

INSPIR II Introductory Training

Navigating the BMC/BU Medical Campus IRB Electronic System

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INSPIR II

- **INSPIR II Help Resources**

- On the IRB Website
- In the INSPIR System and Forms

- **INSPIR II Access**

- Get Access to INSPIR
- Login into INSPIR
- Update your INSPIR Profile

- **How to perform some basic INSPIR II functions**

- Create a new IRB Application Draft
- Create and attach consent forms and study documents
- Complete signoff list and submit to the IRB
- Check status and Submissions History
- Respond to stipulations in a Review Response
- Amendments, Continuing Review, and other forms

INSPIR II Help Resources

- On the IRB Website

Visit www.bumc.bu.edu/irb and click on “INSPIR II” then on [“INSPIR II Instructions for Investigators”](#).

The screenshot shows a web browser window with the URL <http://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/>. The browser's address bar and search bar are visible. A yellow box highlights the text "INSPIR Help on the IRB Website" with a green arrow pointing to the "INSPIR II" link in the navigation menu. The website header includes "Boston University Medical Campus Institutional Review Board" and a search bar. The navigation menu contains links for "BUMC IRB INFO", "INSPIR II", "TRAINING GRANTS", "HIRB", "WIRB", "MONITORING & REPORTING", "IRB GUIDANCE", and "INTERPRETER SERVICES". The main content area displays "INSPIR II Instructions for Investigators" and "How To" sections. A "General" section lists several links: "How to get access to INSPIR II", "How to log-in to INSPIR II", "How to update your Personal Profile (required for everyone listed on a study)", "How to upload training certificates to your INSPIR II Profile", "How to print out previously uploaded training certificates from INSPIR II", "How to update the department in your Personal Profile", and "How to get the Study Assistant tab if you don't have it". A right-hand sidebar contains a "Institutional Review Board" section with links for "BUMC IRB Info", "INSPIR II", "Getting Started with INSPIR II", "INSPIR II Instructions for Investigators", "Submit a INSPIR II Help Desk Request", and "INSPIR II Super Users". Below this is a "Training Grants" section with a link for "HIRB".

INSPIR Help on the IRB Website

Boston University Medical Campus
Institutional Review Board

This Site

BUMC IRB INFO **INSPIR II** TRAINING GRANTS HIRB WIRB MONITORING & REPORTING IRB GUIDANCE INTERPRETER SERVICES

INSPIR II Instructions for Investigators

How To

General

- [How to get access to INSPIR II](#)
- [How to log-in to INSPIR II](#)
- [How to update your Personal Profile \(required for everyone listed on a study\)](#)
- [How to upload training certificates to your INSPIR II Profile](#)
- [How to print out previously uploaded training certificates from INSPIR II](#)
- [How to update the department in your Personal Profile](#)
- [How to get the Study Assistant tab if you don't have it](#)

Institutional Review Board

BUMC IRB Info

INSPIR II

- [Getting Started with INSPIR II](#)
- [INSPIR II Instructions for Investigators](#)
- [Submit a INSPIR II Help Desk Request](#)
- [INSPIR II Super Users](#)

Training Grants

HIRB

- In the INSPIR System and Forms
 - The “Help” icon on your INSPIR Home Page

The screenshot shows the INSPIR System Home Page. At the top, there is a navigation bar with the Boston University and Boston Medical Center logos, the user's name (Hello Khaled Khattar, BA), the last login time (03/16/2026 12:01 PM EDT), and navigation icons for Announcements, Help, Tutorial, My Profile, and Log out. Below the navigation bar, there are tabs for My Workspaces and Study Assistant. A help window is open, displaying a list of help topics. Three yellow callout boxes provide instructions: 1. Click on the ? icon, 2. You'll get this popup, 3. Click on a Help Topic.

1 - Click on the ? icon

2 - You'll get this popup

3 - Click on a Help Topic

1 - General Help Instructions

- BMC/BUMC Human Subjects Training Requirements
- How to update your Personal Profile
- How to update the department in your Personal

4 - Continuing Review/Progress Report

- How to create and submit a Continuing Review
- How to sign off on the Continuing Review as PI
- How to respond to a Review Response for a Continuing Review

4 - Other Submission Forms

- How To Close an Exempt Study
- How to create and submit a Final/Closure Report (Non-Exempt and Ceded)
- How to create and submit a Reportable Events and New Information Form
- How to Create and Submit a Protocol Exception Form

- In the INSPIR System and Forms
 - The “Help” icon in the form you’re working on for help on that section

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

Account: Administrator
 Department: BMC/BUMC - MED - Institutional Review Board
 Navigation: Home > my studies > study mgmt. > application list

Home | Logout | Help

Study Nickname: Expedited/Full Board 11-17-2015
 PI: Administrator

Study Application [Back]

Print Friendly | Save Section | Save and Continue to Next Section

Section view of Application | Entire view of the Application

- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant Key Personnel access to the study
- 4.0 Review Path Determination**
- 5.0 Human Subject Training and Conflict of Interest
- 6.0 Funding Source
- 7.0 Study Summary
- 8.0 Navigation Menu
- 9.0 Study Site Information
- 10.0 IRB Authorization Agreement - BUMC is the Reviewing Institu ...

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 only non-personal data; Or BU/BMC is not "engaged" in human research.
 BU/BMC (the Relying Institution) cedes its responsibility for the study to the Sponsor's Institutional Review Board.
 This study fits into one or more of the federal Exempt categories or the equivalent federal regulations and fits into one or more of the Equivalent Protections Exemption categories.
 None of the above. This study requires Expedited review or the review of a full protocol.

Not-Human Subjects Research
 Engagement Determination Decision Tree
 Engagement of Institutions in Research (OHRP Guidance)
 Minimal Risk
 Federal Guidance on Exempt Review - 45CFR 46.101(b)(1)-(6).

4.2 Emergency Use

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

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?

1 - Hover your mouse over the "?" icon

2 - You'll get this popup

3 - Click on a Help Topic

- **INSPIR II Access**

- **Get Access to INSPIR**

- There is only one way for an INSPIR user account to be created; and that's by logging into INSPIR for the first time. If the study team cannot find you in INSPIR to add you to their study, this means that you have never logged in to INSPIR before to create your INSPIR account.
 - You will need a BU username and Kerberos password, or a BMC username and BMC password to login to the INSPIR system.
 - If you have a BU username and Kerberos password, your BU username is the text part of your BU email address before “@bu.edu”; for example, if your BU email address is “jdoe@bu.edu”, then your username is “jdoe”
 - If you have a BMC username and BMC password, your BMC username is usually the first 2 letters of your first name followed by the first 5 or 6 letters of your last name; for example, if your first name is Jane and last name is Doe, then your BMC username is likely to be “jadoe” (same credentials BMC personnel use to login to BMC EPIC).
 - Please use the step-by-step instructions in this link to troubleshoot your INSPIR Access:

- [How to get access to INSPIR II](#)

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

- 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”.

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

INSPIR II

Integrated Network for Subject Protection In Research

Username (not email):

Password:

Log In

[System/Browser Requirements](#)



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

Logging in brings you to your personal HOME Page

If you still have the “Display Study Assistant Tutorial at login” box checked, you will get the tutorial popup below.

The screenshot displays the Boston University Medical Campus Study Assistant interface. At the top, the user is identified as Khaled Khattar, BA, with a login timestamp of 11/13/2023 10:16 PM EST. Navigation options include Announcements, Help, Tutorial, My Profile, and Log out. The main content area shows a 'Study Assistant' section with various options like 'Create a New Study', 'Start a Submission', and 'View the Current Study'. A 'Study Assistant Tutorial List' popup window is overlaid on the page. The popup has a title bar and a close button (X). The main heading of the popup is 'Welcome to Study Assistant Tutorial List' with the instruction 'Select the tutorial for the Study Assistant module.' Below this is a 'List of Tutorials' section with a 'Select' column and a list of tutorial topics, each with a book icon: 'Study Assistant UI Overview', 'How to Submit a New Study Application?', 'How do I find the latest Approved Versions of my Study documents (Application, Consents, etc)?', and 'How do I find the latest Approved Versions of my Study documents (Application, Consents, etc)?'. A checkbox at the bottom left of the popup is checked and labeled 'Display Study Assistant tutorial at login'. A 'Close Tutorial Selection' button is located at the bottom right. Two blue callout boxes with arrows provide instructions: one points to the 'Study Assistant UI Overview' link with the text 'You can watch the tutorial by clicking on a tutorial's link', and another points to the 'Close Tutorial Selection' button with the text 'Or close tutorial by clicking on this button'.

