## How to create a new study draft in INSPIR II

STON VERSITY DICAL MPUC

your last login was 10/11/2022 08:16 AM EDT Study Assistant

Hello Khaled Khattar, BA

My Workspaces 🛛 🖃

Featured Study Operations								
Create a New Study								
Start a Sur Form for one of My Studies								
View the C	pprovals for one of My Studies							
View the S	on History for one of My Studies							
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	By the Numb	ers	
Submissions in Process 54	Forms Pending Submission 53	Pending My Response 4	Higl
	Tasks		
All Tasks		3	5
Study Tasks			3

When you login into INSPIR II (<u>https://inspir.bu.edu/</u>), 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.

BOSTON UNIVERSITY MEDICAL CAMPUS	(?) Help ▲ My Profile
My Workspaces Study Study Application	🗹 Back 🕻
Section view of Application Entire view of the Application	Save Section Save and Continue to Next Section +
1.0 B 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.

BOSTON UNIVERSITY MEDICAL CAMPUS	ON P		ED - Institutional Review Board			? Help	My Profile -	Log out
My Workspaces	■ IRB Number: H- Study Alias: Dem	4278 Study	Study Application (Version 1.0)					🖪 Back
Section view of App	lication Entire vie	v of the Applicatio	1		Print Friendly	Save Section	Save and Continue	e to Next Section
1.0   General Informat     2.0   Setup Department     Access	at(s) 2.1 List d that t appro	e primary depart riate "section" sl	ted with this study (Note: The primary departme nent listed is correct (in some cases the "default"	nt should accurately reflect the primary Department department of BU/BMC Medicine has been selected) he PI is from Neurology or Infectious Disease). If the	. For large departi	ments, the PI's		
		<i>,</i>	Inent Name JMC - MED - Institutional Review Board		Ac	dd Department		partment
	not, arrows You	check ). The can ac	the small box to n click on "Add" t d multiple depa	department listed the left and click of to add the right de rtments if multipl "Save and Continu	on "Re partm e ones	emove ient (: are i	e" (gree red arr nvolvee	en ow). d.

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	Account: Administrator Department: BMC/BUMC - <i>MED</i> - Institutional Review Board Path: Home		? Help	My Profile 🕶	C Log out
	Number:         H-44278 Demo         Study         Study Application (Version 1.0)				🖪 Back
		Print Friendly	Save Section	Save and Continue to	o 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	3.0 List of Internal (BMC/BUMC) Study Personnel. All personnel listed in this section will have access (limited or full access).	s to this study	Click H	ere to Setup Study Perso	onnel
to the study	3.1 * <u>Please add a Principal Investigator for the study:</u> (Note: Only <u>faculty members</u> can serve as Principal Investigators on IRB protocols for studies at the <u>School of Dental Medicin</u>	<u>ne)</u> :			?
	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 sub of any research related activities, including enrollment, consenting, collection of study data, interventions, long-term follow-u or as Research Support Staff in B).:		ifiable data in the	performance	
	A) Additional Investigators	Т	<mark>o fill o</mark>	ut this	
	Name Role	Sec	rtion	<mark>click on</mark>	
	No Additional Investigators have been added		· · ·		
	B) Research Support Staff			e to Set	up
	Name Role		Key S	tudy	
	No Research Support Staff have been added	Per	sonne	l" butto	n
	3.3 * Please add a Study Contact:	(	<mark>blue a</mark>	rrow).	

#### 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.

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UNIVERSITY MEDICAL CAMPUS		Setup Study Personal		
My Wo	User Search by Study	Last Name: Khattar	First Name:	Find User/Search Directory
11, 110		User Search by Study: All Departments	<b>v</b>	
	① This section is used to build the list of personnel on the	Select Training Name Department	Email	Section
Section	study. User Search by Study allows you to search for a			
1.0 🖹 Gene 2.0 🗎 Setu	named person and associated them with a role	No results found		
	on the study.			
3.0 Crant				
		Selected Study Personnel:		
		Principal Investigator		ii
		Name	Role	
		No Personnel has been selected for this group.		
		Additional Investigators		•
		Name	Roie	
		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-bystep instructions in the link below to login and create their INSPIR account: <u>http://www.bumc.bu.edu/irb/files/2016/10/Access-to-INSPIR.pdf</u> 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 Perso	nnel			× Log o
User Search by Study	Last No.	re: Khattar	First Nam V	ne:	Find User/Search Directory	] Ba
This section is used to build the list of personnel on the study. User Search by Study.	Select - Na	-	Department	Email		Sectio
allows you to sea named person an associated them with a role		Khaled, BA	() Institutional Review Board (primar	y) kkhattar@bu	u.edu	
on the study.						J
						)
	Selected Study Personnel	1:				_
	Principal Investigator					î 📰
	Name			Role		
	No Personnel has been selected for	or this group.				
	Additional Investigators					
	Name			Role		
	No Personnel has been selected f	or 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: <u>http://www.bumc.bu.edu/irb/files/2016/10/Access-to-INSPIR.pdf</u>

