

Adding/Removing Administrative Assistants or Study Contacts from an Already Approved Study




Administrative Assistants

- Only BU/BMC faculty/staff/students who will not have any contact with human subjects or their identifiable data during the study can be added as an Administrative Assistant.
- Administrative Assistants would show up in Section 3 of the IRB application.
- In order to be listed, an Administrative Assistant **MUST** have an INSPIR account
- Study team can add/remove an Administrative Assistant anytime without having to submit any forms to the IRB.


Study Contacts

- This role is given to anyone on the study who needs to receive the study email notifications and tasks about the study.
- This is not a real role on the study. Before anyone can be added as a Study Contact on the study, they need to have a real role on the study and thus they need to be listed somewhere else on the study such as a study staff , co-investigator, or Administrative Assistant.
- A Study Contact will also have a task created in their “Incomplete Tasks” screen every time there is a task related to this study .
- Study Contacts would show up in Section 3 of the IRB application.
- By default, a Principal Investigator will be listed as a Study Contact and will receive all study correspondence and tasks.
- Study team can add/remove a Study Contact anytime without having to submit any forms to the IRB.



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CAMPUS




BOSTON
MEDICAL


CENTER


Account: Khaled Khattar, BA


Department: BMC/BUMC - MED - Institutional Review Board

Path: [Home](#)


[Announcements](#)


[Help](#)


[My Profile](#)


[Log out](#)

My Workspaces


IRB Number: **H-31000**

Study Alias: 2-18-2011-

PI: Administrator

Study

Submissions


[Back](#)

Click on “Study Management”- blue arrow

IRB Number: **H-31000**
PI: Administrator, BA

Study Management

Back

Study Status: **Approved / Open - Expedited** IRB Number : **H-31000** Study Title : Testing
IRB Expiration Date: 02/16/2015

Submissions **Study Management**

Study Details

- Study Summary/Profile
- Screen Access
- Key Personnel**
- External Personnel
- Department Access

Click on "Key Personnel"

Study Tasks

- Study Notebook

Sponsors & Subrecipients

- Sponsor

Drugs and Devices

- Drug/Biologic/Chemical agents
- Devices

Enrollment Criteria

- Inclusion Criteria

Adding an Administrative Assistant or Study Contact

(To remove an Administrative Assistant or Study Contact skip to
slide 15)



This opens the “Define Study Access” page.

BOSTON UNIVERSITY
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MEDICAL

EXCEPTIONAL CARE. WITHOUT EXCEPTION.

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

Announcements 7

Help

My Profile

My Workspaces

Study

Define Study Access

Back

IRB Number: H-31000

Study Alias: 2-18-2011-

PI: Administrator

Study Status: Exempt - limited IRB

IRB Number : H-31000

Study Title : Testing

Save Access to the Study

Active

History

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
Administrator	Principal Investigator	View Training Record

Responsibility
☐ Student
☐ Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Sponsor must be supplied BOTH in Section 3.3 (Study Contact) AND in Section 3.2

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 data analysis, either as Co-Investigators in A) or as Research Support Staff in B):.

A) Additional Investigators

Name	Role	Training Record
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Click on “Click Here to Setup Personnel” button - blue arrow

This opens the “Setup Study Personnel” pop-up page.

The screenshot shows the 'Setup Study Personnel' window. A green arrow labeled '1' points to the 'Last Name' input field. A blue arrow labeled '2' points to the 'Find User/Search Directory' button. Below the search fields is a table with columns: Select, Training, Name, Department, and Email. The table currently shows 'No results found'. To the left of the table is an information icon and text: '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.'

1- Enter the last name (green arrow)
2- Click on “Find User/Search Directory” button (blue arrow)

Selected Study Personnel:

Principal Investigator	
Name	Role
Administrator	Principal Investigator

Additional Investigators

Name	Role
Crowley, Emily, MPH	Co-Investigator
Finn, Brandon, BA, CIP, Senior IRB Analyst	Co-Investigator

Tip – The “User Search by Study” filter should stay as “All Departments” to avoid filtering out some users. If you still can’t find this person in INSPIR, this means that they had never logged in to INSPIR before. Please have them follow the instructions in this link (<https://www.bumc.bu.edu/irb/files/2016/10/Access-to-INSPIR.pdf>) to create their INSPIR account.

Setup Study Personnel

User Search by Study

Create My Personnel Pool


Last Name: khattar

First Name:

User Search by Study: All Departments

Find User/Search Directory

i 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.

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

Once you have found the name you are looking for, click on the "Select" icon (red arrow) to add this person to the personnel list.


Principal Investigator

Name	Role
Administrator	Principal Investigator

Additional Investigators

Name	Role
Crowley, Emily, MPH	Co-Investigator
Finn, Brandon, BA, CIP, Senior IRB Analyst	Co-Investigator
Franco, Daly, BA, CIP, Senior IRB Analyst	Co-Investigator

Close Setup of Study Personnel

Name	Role	Training Record
Crowley, Emily, MPH	Co-Investigator	 View Training Record

This opens the “Add Personnel Role” pop-up page.

Setup Study Personnel

Add Personnel Role

Select the Role for **Khaled Khattar, BA** :

☐ Study Contact

☐ Department Administrator

☐ Administrative Assistant

--none--

- If you are adding a Study Contact, select the corresponding radio button (red arrow)
- If you are adding an Administrative Assistant, select the corresponding radio button (blue arrow)

Once you have selected the role, click on the “Save” button (green arrow).