Hello Khaled Khattar, BA
your last login was
11/13/2023 10:16 PM EST

Announcements 7 Help Tutorial My Profile Log out

My Workspaces Study Assistant

Study Assistant Tutorial List

Welcome to Study Assistant Tutorial List
Select the tutorial for the Study Assistant module.

Select List of Tutorials

- Study Assistant UI Overview
- How to Submit a New Study Application?
- How do I find the latest Approved Versions of my Study documents (Application, Consents, etc)?
- How do I find the latest Approved Versions of my Study documents (Application, Consents, etc)?

Display Study Assistant tutorial at login

Close Tutorial Selection

You can watch the tutorial by clicking on a tutorial's link

Or close tutorial by clicking on this button

This is how your HOME Page will look like when the tutorial popup is closed

The screenshot shows the user interface of the Boston University Study Assistant. At the top, there is a header with the Boston University and Boston Medical Center logos, a user greeting for Khaled Khattar, and navigation links for Announcements, Help, Tutorial, My Profile, and Log out. Below the header, there are two main sections: 'Featured Study Operations' and 'By the Numbers'. The 'Featured Study Operations' section contains five buttons for creating a new study, starting a submission form, viewing current approvals, viewing submission history, and managing studies. The 'By the Numbers' section shows counts for Submissions in Process, Forms Pending Submission, and Pending Responses, along with a task summary for All Tasks (42) and Study Tasks (40). A 'Study Tasks' section is visible at the bottom, showing a table of tasks with columns for Task Type, Date Received, Study Status, Study Title, Principal Investigator, Review Board, IRB Number, IRB Expiration, Priority, and Complete By. Annotations include a blue box pointing to the 'Featured Study Operations' section, a yellow box pointing to the 'By the Numbers' section, and a blue box pointing to the 'Study Tasks' section.

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 Responses: 3
- All Tasks: 42
- Study Tasks: 40

Study Tasks

Outstanding | Completed

Task List: All | Review Board: All | Filter By: --none--

40 result(s) found... 1 - 10

Click to open	Details	Task Type	Date Received	Study Status	Study Title	Principal Investigator	Review Board	IRB Number	IRB Expiration	Priority	Complete By
<input type="checkbox"/>		Waiting Submission	03/16/2026 03:32 PM EDT	Draft	Expedited/Full Board 3-16-2026	Administrator	IRB	H-46822		No Priority	<input type="text"/>

Other sections available on your HOME page

Studies Submission Status - In Progress

55 result(s) found... 1 - 10

List of pending submissions

Click to open Study Dashboard	Reference Number	Review Board	IRB Number	Form Name	Study Title	Form Author	Date Submitted	Actions
					Study Nickname			
	1120196	IRB	H-36572	Initial Review Submission Form	Expedited/Full Board 11-25-2019 test	Administrator	02/09/2026 08:00 AM EST	 Incomplete Tasks Open Steps to Complete
	1229778	IRB	H-31000	Change Request and Amendments	2-18-2011-	Administrator	06/18/2019 11:52 AM EDT	 Incomplete Tasks Open Steps to Complete

All Studies

53 result(s) found... 1 - 10

List of studies that you have access to

All
Draft
IRB

Click to open Study Dashboard	Study Status	Review Board	IRB Number	IRB Expiration	Study Title	Principal Investigator	Actions							
					Study Nickname		Applications	Documents	Forms	Hide	Exempt	Copy	Delete	Correspond
	Draft	IRB	H-46822		Expedited/Full Board 11-25-2019 test	Administrator								
	Pending - Initial Review	IRB	H-36572		Expedited/Full Board 11-25-2019 test	Administrator								

- **INSPIR II Access**

- **Update your INSPIR Profile**

- The first thing you should do when you login for the first time is to update your INSPIR Account Information.

The screenshot shows the INSPIR II home page. At the top left, there are logos for Boston University Medical Campus and Boston Medical Center. The user's name and login information are displayed: "Hello Khaled Khattar, BA your last login was 10/11/2022 08:16 AM EDT". Navigation links include "My Workspaces", "Study Assistant", "Announcements", "Help", "Tutorial", "My Profile", and "Log out". The main content area is divided into three sections: "Featured Study Operations" with buttons for "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", and "View and Manage My Studies"; "By the Numbers" with a table of statistics; and "Tasks" with a table of task counts.

By the Numbers			
Submissions in Process	Forms Pending Submission	Pending My Response	High
54	53	4	>

Tasks	
All Tasks	35
Study Tasks	33

A blue thought bubble with the text "This is my home page" is positioned over the "Featured Study Operations" section. A green arrow points from the "Study Assistant" link to the "Featured Study Operations" section. A blue arrow points from the "My Profile" link to the "My Profile" dropdown menu.

Note: If you don't see "Study Assistant", submit the ticket in the link below and provide us with your department and institution information:

<https://www.bumc.bu.edu/irb/inspir-ii-help-desk-request/>

Hover your mouse pointer over "My Profile" to extend the dropdown list and then click on My Account

This is My Account Page sub-page: Profile

Blue star fields can't be changed

Yellow arrow fields need to be updated: Degree, Specialty, Primary Number, Location, and Affiliation. (Please list section or center within the department in the Mailing Address)

BO
UNI

M

Study Assistant

Save Changes

Profile

* Last Name: Khattar

Job Title: Application Support Specialist

Biosketch, CV, Pubs

Training History

Medical Licenses

Signature

Disclosures

Signoff Availability

Notes

Status: Active

Degree: BA

Gender: Male

Employee ID:

Specialty: Add Remove

Relationship to Institution: Affiliated Non-Affiliated

Affiliation: Add Remove

BUSM or Dental Faculty/Staff

International capacity: Scientist Non-Scientist

First Name: Khaled Middle Name:

Contact Information (* fields required)

* Email Address: kkhattar@bu.edu

* Phone: (617) 638-7203

Cell Phone:

Pager:

Fax: 617-638-7234

Mailing Address: Robinson 4, Room 414I

Department(s)

BMC/BUMC-Institutional Review Board(IRB)

If any

Required

Put your Department/Section and location here

Not Required

If Affiliated

If the department /section is not correct, please submit a ticket at <https://www.bumc.bu.edu/irb/inspir-ii-help-desk-request/> with the correct department/section.

Update Profile

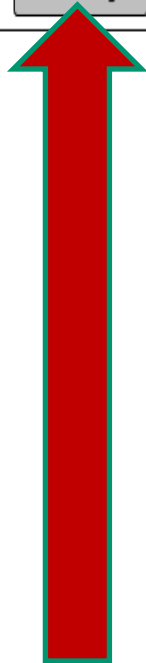
Then **SAVE** changes (red arrow)

My Workspace

Back

Research Workspace

Save Changes



Study Assistant

- Profile
- Biosketch, CV, Pubs
- Training History
- Medical Licenses
- Signature
- Disclosures
- Signoff Availability
- Notes

* Last Name: Khattar	First Name: Khaled	Middle Name: <input type="text"/>
Job Title: Application Support Specialist	Contact Information Use for System Notifications	
Status: Active	(* fields required)	
Degree: BA	* Email Address: kkhattar@bu.edu	
Gender: Male	* Phone: (617) 638-7203	
Employee ID:	Cell Phone: <input type="text"/>	
Specialty: <input type="button" value="Add"/> <input type="button" value="Remove"/>	Pager: <input type="text"/>	
Relationship to the Institution: <input checked="" type="radio"/> Affiliated <input type="radio"/> Non-Affiliated	Fax: 617-638-7234	
Affiliation: <input type="button" value="Add"/> <input type="button" value="Remove"/>	Mailing Address: Robinson 4, Room 414I	
<input type="checkbox"/> BUSM or Dental Faculty/Staff	Department(s)	
Representational capacity: <input type="radio"/> Scientist <input type="radio"/> Non-Scientist	• BMC/BUMC-Institutional Review Board(IRB)	

Summary

- Once you update your personal profile make sure that you “save the changes”
- No one can update your profile for you- you must update your own profile. It is a violation of BU and BMC’s Institutional policy to give someone your username and password or to use someone else’s username and password.
- It is only necessary to update your personal profile once (unless something in your profile changes). It does not need to be updated for each protocol submitted.
- For each new study submitted, all study personnel will need to have an updated personal profile.