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).

EDICAL A M P U S			Setup Study Personnel		x Log out
My Wo	User Search by Study		Add Personnel Role	× Find I	User/Search Directory
Section	<ul> <li>This section is used to by the list of personnel on t study. User Search by St</li> </ul>	elect the Role for Khaled Khattar, BA :		· · · · · · · · · · · · · · · · · · ·	Section
B Gene Setur Gran to th	allows you to search for named person and associated them with a r on the study.	Principal Investigator	Supervising Principal Investigato	Resident edu Student, Resident, or Fellow, the name of the or (formerly known as Faculty Sponsor) must be tudy Contact) AND in Section 3.4 (Supervising Principal	
		O Additional Investigators	none	~	
		O Research Support Staff	none	~	
		O Study Contact			
		O Supervising Principal Investigator			
		O Department Administrator	none	~	
		O Administrative Assistant			
	v	Vould you like to include as a Study Contact	? Yes O No	Cancel Save	
				Close S	Setup of Study Personnel
					4

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 <u>slides 7</u> 10.
- If you are done selecting all study personnel, you would click on "Close Setup of Study Personnel" button (yellow arrow).

UNIVERSITY MEDICAL CAMPUS				Setup Study Per	sonnel					x	Log out
My Wo	User Search by Study Create My Personnel Pool		User Sea	Last Name: Khattar Irch by Study: All Departments	]	First Name:			Find User/Search Directory		Back
Section	This section is used to build	Select	Training	Name		Department		Email			Section
1.0 🖹 Gene	the list of personnel on the study. User Search by Study allows you to search for a	දු	ଙ୍କ	Khattar, Khaled, BA	(ì	Institutional Review Board (primary)		kkhattar@bu.	edu		
2.0 🖹 Setur 3.0 🗎 Grant to the	named person and associated them with a role on the study.										)
		Selected	Study P	ersonnel:							
		Principal I	nvestigato	r						î	
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	e: You need to list a Principal Investigat		ist th	e following:			ole Clear Key Study F		Close Setup of Study Personnel		
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- 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)

BOSTON UNIVERSITY MEDICAL CAMPUS	Account: Administrator Department: BMC/BUMC - MED - Institutional Review Board Path: Home			? Help	My Profile 👻 🚺 🗲 Log	out
	Number: H-44278 Study Study Application (Ver	rsion 1.0)			💽 Ba	ack
			Print Frie	endly Save Section	Save and Continue to Next Sect	tion
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 Personn (limited or full access).	el. All personnel listed in this	s section will have access to this s		e to Setup Study Person	
	3.1 * <u>Please add a Principal Inves</u> (Note: Only <u>faculty members</u> rve as Principal Inves	tigators on IRB protocols for studies	at the <u>School of Dental Medicine</u> ) :			
	Name	Role	Training I	Record		
	Khaled Khattar, BA	Principal Investigator		w Training Record		
	Responsibility         Student         Fellow         If the Principal Investigator is a Student, Resident, or Fellow, Contact) AND in Section 3.4 (Supervising Principal Investigator         3.2 If applicable, please select the Research Staff personnel. In of any research related activities, including enrollment, cor or as Research Support Staff in B).:         A) Additional Investigators	or) below.	Once you personnel, c Continue to N	click on "S	Save and	
	Name	Role	Trainin	ng Record		
	Finn, Brandon, BA, CIP, Senior IRB Analyst	Co-Investigator	✓ G <u>vi</u>	iew Training Record		
	Franco, Daly, BA, CIP, Senior IRB Analyst	Co-Investigator	✓ G <u>vi</u>	iew Training Record		
	Testerman, Mark, BS, CIP, Senior IRB Analyst II	Co-Investigator	<u>∽</u>	iew Training Record		
	Themelis, Lin, MA, CIP, IRB Administrator	Co-Investigator	<u>∽</u>	iew Training Record		

