtained prior to making any change to the approved protocol; that IRB approval for continuation is obtained prior to the start of the study; and

To sign off on the protocol is a 3 step process for the PI:

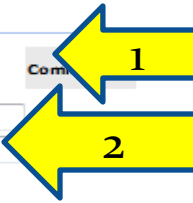
1. PI clicks **Approve** or **Deny**
2. PI enters his/her BU user-name and Kerberos password to authenticate
3. Then clicks "Save Signoff" - this will Submit the protocol

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

Approve  Deny

This form requires your electronic signature.  
Please enter your User ID & Password:

User ID: [ ]  
Password: [ ]



Save Signoff