- How to perform some basic INSPIR II functions
 - Create a new IRB Application Draft

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	4	>

Tasks

All Tasks	35
Study Tasks	33

When you login into INSPIR II (<https://inspir.bu.edu/>), you will get to this page. This is your Home page

Click on **“Create a New Study”**

The system will create and open a new Study Application form.

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home

Help My Profile Log out

My Workspaces Study Study Application Back

Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information

1.0 General Information

* Please enter the official title of your study::

Demo Study

* Please enter the Study Nickname you would like to use to reference the study::

Demo

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

This is the first section of the Study Application. Type in the title and a nickname for the study. Then click on “Save and Continue to the next Section” button to proceed.

The system will start building the Study Application section by section. You can click on these sections/tabs in the left panel to jump back to them.

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home

IRB Number: H-44278
Study Alias: Demo

Study Application (Version 1.0)

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access

2.0 Add departments

2.1 List departments associated with this study (Note: The primary department should accurately reflect the primary Department or Section of the PI. Please verify that the primary department listed is correct (in some cases the "default" department of BU/BMC Medicine has been selected). For large departments, the PI's appropriate "section" should be listed as the primary department (e.g. if the PI is from Neurology or Infectious Disease). If the PI is from the SPH - select the appropriate department within SPH (e.g. Epidemiology) as primary.):

Is Primary?	Department Name
<input type="checkbox"/>	<input checked="" type="radio"/> BMC/BUMC - MED - Institutional Review Board

Add Department Remove Department

Make sure you have the right department listed here (brown arrow). If not, check the small box to the left and click on "Remove" (green arrows). Then click on "Add" to add the right department (red arrow). You can add multiple departments if multiple ones are involved. When you're done click on "Save and Continue..." (purple arrow)

The system will open Section “3.0 Grant Key Personnel access to the study”. In this section, you need to enter all internal personnel. Only those entered here will have access to this study.

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

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home

Help My Profile Log out

My Workspaces IRB Number: **H-44278** Study **Study Application (Version 1.0)** Back

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study

3.0 List of Internal (BMC/BUMC) Study Personnel. All personnel listed in this section will have access to this study (limited or full access).

Click Here to Setup Study Personnel

3.1 * Please add a Principal Investigator for the study:
(Note: Only faculty members can serve as Principal Investigators on IRB protocols for studies at the School of Dental Medicine):

Name	Role	Training Record
No Principal Investigator has been added		

3.2 If applicable, please select the Research Staff personnel. Individuals must be listed if they will have contact with research subjects or their identifiable data in the performance of any research related activities, including enrollment, consenting, collection of study data, interventions, long-term follow-up or as Research Support Staff in B):

A) Additional Investigators

Name	Role
No Additional Investigators have been added	

B) Research Support Staff

Name	Role
No Research Support Staff have been added	

3.3 * Please add a Study Contact:

To fill out this section, click on “Click Here to Setup Key Study Personnel” button (blue arrow).

Notes for adding New Investigators

- “Study Contact” is not a real study role. So, anyone that is listed as a Study Contact will also need to be listed under another study role such as “Additional Investigators” or “Research Staff”, if they are not already listed there.
- If the investigator(s) that are being added will need to receive email notifications about the protocol and be assigned tasks in their INSPIR Home page, you will also have to give them the “Study Contact” Role.

The system will open the “Setup Study Personnel” popup.

1- Enter the last name (green arrow)

2- Click on the “Find User/Search Directory” button (yellow arrow) to search for the person.

User Search by Study

This section is used to build the list of personnel on the study. User Search by Study allows you to search for a named person and associated them with a role on the study.

Last Name: Khattar First Name: Find User/Search Directory

User Search by Study: All Departments

Select	Training	Name	Department	Email
No results found				

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
No Personnel has been selected for this group.	

Research Support Staff

Name	Role
------	------

Clear Key Study Personnel Close Setup of Study Personnel

3.3 * Please add a Study Contact:

Tip - If you can't find this person in INSPIR, ask that person to login to INSPIR for the first time and their INSPIR account will be created. They can use the step-by-step instructions in the link below to login and create their INSPIR account:

<http://www.bumc.bu.edu/irb/files/2016/10/Access-to-INSPIR.pdf>

If the person you are looking for has an INSPIR account, their name will show up like in the screenshot below (blue arrow)

1. First check that they are up-to-date with training by clicking on the training icon (green arrow). If they don't have the required IRB training, please do not add them.
2. Click on the "Select" icon (yellow arrow) to select this person.

Setup Study Personnel

User Search by Study

Last Name: Khattar First Name:

Search by Department: All Departments Find User/Search Directory

Select	Name	Department	Email
	Khattar, Khaled, BA	Institutional Review Board (primary)	kkhattar@bu.edu

Selected Study Personnel:

Principal Investigator

Name	Role
No Personnel has been selected for this group.	

Additional Investigators

Name	Role
No Personnel has been selected for this group.	

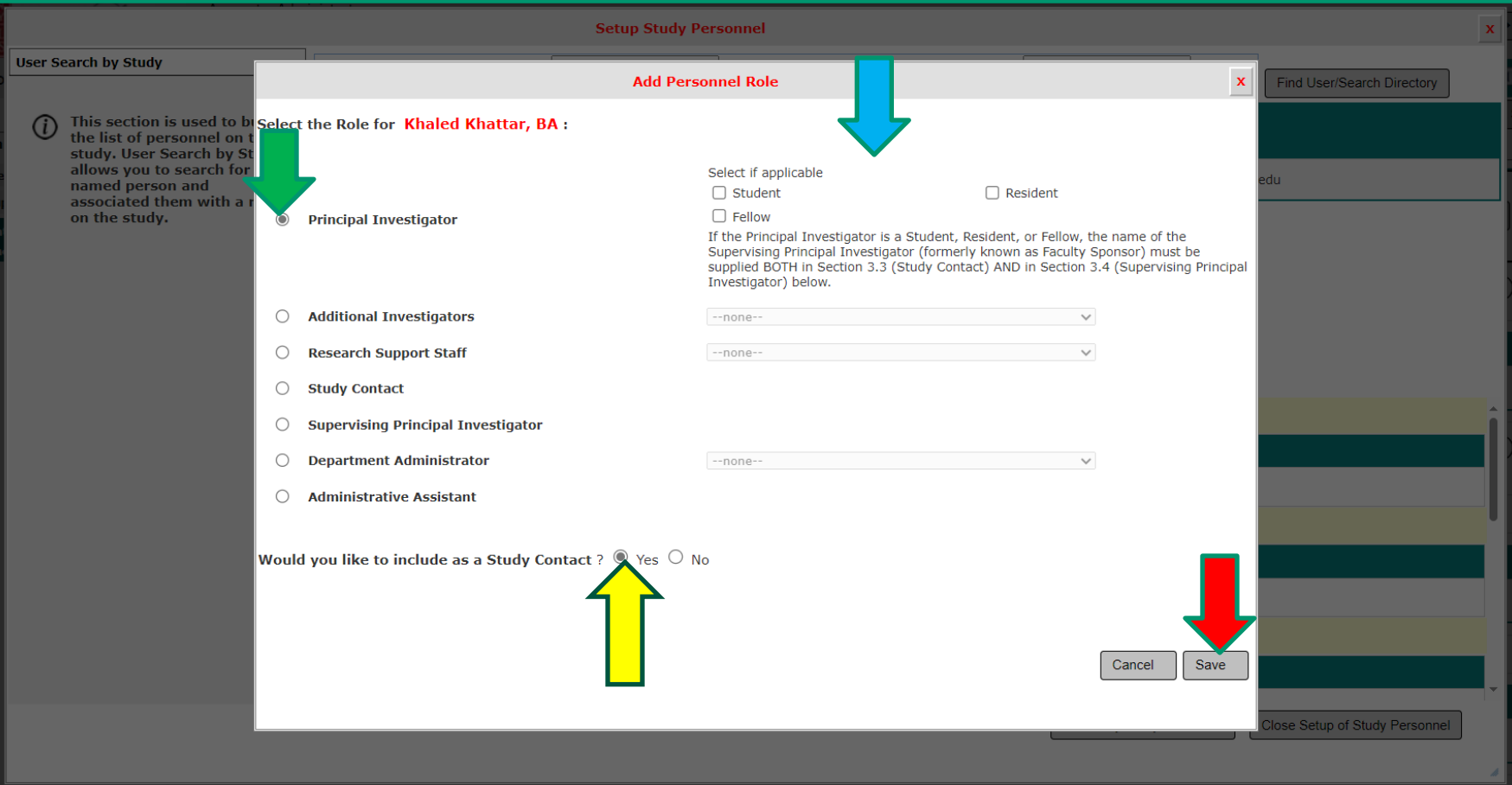
Research Support Staff

Name	Role
------	------

Tip - If you can't find this person in INSPIR, ask that person to login to INSPIR for the first time and their INSPIR account will be created. They can use the step-by-step instructions in the link below to login and create their INSPIR account:
<http://www.bumc.bu.edu/irb/files/2016/10/Access-to-INSPIR.pdf>

This will open the “Add Personnel Role” popup.