#### The system will transition you to Section 4.0 "Review Path Determination"

BOSTON UNIVERSITY MEDICAL CAMPUS	Account: Administrator Department: BMC/BUMC - <i>MED</i> - Path: Home	Institutional Review Board	Help	My Profile -	C+ Log out
My Workspaces Study	Number: H-44278	Study Application (Version 1.0)			🖪 Back
Section view of Application	Entire view of the Application	Print Friendly Save	e Section	Save and Continue to	o Next Section
1.0       General Information         2.0       Setup Department(s)	4.0	Review Path Determination			
3.0 Grant Key Personnel access to the study	4.1 Review Path Determination	a of Net Human Subject Research (NHCR). Examples are non-research Quality Improvement/Quality Accurace projector studies that is	involvo	(?	)
4.0 B Review Path Determination	obtaining anonymous data/tissu	n of Not Human Subject Research (NHSR). Examples are non-research Quality Improvement/Quality Assurance projects; studies that in ses or coded data; or BMC/BU Medical Campus is not 'engaged' in human subjects research. elying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement. is study involve chart reviews.	nvoive	Ċ	/
	<ul> <li>This study fits into one or more categories.</li> </ul>	of the federal Exempt categories or the study does not have external funding and fits into one or more of the Equivalent Protections Executives Expedited review or the review of the Full Board.	Exempt		
	4.2 Emergency Use Report				
		Use of an Investigational Drug or Device that has already occurred? For more information, click <u>here</u> . If Yes, please click <u>her</u> step by step instructions on how to submit this emergency use to the IRB.	<u>re</u> for a		
	• 1,1 ,			,1	

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 <u>branching</u> 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				Add Multiple Documents			
Detac	Version	Sponsor Version	Title		Category	Expiration Date	View Document
No Doo	ument(s) hav	e been attached	l to this f	orm.			

• If you decide to add a study document within the Study Application, please follow the instructions in this link:

https://www.bumc.bu.edu/irb/files/2016/10/How-to-Add-a-New-Study-Document.pdf

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

BOSTON UNIVERSITY MEDICAL CAMPUS	Account: Administrator Department: BMC/BUMC - <i>MED</i> - Institutional Review Board Path: Home > study mgmt.	? Help	My Profile 👻 🚺 C+ Log out
My Workspaces 🔳 🖪	RB Number: H-44278 tudy Alias: Demo Study Initial Review Submission Form - (Version 1.0) Initial Review Submission Form - (Version 1.0)		🖪 Back
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Initial Review Subr	nission Packet		Î
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Study Title:			
Demo Study	and that the Study Application has been		
IRB Number:			
H-44278	built in the system and being attached to		
Principal Investigator:			
<b>PI Name:</b> Khaled Khattar, BA	this packet.		
PI Email Address:			
kkhattar@bu.edu			
PI Phone Number: (617) 638-7203			
Study Application F Attach the IRB application you	i completed for this prot		
(For an Initial Submission the	application will automate tach for you)		
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$\otimes$	Study Application (Version 1.0)		
Concert Decourse			
Consent Docume		ed below as part of this submission (click on the Heln (?) ic	on 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. Follow the instructions in this link:

- How to add a new Consent Form

NIVERSITY AEDICAL AMPUS	Account: Administrator Department: BMC/BUMC - <i>MED</i> - Institutional Review Board Path: Home > study mgmt.		(	?) Help 💄 My Profile 🗸 🕞 Log out
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Form				
PI Phone Number (617) 638-7203				
Study Applic	Form			
Attach the IRB app (For an Initial Subr	u completed for this protocol: e application will automatically attach for you)			
Deattach Rev Att:	Edît/ View Title		Scroll Down a	little
8	Study Application (Version 1.0)			
Consent Doc	ts			
In this section, y instructions):	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
Add a New Cor	ant			?
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No Consent(s) have been at		Language Expiration Date	Consent Outcome View Document	
Other Study Docu	nents			
	tached in the Study Application, DO NOT upload it again here. This will create duplicates of docum Id and attach any other study documents (e.g. protocol, investigators brochure, recruitment mater uctions.		ellaneous documents) <u>that have not been attached as p</u>	art of the Study Application. Click on the Help
Select or Revise B	Add a New Document Add Multiple Documents			?
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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. Follow the instructions in this link:

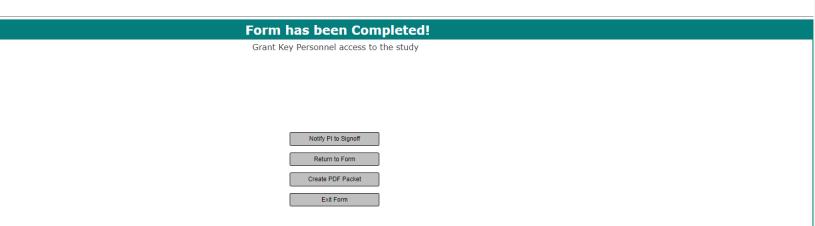
- How to add a new Study Document

BOSTON UNIVERSIT MEDICAL CAMPUS	· Institutional Re	view Board					(	? Help 💄 My	y Profile 👻 🏾 🏾	C+Log out
My Workspaces My Workspaces My Khatar, Khaled, BA	Initial Rev	iew Submission Form - (Version 1	.0)							🖪 Back
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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	r you)								_	
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Other Study Documents										
If a document was already attached in the Study Application In this section, you can upload and attach any other stu- icon (?) on the right for instructions.	t upload it aga .g. protoco	in here. This will create duplicates of docu I, investigators brochure, recruitment mat	nents which will need to be verials, instruments, case repo	o <mark>ided later.</mark> rt forms, study handou	ts or other miscel	llaneous documents) <u>that h</u> a	ave not been attached as	part of the Study Appli	<u>ication</u> . Click or	n the Help
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BOSTON UNIVERSITY MEDICAL CAMPUS     Account: Administrator       Department: BMC/BUMC - MED - Institutional Review Board       Path: Home > study mgmt.	(?) Help Log out
My Workspaces My King Katas Chamber: H-44278 Study Alias: Demo PI: Khattas Khaled, BA Study Alias: Demo	<b>E</b> Back
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Additional Special Routing	
<ul> <li>Your submission might be routed automatically to one or more "Special Routing" signoffs. For more information, click <u>here</u>.</li> <li>You can track your submission by following the instructions <u>here</u>.</li> </ul>	C 11 1 1
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 re Implicit and Explicit Bias in Research	Scroll down and
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, embedo 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 recomme and minimize racism, sexism and other forms of bias in research design and reporting. Please see the <b>Report from the Committee to Reduce Implicit and Explicit Bias</b> in Research for further information.	answer all the
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.	"Additional Special
<u>Reduction of Explicit and Implicit Bias in Research Form</u>	<b>⊥</b>
Select or Revise Existing         Add a New Document         Add Multiple Documents	Routing" questions.
Detach Version Sponsor Version Title Category Expiration Date Document Outcome	And when you're
No Document(s) have been attached to this form.	3
In-person Interaction at BMC	done, click on "Save
Does this study involve in-person interaction with research subjects in Boston Medical Center (BMC) space?	Form".
○ 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 regard	dless of their employment status.)
○ Yes ○ No	
Perinatal Research Review Committee	
Does your research fall under any of the following categories:	