Cancel Save

Name	Role	Training Record
Crowley, Emily, MPH	Co-Investigator	View Training Record

User Search by Study

Create My Personnel Pool

Last Name:

User Search by Study:

First Name:

Select	Training	Name	Department	Email
<input checked="" type="checkbox"/>		Khattar, Khaled, BA		Institutional Review Board (primary)

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.

Notice that the person we just added now appears in the personnel list (blue arrow). To add more personnel, repeat steps in screens 10 – 13.

Selected Study Personnel:

<input checked="" type="checkbox"/>	Khattar, Khaled, BA	Department Chair
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Administrative Assistant

	Name	Role
<input checked="" type="checkbox"/>	Alvarenga, Jorge	Administrative Assistant
<input checked="" type="checkbox"/>	Ennever, Fanny Knox, PhD	Administrative Assistant
<input checked="" type="checkbox"/>	Khattar, Khaled, BA	Administrative Assistant
<input checked="" type="checkbox"/>	Merrill, Jamie, MPH, IRB Director	Administrative Assistant
		Administrative Assistant

When you are done adding personnel, click on “Close Setup of Study Personnel” button (green arrow).

Selected Study Personnel:

(X) | Khattar, Khaled, BA

Administrative Assistant

	Name	Role
(X)	Alvarenga, Jorge	Administrative Assistant
(X)	Ennever, Fanny Knox, PhD	Administrative Assistant
(X)	Khattar, Khaled, BA	Administrative Assistant
(X)	Merrill, Jamie, MPH, IRB Director	Administrative Assistant
11:	1 1: 1	Administrative Assistant

Close Setup of Study Personnel

Crowley, Emily, MPH

Co-Investigator

 [View Training Record](#)

This brings you back to the “Define Study Access” page.

Study Status: Exempt - limited IRB ▾

IRB Number : H-31000

Study Title : Testing

Active

History

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

Save Access to the Study

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
Administrator	Principal Investigator

Responsibility

☐ Student

☐ Resident

☐ Fellow

Click on “Save Access to the Study” button (blue arrow) to save your changes

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Supervising Principal Investigator (formerly known as Faculty Sponsor) must be supplied BOTH in Section 3.3 (Study 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 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 data analysis, either as Co-Investigators in A) or as Research Support Staff in B):.

A) Additional Investigators

Name	Role	Training Record
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Removing an Existing Administrative Assistant or Study Contact



The following instructions are for removing an existing Administrative Assistant or Study Contact from a study

My Workspaces ▾

IRB Number: **H-31000**

Study Alias: 2-18-2011-

PI: Administrator

Study

Define Study Access

◀ Back

Study Status: Exempt - limited IRB ▾

IRB Number : H-31000

Study Title : Testing

Save Access to the Study

- Active
- History

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
Administrator	Principal Investigator	View Training Record

Responsibility

☐ Student

☐ Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Sponsor must be supplied BOTH in Section 3.3 (Study Contact) AND in Section 3.2

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 data analysis, either as Co-Investigators in A) or as Research Support Staff in B):.

A) Additional Investigators

Name	Role	Training Record
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Click on “Click Here to Setup Personnel” button - blue arrow

Setup Study Personnel
X

User Search by Study

Create My Personnel Pool

i 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:

First Name:

User Search by Study:

All Departments

Find User/Search Directory

Select	Training	Name	Department	Email
No results found				

Selected Study Personnel:

Principal Investigator

	Name	Role

Additional Investigators

	Name	Role
	Crowley, Emily, MPH	Co-Investigator
	Finn, Brandon, BA, CIP, Senior IRB Analyst	Co-Investigator
	Franco, Daly, BA, CIP, Senior IRB Analyst	Co-Investigator

Close Setup of Study Personnel

Back

Go to the Study

?

?

Name	Role	Training Record
Crowley, Emily, MPH	Co-Investigator	<div style="display: flex; align-items: center;"> View Training Record </div>

X

Create My Personnel Pool

First Name:

All Departments

[Find User/Search Directory](#)

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.

Training

Department

Email

No results found

Principal Investigator

I

	Name	Role
	Crowley, Emily, MPH	Co-Investigator
	Finn, Brandon, BA, CIP, Senior IRB Analyst	Co-Investigator
	Franco, Daly, BA, CIP, Senior IRB Analyst	Co-Investigator

Close Setup of Study Personnel

Crowley, Emily, MPH

[!\[\]\(b64b40baaee5acddc1eab8538ba84754_img.jpg\) View Training Record](#)

Setup Study Personnel

User Search by Study

Create My Personnel Pool



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:

First Name:

User Search by Study:

All Departments

Find User/Search Directory

Select

Training

Name

Department

Email

No results found

- 1- Click on the "Delete" icon to delete a specific personnel (blue arrow).
- 2- When you're done removing personnel, click the "Close Setup of Study Personnel" button (green arrow) to close this pop-up page.

1

X

X

X

Name

Role

Alvarenga, Jorge

Administrative Assistant

Ennever, Fanny Knox, PhD

Administrative Assistant

Khattar, Khaled, BA

Administrative Assistant

Merrill, Jamie, MPH, IRB Director

Administrative Assistant

Roth, Mary-Tara, RN, MSN, MPH

Administrative Assistant

2

Close Setup of Study Personnel

Crowley, Emily, MPH

Co-Investigator

View Training Record

This brings you back to the “Define Study Access” page.

Study Status: Exempt - limited IRB

IRB Number : H-31000

Study Title : Testing

Active

History

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Administrator	Principal Investigator

Responsibility

☐ Student

☐ Resident

☐ Fellow

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A) Additional Investigators

Name	Role	Training Record
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Click on “Save Access to the Study” button (blue arrow) to save your changes

Save Access to the Study

Click Here to Setup Study Personnel