1. Select their role on the study by clicking on one of the listed roles’ radio buttons (green arrow).
2. Some roles require that you select the user’s role subcategory from check boxes or a drop-down menu- (blue arrow). Select the user’s role subcategory if applicable.
3. If you want this person to get study tasks and all study email notifications, select “Yes” (yellow arrow) for “Would you like to include as a Study Contact ? ”, otherwise select “No”.
4. When you are done, click on the “Save” button (red arrow).



3.3 * Please add a Study Contact:

This will take you back to the “Setup Study Personnel” popup.

- Note that the person just added is showing up in the appropriate section/role (green arrow).
- To add more personnel, repeat steps in slides 7 - 10.
- If you are done selecting all study personnel, you would click on “Close Setup of Study Personnel” button (yellow arrow).

Setup Study Personnel

User Search by Study

Last Name: First Name:

User Search by Study: Find User/Search Directory

Select	Training	Name	Department	Email
<input type="checkbox"/>		Khattar, Khaled, BA	Institutional Review Board (primary)	kkhattar@bu.edu

Selected Study Personnel:

Principal Investigator

Name	Role
<input checked="" type="checkbox"/> Khattar, Khaled, BA	Principal Investigator

Additional Investigators

Name	Role
No Personnel has been selected for this group.	

Clear Key Study Personnel Close Setup of Study Personnel

Note: You need to list at least the following:

- Principal Investigator
- Department Administrator (Department Chair/Section Chief)
- Supervising Principal Investigator (if PI is a student, resident, or fellow)

This will bring you back to Section “3.0 Grant Key Personnel access to the study”. All your study personnel and their roles should now be listed in this section (green arrow)

Account: Administrator
 Department: BMC/BUMC - MED - Institutional Review Board
 Path: Home

Help My Profile Log out

My Workspaces IRB Number: H-44278 Study Application (Version 1.0) Back

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information
 2.0 Setup Department(s) Access
 3.0 Grant Key Personnel access to the study

3.0 List of Internal (BMC/BUMC) Study Personnel. All personnel listed in this section will have access to this study (limited or full access).

3.1 * Please add a Principal Investigator for the study:
 (Note: Only faculty members serve as Principal Investigators on IRB protocols for studies at the School of Dental Medicine):

Name	Role	Training Record
Khaled Khattar, BA	Principal Investigator	View Training Record

Responsibility
 Student
 Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Supervising Principal Investigator (Contact) AND in Section 3.4 (Supervising Principal Investigator) below.

3.2 If applicable, please select the Research Staff personnel. Individuals must be listed if they are involved in any research related activities, including enrollment, consenting, collection of study data, or as Research Support Staff in B):

A) Additional Investigators

Name	Role	Training Record
Finn, Brandon, BA, CIP, Senior IRB Analyst	Co-Investigator	View Training Record
Franco, Daly, BA, CIP, Senior IRB Analyst	Co-Investigator	View Training Record
Testerman, Mark, BS, CIP, Senior IRB Analyst II	Co-Investigator	View Training Record
Themelis, Lin, MA, CIP, IRB Administrator	Co-Investigator	View Training Record

Click Here to Setup Study Personnel

Once you're done adding personnel, click on "Save and Continue to Next Section" button

The system will transition you to Section 4.0 “Review Path Determination”

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

Account: Administrator
Department: BMC/BUMC - MED - Institutional Review Board
Path: Home

Help My Profile Log out

My Workspaces Study **Study Application (Version 1.0)** Back

IRB Number: **H-44278**
Study Alias: Demo
PI: Khattar, Khaled, BA

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

1.0 General Information
2.0 Setup Department(s) Access
3.0 Grant Key Personnel access to the study
4.0 **Review Path Determination**

4.0 Review Path Determination

4.1 Review Path Determination

- This project meets the definition of Not Human Subject Research (NHSR). Examples are non-research Quality Improvement/Quality Assurance projects; studies that involve obtaining anonymous data/tissues or coded data; or BMC/BU Medical Campus is not 'engaged' in human subjects research.
- BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.
- The only research activities in this study involve chart reviews.
- This study fits into one or more of the federal Exempt categories or the study does not have external funding and fits into one or more of the Equivalent Protections Exempt categories.
- None of the above. This study requires Expedited review or the review of the Full Board.

4.2 Emergency Use Report

Is this a report of an Emergency Use of an Investigational Drug or Device that has already occurred? For more information, click [here](#). If Yes, please click [here](#) for a guidance document that will provide step by step instructions on how to submit this emergency use to the IRB.

Yes No

It is crucial that you answer the questions in this section correctly. Your answers will determine which of the subsequent sections will be displayed and which will be hidden. Click on the “(?)” icon to learn more about the corresponding question before answering it.

As you click “Save and Continue to Next Section”, the rest of the sections will appear in the left-hand column. Sections that have not been visited will not appear there until later.

Draft Protocol

- Section 4 “Review Path Determination” is the first section that will determine the branching for the study.
- Depending on your responses in this section, the rest of the sections will either appear or will be hidden.
- If you change your mind as you are “building” your draft and then you later make changes that will affect the branching, the system will “HIDE” all sections AFTER you reach the branching change and you will need to revisit these sections, Section by Section, and review those pages and then click “Save and Continue...” repeatedly until all the sections re-appear. The system did not delete your answers. If you click “Save and Continue...” they will reappear, unless that section is no longer required after the changes that you have made. New sections might also appear and need to be completed.

Draft Protocol (cont.)

- In many sections, you will encounter the Study Document table (see screenshot below) where you can add documents in the Study Application. This is optional (unless it's required), as you can add your study documents all at once when the system transitions you to the “Initial Review Submission Form” in the “Other Study Documents” section.

Add a New Document		Add Multiple Documents					
Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	View Document
No Document(s) have been attached to this form.							

- We'll show you later how to upload a document in this table. Detailed instructions can be found in the following link:
- [How to add a new Study Document](#)

When all sections have been visited, you will reach the “Review For Completeness” section. Clicking on “Save and Continue to Next Section” will prompt the system to review the Study Application before proceeding to attach it to the “Initial Review Form” packet.

My Workspaces ▾ IRB Number: **H-46822** Study Assistant Study Application (Version 1.0) ◀ Back

Study Nickname: Expedited/Full Board 11-25-2019 ...
PI: Administrator

Print Friendly Save Section Save and Continue to Next Section

Section view of Application Entire view of the Application

- 12.0 Purpose
- 13.0 Subjects
- 14.0 Design/Procedure
- 15.0 Risks & Benefits & Justification for Approval
- 16.0 Data & Safety Monitoring
- 17.0 Recruitment Procedures/Materials
- 18.0 Screening Procedures
- 19.0 Consent Procedures
- 20.0 Privacy and Confidentiality
- 21.0 HIPAA Compliance
- 22.0 Cost/Payment
- 23.0 Biological Sample Collection
- 24.0 Drugs or Biological Agents
- 25.0 Devices
- 26.0 Radiation
- 27.0 Retention of Samples or Data
- 28.0 Genetics
- 29.0 Study Attachments
- 30.0 Review For Completeness**

30.0 Review For Completeness

30.1 **Please read these instructions carefully.** This is the last step in completing the Study Application. In this section, you can prompt the system to run a review of the Study Application where the system will either mark it as "Complete" or list any required sections/questions that you have missed. If the system determines that the Study Application is complete, the system will transition you to a submission form (such as Initial Review form, Review Response form, or Change Request & Amendments form). If the system determines that there is a required section/question that was missed, it will display the "Validation" page and lists the missing section(s)/question(s) as links that will take you to the missing components to be completed.