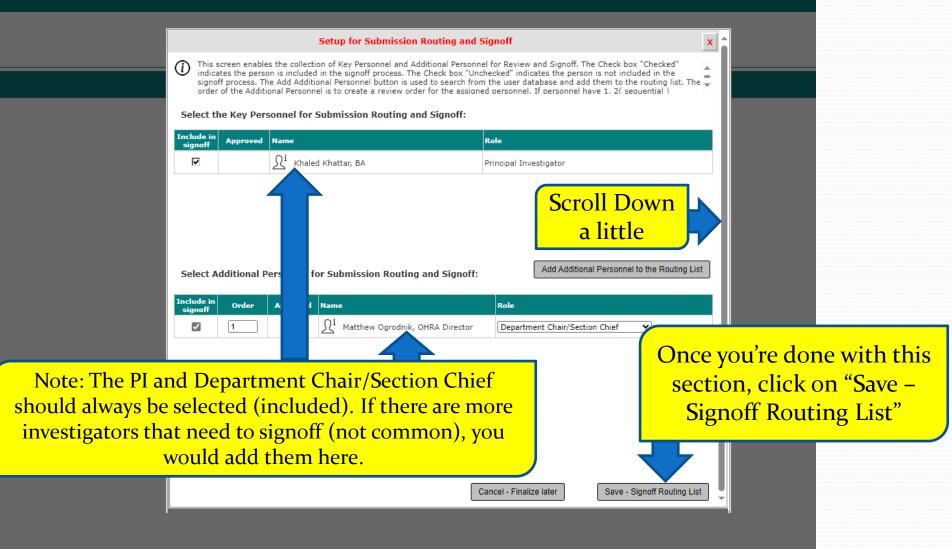
Form



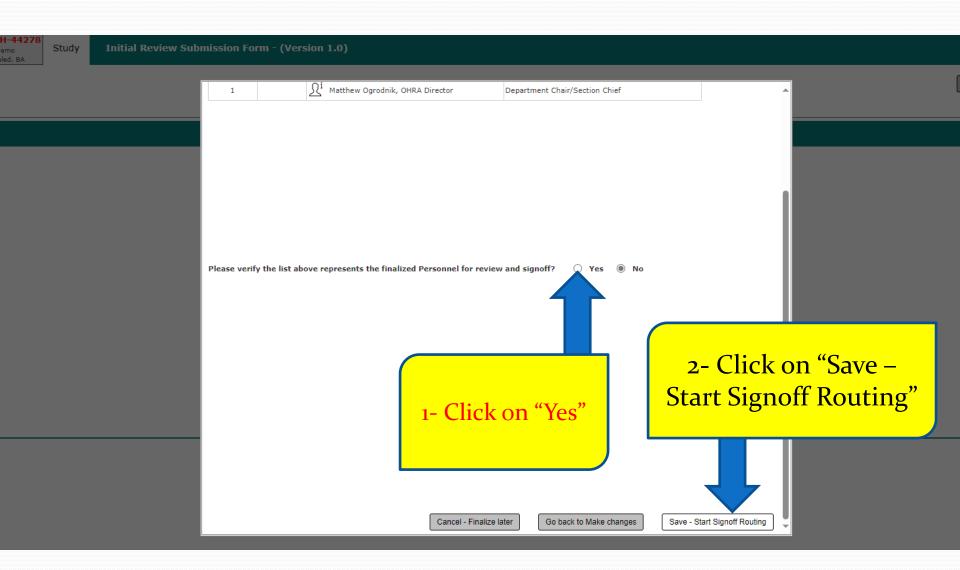
You can click on "Exit Form" to exit this submission and complete later. If you're ready to submit, click on "Signoff and Submit" (not visible here) if you are the PI; or if you are someone other the PI, click on "Notify PI to Signoff".

## 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)



## If you have clicked in the previous screen on "Save – Signoff Routing List", the system will bring you to this screen.



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

BOSTON UNNERSITY MEDICAL CAM PUD: Common Low windor teamon. Common Low windor teamon. Common Low windor teamon. Common Low windor teamon.		utional Review Board		(	Announcements 7	? Help	My Profile +	C+ Log out
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Attestation Statement								
By selecting "Approve" and providing my electronic sign	ture on this certif	fication, I am certifying tha	t					
<ul> <li>All information in this application is correct, includ</li> <li>I will comply with the following PI responsibilities</li> </ul>		of compliance with require	ments for training, recruitment methods, and the filing of all required financial int	nterest disclosure forms.				
safety, to draw subjects from a population selected to 5. Determine that adequate resources will be available to 6. Ensure that prior to beginning work on the study, the required training, qualifications, credentials, and licen 7. Not initiate any human subjects research activities un 8. Be responsible for execution and management of the s 9. Comply with all applicable terms, conditions, assuranc policies (including those pertaining to IRB requirement 10. Follow the IRB-approved research plan by recruiting su process for obtaining and documenting informed conss response to subjects, prospective subjects, and family 11. Maintain all required records, including documentation sponsor, or government agency; and	dividual username ai cocurate to the best udy, to adhere to eth distribute the risks? carry out the study, rrincipal Investigatou es; and are trained il an IRB final outcou tudy, including over es and certifications s, patient confidenti ibjects in a fair and nt; by meeting all a members who requu (regulatory docume	and password as an electronic of their knowledge; and thical principles and standards and benefits fairly, to employ y, including facilities, access to on and appropriately delegat meletter has been received a rsight of all study personnel a referenced in the application, iality, HTPAA, debarment, fina applicable HTPAA and other da dest information or have conce ents, source documents, and s	signature; and appropriate to their discipline, to safeguard the rights and welfare of all human sub an appropriate population, medical and psychological resources for subjects, and a critch team meet all applicable Boston Medical Center and Boston University require dr responsibility for study procedures; and nd all required institutional approvals have been obtained; and di any sub-awardees/subcontractors under their direction and award (grant or contract), and protocol; and with all a to the approved inclusion and exclusion criteria a security requirements; by maintaining the privac	As the PI, read Responsil before si	the "PI bilities'	' list		