This step needs to be completed every time you make changes to the Study Application and before you submit for PI signoff. Failure to complete this step will result in the Study Application being marked as "- Incomplete" which will prevent you from submitting for PI signoff until this step is completed.

To start the "Review for Completeness" process, all you have to do is visit this section and click on the **"Save and Continue to Next Section"** button (not on the "Save Section" button).

When you finish filling out all the sections in the Study Application, the system will transition you to the “Initial Review Submission Form”.

Initial Review Submission Packet

Note: This is the submission form. To create and attach your submission, click on the “Initial Review Submission Form” link. To upload and attach an application, click on the “Study Application” link.

When you get to this page this means that you have visited all the necessary sections and that the Study Application has been built in the system and being attached to this packet.

Scroll Down a little

Study Title:	Demo Study
IRB Number:	H-44278
Principal Investigator:	
PI Name:	Khaled Khattar, BA
PI Email Address:	kkhattar@bu.edu
PI Phone Number:	(617) 638-7203

Study Application Form

Attach the IRB application you completed for this protocol (For an Initial Submission the application will automatically attach for you)

Deattach	Revise/Attach	Edit/View	Title
(X)			Study Application (Version 1.0)

Consent Documents

In this section, you can create a new consent/assent form, or revise an existing one and attach it to this submission. Once this is done, all the new and revised consent/assent forms should be listed below as part of this submission (click on the Help (?) icon on the right for instructions):

Next time you need to access the Study Application, click on the icon under “Edit/View”

This is where all consent forms should be generated and attached to the submission. To add a new consent form, click on the grey button. For detailed instructions, follow the instructions in this link:

- [How to add a new Consent Form](#)

Account: Administrator
 Department: BMC/BUMC - MED - Institutional Review Board
 Path: Home > study mgmt.

IRB Number: **H-44278**
 Study Alias: Demo
 PI: Khattar, Khaled, BA

My Workspaces

Initial Review Submission Form - (Version 1.0)

Print Friendly Refresh Constant Fields Save Form

Form

PI Phone Number
 (617) 638-7203

Study Application Form

Attach the IRB application you completed for this protocol: (For an Initial Submission the application will automatically attach for you)

Detach	Rev Attach	Edit/View	Title
(X)			Study Application (Version 1.0)

Consent Documents

In this section, you can upload and attach a new consent/assent form, or revise an existing one and attach it to this submission. Once this is done, all the new and revised consent/assent forms should be listed below as part of this submission (click on the Help (?) icon on the right for instructions):

Add a New Consent

Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	View Document
No Consent(s) have been attached to this form.								

Other Study Documents

If a document was already attached in the Study Application, DO NOT upload it again here. This will create duplicates of documents which will need to be voided later. In this section, you can upload and attach any other study documents (e.g. protocol, investigators brochure, recruitment materials, instruments, case report forms, study handouts or other miscellaneous documents) that have not been attached as part of the Study Application. Click on the Help icon (?) on the right for instructions.

Select or Revise Existing Add a New Document Add Multiple Documents

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

1. Select one of the two options shown (instructions for these two options will follow):
 - Option 1 - Select to download an RTF Word document of the Consent Form template with all the template languages included in it.
 - Option 2 - Select to upload a consent form Word document that you already have, such as a revised consent form template that you have already downloaded or a Foreign language consent form.

1

Study Consent Add Selection Method: x

Option 1 Add an informed consent from the list of Informed Consent Template Documents?

Option 2 Add an informed consent from an existing electronic document you already have?

2

Next Screen

2. After selecting one of the two options, click on “Next Screen”

- If you selected option 1, proceed to slide # 4 for instructions.
- If you selected option 2, proceed to slide # 10 for instructions.

If option 1 was selected:

Study Consent Add from Template:

Instructions

1. Download the document to your workstation by clicking the **Download** button at the top right side of the screen. Your browser will then ask if you would like to save or open the file named "ConsentDocument.rtf". Click the **Save** option. This will download the file to your workstation.
2. You can now edit this document using any standard word processing program such as MS Word and WordPerfect used on either a MAC or a standard PC. Make sure you save the document to your workstation in .rtf format.
3. Check the document into the iRIS system by clicking the **Check in Document** button. Use the **browse** button and find your document. Select your document, then select the **open** button. Select the **ok** button, then when back in the iRIS system, click the **Save Consent** link.

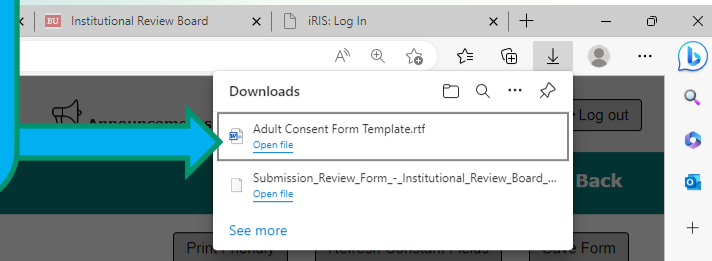
* Please select the Consent Template:

- none--
- Consent Statement for Anonymous Survey/Interview Exempt Research
- Research Assent Form for Children 12-17 Years of Age
- Emergency Use Consent Form
- Non-Exempt Consent Form Template

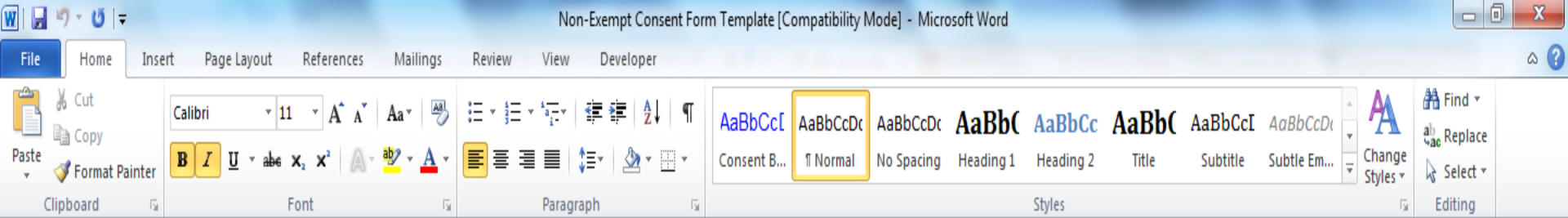
Download Template

You will see this popup. From the “Please select the Consent Template” drop down list, 1. Select one of the available templates.
2. Click on “Download Template” button.

1. The selected Consent template will download. Depending on your web browser, you will get the “Downloads” popup similar to this one. Click on the file to open it.

A screenshot of the 'Study Consent Add' popup form. The form has a title bar with 'Study Consent Add:' and a close button (X). The form contains several fields: '*Consent Title:' with a text input field; '*Select the consent to upload:' with a dashed box containing the text 'Please drop file/click here to upload'; '*Version Number:' with a text input field containing '1' and a suffix '.0'; '*Version Date:' with a date input field containing '03/24/2023'; 'Sponsor Version:' with a text input field; '*Category:' with a dropdown menu showing '--none--'; '*Language:' with a dropdown menu showing 'English'; 'Description:' with a large text area; and 'Comments:' with another large text area. At the bottom of the form are two buttons: 'Close, don't save any changes' and 'Save Consent'. A blue arrow points from the 'Downloads' popup to the 'Study Consent Add' form, and another blue arrow points from the 'Close, don't save any changes' button to the bottom text box.

2. In INSPIR, you will also get the “Study Consent Add” popup. Close this popup since you will not upload the document at this time.



BOSTON UNIVERSITY SCHOOLS OF MEDICINE,
PUBLIC HEALTH, DENTAL MEDICINE AND
THE BOSTON MEDICAL CENTER



RESEARCH CONSENT FORM

(Type your Research Consent Form Description/Title" here)

Title of Project:

Principal Investigator:

This is a template for completing a research consent form.

The consent form template should open in Word. Make sure you “save as” this file on your Desktop or somewhere you can find later. Start making your changes and don’t forget to save your changes.

Instructions for option # 1

In INSPIR, go back to where you started, to the screen where you can add a new consent form.

Select or Revise Existing

Add a New Consent

Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	View Document
--------	---------	-----------------	-------	----------	----------	-----------------	-----------------	---------------

No Consent(s) have been attached to this form.

Click again on the “Add a New Consent” button.

Instructions for option # 1

1. This time, select option # 2 to upload the revised consent form.

Number: **H-36572**
y Nickname: Expedited/Full Board 6-1-2017 Administrator, --none--

Study Assistant

Initial Review Submission Form - (Version 1.0)

Print Friendly Refresh Constant Fields Save Form

Study Consent Add Selection Method:

Add an informed consent from the list of Informed Consent Template Documents?

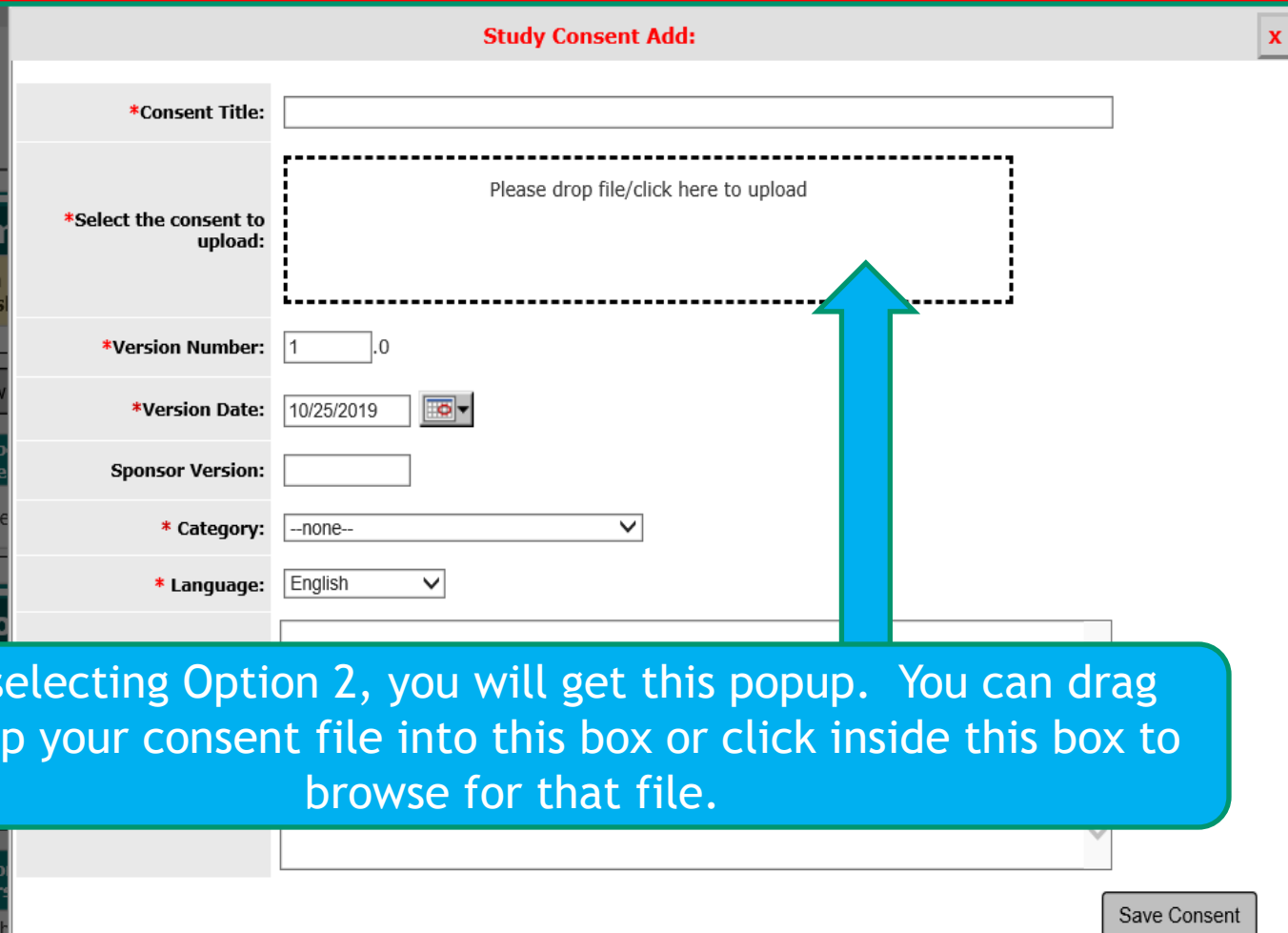
Add an informed consent from an existing electronic document you already have?

Next Screen

2. Click on "Next Screen"

Instructions for options # 1 and # 2

Before uploading, make sure that the consent form that you want to upload is clean (i.e. Track changes had been all accepted, there are no comments on the right margin, Headers and Footers are there, etc...). In other words, it should look the way you want the final consent form to look minus the approval stamp which will be applied later when it is approved by the IRB.



The screenshot shows a 'Study Consent Add' popup window with the following fields:

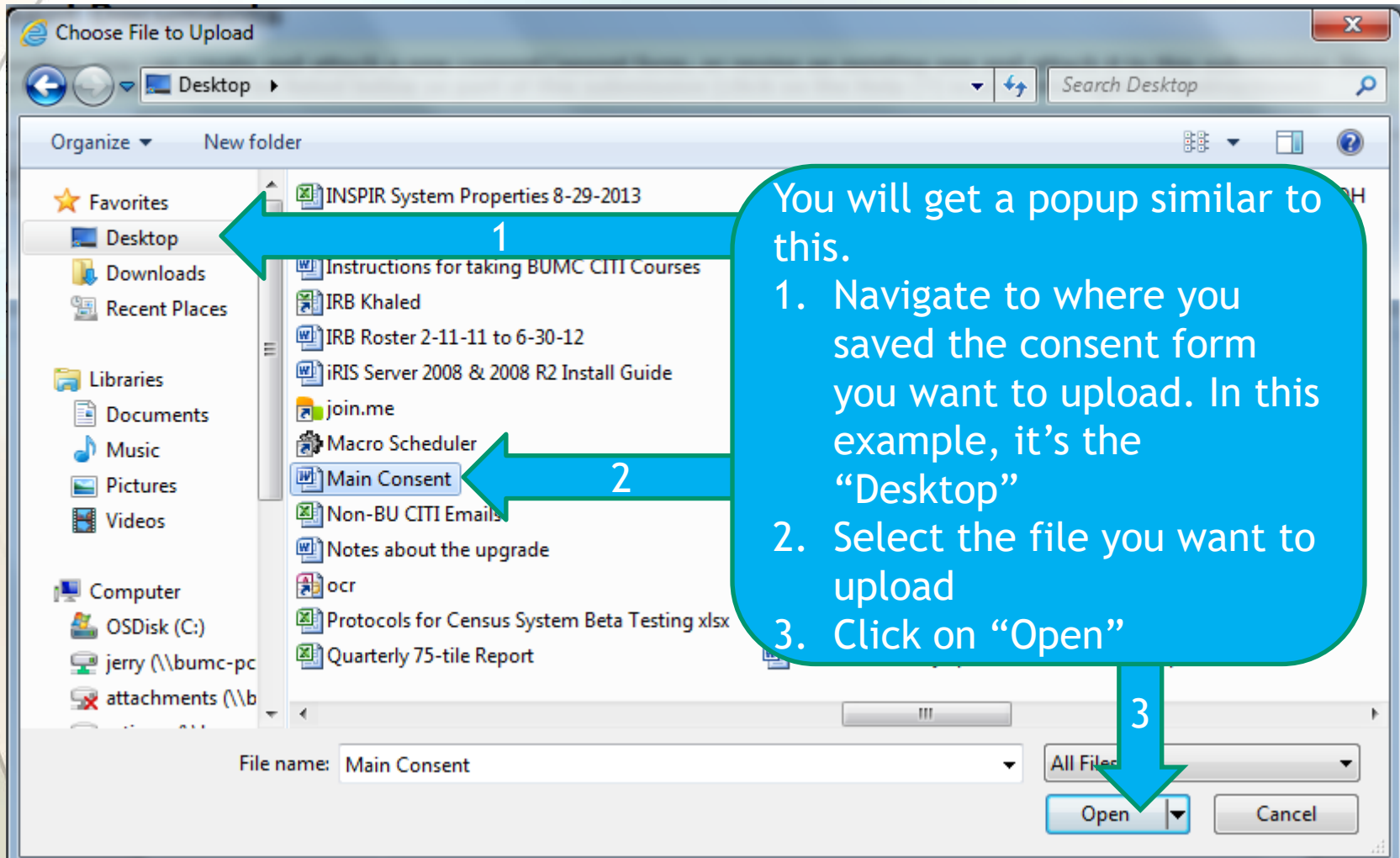
- *Consent Title:**
- *Select the consent to upload:** A dashed box containing the text 'Please drop file/click here to upload'. A blue arrow points to this box.
- *Version Number:** .0
- *Version Date:**
- Sponsor Version:**
- * Category:**
- * Language:**

Buttons: 'Save Form' (top right), 'Save Consent' (bottom right).