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

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By selecting "Approve" and p	rovidina	my electronic signa	ture on this	certification. I a	m certifying t	at least state of the second st				
All information in this a	applicatio	on is correct, includ	ing confirma			 ements for training, recruitment methods, and the filing of all required financial interest disclosure forms.				
<ul> <li>I will comply with the f</li> </ul>	following	PI responsibilities:								
<ol><li>Personally log into the e</li></ol>	electronic	system using their ind	dividual userna	ame and password	as an electroni	bout whether submission to the IRB is required; and signature; and				
	ct individu	als conducting the stu	udy, to adhere	to ethical principl	es and standard	appropriate to their discipline, to safeguard the rights and welfare of all human subjects, to minimize risks, to have adequate provi				
<ol><li>Determine that adequat</li></ol>	te resourc	es will be available to	carry out the	study, including fa	cilities, access	additional safeguards necessary to protect vulnerable populations, to safeguard research data, and to meet all applicable HIPAA req o an appropriate population, medical and psychological resources for subjects, and sufficient time from himself or herself and staff to	o conduct the research; and			
required training, qualif	ications, o	credentials, and licens	es; and are tra	ained on and appr	opriately delega	earch team meet all applicable Boston Medical Center and Boston University requirements for the disclosure and management of cor ed responsibility for study procedures; and	iflicts of interest; have all			
<ol><li>Be responsible for exec</li></ol>	ution and	management of the s	tudy, including	g oversight of all s	tudy personnel	and all required institutional approvals have been obtained; and nd any sub-awardees/subcontractors under their direction; and , award (grant or contract), and protocol; and with all applicable state, federal, and local laws, rules, regulations, policies, and guide	elines, as well as institutional			
policies (including those	e pertainir	ig to IRB requirement	s, patient conf	fidentiality, HIPAA,	debarment, fin	, awar (grant or contract), and protocol, and with an approach state, rederar, and local laws, rules, regulations, policies, and guide nces and record retention) related to this study; and g to the approved inclusion and exclusion criteria and maintaining	sines, as well as institutional			
process for obtaining an	nd docum	enting informed conse	nt; by meetin	ig all applicable HI	PAA and other d	ta security requirements; by maintaining the privacy of subject	,,			
<ol> <li>Maintain all required re- sponsor, or government</li> </ol>	cords, inc agency;	luding documentation and	(regulatory do	ocuments, source	documents, and	study data) that demonstrates compliance with the IRB-appro 1- Check Appro	ve			
<ol> <li>Comply with all requirer and</li> </ol>	ments for	identifying and report	ing Unanticipa	ated Problems, Adv	verse Events, d					
						sent form, or study personnel unless the change is immedes without expiration dates; and that a Final Report is sublease <b>2–</b> Click on "Save	e Signof	f"		
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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.

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## To access/view this draft once you close out of it, follow the instructions in the link below:

<u>https://www.bumc.bu.edu/irb/files/2016/1</u> <u>0/How-to-open-a-draft-INSPIR-II-</u>

protocol.pdf

## Other INSPIR II Help Resources

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

investigators/)

- <u>How to log-in to INSPIR II</u>
- How to update your Personal Profile
- How to get the Study Assistant tab if you don't have it
- How to open a draft INSPIR II protocol
- How to sign off on protocol as PI
- How to sign off on protocol by Department Chairs
- How to add new internal investigators/research staff
- How to add external investigators
- How to respond to a Review Response for an Initial Review
- How to create and submit a Progress Report
- How to respond to a Review Response for a Continuing Review
- How to create and submit an Amendment
- How to respond to a Review Response for an Amendment
- How to add a new Consent Form
- How to revise an existing Consent Form
- <u>How to add a new Study Document</u>
- How to revise an existing Study Document