After selecting Option 2, you will get this popup. You can drag and drop your consent file into this box or click inside this box to browse for that file.


Instructions for options # 1 and # 2 - continued

If you dragged and dropped the consent file into the box, go to the next slide.
If you clicked inside the box to browse, you will get this popup.




IRB Number: H-36572
Study Nickname: Expedited/F
PI: Administrator, --none--

Study Consent Add: X



***Consent Title:** 

***Select the consent to upload:**


Adult Consent Form Template.rtf
0.8 MB
[Remove file](#)




***Version Number:** .0

***Version Date:**  


Sponsor Version:

*** Category:** 

*** Language:** 

Description:

Comments:



The system will bring you back to this popup. Note the name and path of the file to be uploaded (green arrow). Type in a title to your consent form (yellow arrow) and make sure the version date is current (red arrow). Also, select the appropriate category and language (purple arrows). Make all the necessary changes to this popup and then click on "Save Consent" (blue arrow).

Instructions for options # 1 and # 2 - continued

This will bring you back to where you started in the form.

The consent form that you have just uploaded should appear on this table/list. You can verify that you have uploaded the right consent form by clicking on the “View Document” icon to open it (yellow arrow). You can detach (not common) from this submission any consent form that you don’t want to submit to the IRB by clicking on the (X) icon next to it (red arrow).

	Version	Sp Ve	Title	Category	Language	Expiration Date	Consent Outcome	View Document
(X)	1.0		Main Consent Form	Adult Consent	English			290.69 KB

To revise the consent form that you have just uploaded or to attach to this form a different existing consent form, click on “Select or Revise Existing” and follow the instructions in this link:

- [How to revise an existing Consent Form](#)

You’re done adding the consent form. You can start over if you have additional Consent forms.

This section is where any additional study documents are uploaded and attached to the submission. To add a new study document, click on the grey button . For detailed instructions, follow the instructions in this link :

- [How to add a new Study Document](#)

Account: Administrator
Department: BMC/BU
Path: Home > study n

Help My Profile Log out

My Workspaces IRB Number: H-44278
Study Alias: Demo
PI: Khattar, Khaled, BA

Initial Review Submission Form - (Version 1.0)

Print Friendly Refresh Constant Fields Save Form

Form

PI Phone Number:
(617) 638-7203

Study Application Form

Attach the IRB application you completed for this protocol:
(For an Initial Submission the application will automatically attach to you)

Detach	Revise/Attach	Edit/View	Title
(X)			Study Application 1.0)

Consent Documents

In this section, you can create and attach a new consent/assent form, or revise an existing one and attach it to this submission. Once this is done, all the new and revised consent/assent forms should be listed below as part of this submission (click on the Help (?) icon on the right for instructions):

Add a New Consent

Detach	Version	Sponsor Version	Title	Category	Language	Expiration Date	Consent Outcome	View Document
No Consent(s) have been attached to this form.								

Other Study Documents

If a document was already attached in the Study Application Form, you can upload it again here. This will create duplicates of documents which will need to be voided later.
In this section, you can upload and attach any other study documents (e.g. protocol, investigators brochure, recruitment materials, instruments, case report forms, study handouts or other miscellaneous documents) that have not been attached as part of the Study Application. Click on the Help (?) icon on the right for instructions.

Select or Revise Existing Add a New Document Add Multiple Documents

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

Scroll Down a little

This opens the “Study Document Add Verification” pop-up.

Study Document Add Verification

If you already have the revised document on your computer, skip downloading the document for editing and proceed to uploading the revised document.

Select Category: --none--
Version #:
Version Date: between
Document Outcome: --none--

Title:
Search level: Top All
Expiration Date: between

Filter Documents

Upload a New Document Not on the List

Here are the documents for all categories.
Please click on the Create Revision icon to revise an existing document below or click on Upload a New Document Not on the List to upload a new document to the study.

11 result(s) found...

Upload Revised Document	Title	Category	Version	Version Date	Download Document for Editing	Document Outcome	insor Version	View Document
(Read Only)	testing pptx	Flyer	1.2	04/23/2019				247.98 KB
(Read Only)	PI Responsibilities	Signed PI or Supervising PI Responsibilities	1.0	06/26/2020				419.36 KB
(Read Only)	Recruitment Materials Test	Flyer	1.0	12/03/2019				114.55 KB
(Read Only)	test	Not Defined	1.0	08/23/2019				11.30 KB
(Read Only)	Power Point to P DF Test *Added by the I RB	Flyer	1.0	09/05/2018		Approved and Stamped		636.49 KB
(Read Only)	test	FDA Document	1.0	08/27/2018				91.06 KB
(Read Only)	testing stamp	Other	1.1	07/19/2016				360.02 KB
(Read Only)	testing doc file *Added by the I RB	Materials handed out to subjects	1.0	07/19/2016		Approved and Stamped		135.39 KB
(Read Only)	testing stamp *Added by the I RB	Materials handed out to subjects	1.0	07/19/2016		Approved and Stamped		205.14 KB

Cancel Document Add

Click on “Upload a New Document Not on the List” button

This opens the “Study Document Add” pop-up.

The screenshot shows a web-based form titled "Study Document Add". The form has a sidebar on the left with the following fields: "Document Title" (text input), "Select the document to upload:" (a dashed box with the text "Please drop file/click here to upload"), "Version Number:" (input with "1" and ".0"), "Version Date:" (input with "10/27/2023" and a calendar icon), "Sponsor Version:" (text input), "Category:" (dropdown menu with "--none--"), "Description:" (text area), and "Comments:" (text area). At the bottom right, there are two buttons: "Save Document" and "Cancel, don't save any changes". A blue arrow points from the bottom of the page up to the dashed box.

You can either:

- Drag and drop your document in the “Select the Document to upload” box; Or
- Click inside this box and follow your system’s prompts to navigate to where you saved the document to upload it.

My Workspaces My IRB Number: H-44278
Study Alias: Demo
PI: Khattar, Khaled, BA

Study Initial Review Submission Form - (Version 1.0)

Back

Print Friendly Refresh Constant Fields Save Form

Form

Additional Special Routing

- Your submission might be routed automatically to one or more "Special Routing" signoffs. For more information, click here.
- You can track your submission by following the instructions here.
- Once all the required signoffs are collected and your submission is received by the IRB, you will receive a system notification stating that the submission was received.

Implicit and Explicit Bias in Research

Boston Medical Center (BMC) and Boston University School of Medicine (BUSM) are committed to equity, diversity and inclusion across our tripartite mission of patient care, research and education. With regards to research, embedded inclusion from study inception through publication leads to more innovative, creative science that improves health across diverse communities. Therefore, the Committee to Reduce Implicit and Explicit Bias in Research has recommended and minimize racism, sexism and other forms of bias in research design and reporting. Please see the Report from the Committee to Reduce Implicit and Explicit Bias in Research for further information.

Please complete and attach the following form. The responses to the questions in this form will be reviewed by the Department Chair/Section Chief at the time of routing sign-off, with the goal of ensuring that the potential for questions about this process and/or completing this form, please contact Dr. Megan Bair-Merritt at Megan.Bair-Merritt@bmc.org.

- Reduction of Explicit and Implicit Bias in Research Form

Select or Revise Existing Add a New Document Add Multiple Documents

Detach	Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome
No Document(s) have been attached to this form.						

In-person Interaction at BMC

Does this study involve in-person interaction with research subjects in Boston Medical Center (BMC) space?

- Yes
- No

Boston Medical Center Employees

Does this study involve targeting Boston Medical Center Employees (faculty, staff, laboratory personnel, or trainees) for recruitment? (Answer No if BMC employees might incidentally participate but are recruited regardless of their employment status.)

- Yes
- No

Perinatal Research Review Committee

Does your research fall under any of the following categories:

Scroll down and answer all the "Additional Special Routing" questions. And when you're done, click on "Save Form".

Print Friendly

Form

Form has been Completed!

Grant Key Personnel access to the study

- Notify PI to Signoff
- Return to Form
- Create PDF Packet
- Exit Form

You can click on “Exit Form” to exit this submission and complete later. If you’re ready to submit, click on “Signoff and Submit” (not visible here) if you are the PI; or if you are someone other the PI, click on “Notify PI to Signoff”.

If you have clicked in the previous screen on either “Signoff and Submit” or “Notify PI to signoff”, the system will bring you to this screen to setup signoff list.

Initial Review Submission Form - (Version 1.0)

Setup for Submission Routing and Signoff

i This screen enables the collection of Key Personnel and Additional Personnel for Review and Signoff. The Check box "Checked" indicates the person is included in the signoff process. The Check box "Unchecked" indicates the person is not included in the signoff process. The Add Additional Personnel button is used to search from the user database and add them to the routing list. The order of the Additional Personnel is to create a review order for the assigned personnel. If personnel have 1, 2(sequential)

Select the Key Personnel for Submission Routing and Signoff:

Include in signoff	Approved	Name	Role
<input checked="" type="checkbox"/>		Khaled Khattar, BA	Principal Investigator

Select Additional Personnel for Submission Routing and Signoff:

Include in signoff	Order	Name	Role
<input checked="" type="checkbox"/>	1	Matthew Ogradnik, OHRA Director	Department Chair/Section Chief

Scroll Down a little

Once you're done with this section, click on "Save - Signoff Routing List"


Note: The PI and Department Chair/Section Chief should always be selected (included). If there are more investigators that need to signoff (not common), you would add them here.

If you have clicked in the previous screen on “Save - Signoff Routing List”, the system will bring you to this screen.

H-44278
emo
led, BA

Study

Initial Review Submission Form - (Version 1.0)

1	 Matthew Ogradnik, OHRA Director	Department Chair/Section Chief
---	---	--------------------------------

Please verify the list above represents the finalized Personnel for review and signoff? Yes No

1- Click on “Yes”

2- Click on “Save - Start Signoff Routing”

Cancel - Finalize later Go back to Make changes Save - Start Signoff Routing

If you are not the PI, skip this slide and the next one to slide # 24. If you are the PI listed on this study, the system will take you to the PI's "Submission Routing Signoff" page.



Account: Khaled Khattar, BA
Department: BMC/BUJC - MED - Institutional Review Board
Path: Home

Announcements 7 Help My Profile Log Out

My Workspaces Study Submission Routing Signoff Back

Save Signoff

Study Title: Demo Study
Submission Reference Number: 1626416

Create PDF Packet

Submission Form(s):

Include in PDF Packet	Compare to Last Approved	View in Separate Window	Submission Component Name
<input type="checkbox"/>			Initial Review Submission Form
Application			
<input type="checkbox"/>			Study Application
Document(s)			
Category : Protocol			
<input type="checkbox"/>			Study Protocol
Category : Reducing Implicit and Explicit Bias in Research Form			
<input type="checkbox"/>			Bias form

Scroll Down a little

Attestation Statement

By selecting "Approve" and providing my electronic signature on this certification, I am certifying that

- All information in this application is correct, including confirmations of compliance with requirements for training, recruitment methods, and the filing of all required financial interest disclosure forms.
- I will comply with the following PI responsibilities:

- 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
- Personally log into the electronic system using their individual username and password as an electronic signature; and
- Provide information to the HRPP that is complete and accurate to the best of their knowledge; and
- 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 of all human subjects, 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 ensure 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 safety;
- 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 safety;
- 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 required training, qualifications, credentials, and licenses; and are trained on and appropriately delegated responsibility for study procedures; and
- Not initiate any human subjects research activities until an IRB final outcome letter has been received and all required institutional approvals have been obtained; and
- Be responsible for execution and management of the study, including oversight of all study personnel and any sub-awardees/subcontractors under their direction; and
- Comply with all applicable terms, conditions, assurances and certifications referenced in the application, award (grant or contract), and protocol; and with all applicable state, federal, and local policies (including those pertaining to IRB requirements, patient confidentiality, HIPAA, debarment, finances and record retention) related to this study; and
- Follow the IRB-approved research plan by recruiting subjects in a fair and equitable manner; by adhering to the approved inclusion and exclusion criteria; by following the approved process for obtaining and documenting informed consent; by meeting all applicable HIPAA and other data security requirements; by maintaining the privacy of subjects; by responding to subjects, prospective subjects, and family members who request information or have concerns or complaints; and by providing aggregate and de-identified information to the IRB; and
- Maintain all required records, including documentation (regulatory documents, source documents, and study data) that demonstrates compliance with the IRB-approved study application sponsor, or government agency; and
- Comply with all requirements for identifying and reporting Unanticipated Problems, Adverse Events, deviations, and safety monitors' reports, and any other new or significant information and

As the PI, you need to read the "PI Responsibilities" list before signing off.

You are still in the PI's "Submission Routing Signoff" page.

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

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

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<input type="checkbox"/>		Initial Review Submission Form
Submission Form(s):		
Application		
<input type="checkbox"/>		Study Application
Document(s)		
Category : Protocol		
<input type="checkbox"/>		Study Protocol
Category : Reducing Implicit and Explicit Bias in Research Form		
<input type="checkbox"/>		Bias form

Attestation Statement

By selecting "Approve" and providing my electronic signature on this certification, I am certifying that

- All information in this application is correct, including confirmations of compliance with requirements for training, recruitment methods, and the filing of all required financial interest disclosure forms.
- I will comply with the following PI responsibilities:

- 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
- Personally log into the electronic system using their individual username and password as an electronic signature; and
- Provide information to the HRPP that is complete and accurate to the best of their knowledge; and
- 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 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
- 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
- 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
- Not initiate any human subjects research activities until an IRB final outcome letter has been received and all required institutional approvals have been obtained; and
- Be responsible for execution and management of the study, including oversight of all study personnel and any sub-awardees/subcontractors under their direction; and
- Comply with all applicable terms, conditions, assurances and certifications referenced in the application, award (grant or contract), and protocol; and with all applicable state, federal, and local laws, rules, regulations, policies, and guidelines, as well as institutional policies (including those pertaining to IRB requirements, patient confidentiality, HIPAA, debarment, finances and record retention) related to this study; and
- 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 maintaining the process for obtaining and documenting informed consent; by meeting all applicable HIPAA and other data security requirements; by maintaining the privacy of subjects' response to subjects, prospective subjects, and family members who request information or have concerns or complaints; and by providing aggregate and/or individual data to the sponsor, or government agency; and
- Maintain all required records, including documentation (regulatory documents, source documents, and study data) that demonstrates compliance with the IRB-approved sponsor, or government agency; and
- Comply with all requirements for identifying and reporting Unanticipated Problems, Adverse Events, deviations, and safety monitors' reports, and any other new or revised information; and
- 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 immediate and necessary to protect the safety of subjects; that a status check-in is provided before the due date for studies without expiration dates; and that a Final Report is submitted prior to the study expiration date; that a status check-in is provided before the due date for studies without expiration dates; and that a Final Report is submitted prior to the study expiration date; and that a Final Report is submitted prior to the study expiration date.

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

1 Save Signoff 2

1- Check "Approve"
2- Click on "Save Signoff".
This will forward this submission to the next signoff.

Note: Please never "Deny" the submission here. Instead, you or a study team can retract the submission for more changes by following these instruction:
<https://www.bumc.bu.edu/irb/files/2016/10/How-to-retract-a-submission.pdf>

The system will transition you to the “Studies Submission Status - In Progress” section in your Home page where you can check submission progress including signoff progress.

To check on a submission status anytime after submission, go to your Home page and scroll down to this section.

45 result(s) found... 1 - 10 ▶

Click to open Study Dashboard	Reference Number	Review Board	IRB Number	Form Name	Study Title		Form Author	Date Submitted	Actions
					Study Alias				
	1626416	IRB	H-44278	Initial Review Submission Form	Demo Study	Demo	Administrator	11/14/2023 09:56 AM EST	Incomplete Tasks Open Steps to Complete
Pre-Submission									
Task Status	Task Action/Details	Task Name							
		Pre-Submission						11/14/2023 09:54 AM EST	Retract Submission

2. Click on the “+” icon to display all the steps taken by this submission

1. Click on the “Steps” icon to expand it

Questions

If you need help with the INSPIR System, feel free to call me between 7:30 AM and 3:30 PM.

Khaled Khattar

IRB INSPIR Application Administrator

Phone: 617-638-7203, Email: kkhattar@bu.edu