

From: [IRB](#)
To: [IRB](#)
Subject: OSU/OHSU Research Collaborations - New Instructions
Date: Friday, February 20, 2015 4:13:26 PM
Attachments: [Adding OSU IRB Staff to study - screenshots.2.17.2015.docx](#)

Dear Investigators,

You are receiving this email because you are an OSU employee who either conducts human subjects research at OHSU or collaborates with an OHSU researcher. As you are aware, the OHSU and OSU IRBs have a Memorandum of Understanding (MOU) that enables OSU to defer oversight to OHSU under certain circumstances. After OSU makes the determination to defer oversight, it is the PI's responsibility to ensure that OSU receives a copy of all approval and approved documents from OHSU.

For your convenience, the OSU IRB Staff can now obtain those documents for you!

If you would like for the OSU IRB Staff to download the relevant documents directly from OHSU's electronic IRB system, please follow the instructions below. If you prefer, you may continue to download these documents yourself and email them to irb@oregonstate.edu **within 30 days of any action**. An OSU-specific Supplement is required in either case.

Step I. Submit an OSU-specific Supplement to OSU's IRB

1. Download and complete the OSU-specific Supplement so that the OSU IRB can determine whether or not to defer oversight to OHSU
2. The OSU IRB will issue a deferral notice when a determination is made

Step II. Submit the study to OHSU's IRB

1. Submit the study via OHSU's electronic IRB system

NEW! Step III. ADD "OSU IRB STAFF" TO THE STUDY TEAM

1. Log into the OHSU IRB system and go to the "Add Personnel Section"
2. In the "*Select Person" type "OSUIRB" and select OSUIRB Staff from the list
3. Under Responsibilities
 - a. select the "Administrative/Financial Responsibilities Only" box
4. Under Conflict of Interest
 - a. select "no" AND check the "The question above is not applicable..." box
5. Under Rights
 - a. select "no" to Edits Rights
 - b. select "yes" to Read Rights
6. Under Non-OHSU Personnel
 - a. select the "Check if this person is not affiliated with OHSU?" box
 - b. select "3. Other" for what type of agreement is in place
 - c. Type "MOU" in the "if other please explain" box
 - d. Select "yes" for "Is there a conflict of interest in research policy..."
 - e. Select "yes" for "Has this person completed RCR training?"

7. Under Customize E-mail Notifications
 - a. **DO NOT ADD OSU IRB TO EITHER LIST OF NOTIFICATIONS.**
8. Forward approval-related emails to irb@oregonstate.edu within 30 days of receipt.
When a submission of any kind has been approved, the OHSU system generates an email that the PI receives. Simply forward us the email to notify us that something has been approved. The OSU IRB Staff will take care of the rest!

Please note that you may also add OSU IRB Staff to studies that have already been approved.

The above instructions can also be found by viewing the [answer](#) to the FAQ on the IRB website.

I encourage you to look at the attached document which includes screen shots and visual instructions.

Please feel free to forward this email to any colleagues who may be considering collaborating with OHSU.

Type in 'OSUIRB' and select OSUIRB Staff from the list.

Add Personnel Extended

Personnel Selection

Use this page to add or edit members of the study team. If the person you are adding is not an OHSU employee (e.g. a collaborator from another university) they will first need to be added into the system. To add a non-OHSU person to the system, please start by filling out the following form, https://www.ohsu.edu/research/rda/eid_request.php.

* Select Person:

Responsibilities	Select Person			
	Last	First	Middle Name	Organization
Does this person	OSUIRB	Staff		Oregon Health & Science University

- ☐ Determine eligibility
- ☐ Consent subjects
- ☐ Primary study contact
- ☐ Administrative/Financial Responsibilities Only (this person has no involvement with subjects or study)

Select 'Administrative/Financial Responsibilities Only', indicate no Conflict of Interest and mark question not applicable:

Add Personnel Extended

<https://irb.ohsu.edu/irb/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?po...>

Add Personnel Extended

Personnel Selection

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* Select Person: [Staff OSUIRB](#)

Responsibilities

Does this person have any of the following responsibilities? (Check all that apply.)

- ☐ Determine eligibility
- ☐ Consent subjects
- ☐ Primary study contact
- ☒ Administrative/Financial Responsibilities Only (this person has no involvement with subjects or study data)
- ☐ Data analysis
- ☐ Analysis of unanticipated problems (UPs)/adverse events

Conflict of Interest

* Do you have a potential conflict of interest with this study? ☐ Yes ☒ No [Clear](#)

"Yes" indicates that you have a significant financial interest in the sponsoring agency or manufacturer/licensee of investigational product under study. If you have only administrative responsibilities for this study and have no involvement with subjects or study data, answer this question as "no". To view the conflict of interest policy, please visit: <http://www.ohsu.edu/xd/research/about/integrity/coi/>

☒ The question above is not applicable because I have only administrative responsibilities for this study and have no involvement with subjects or study data (check this box and check "no" to the potential Col question above)

Principal Investigator Questions

Indicate 'No' to Edit Rights and 'Yes' to Read rights:

Principal Investigator Questions

The following questions pertain only to the Principal Investigator.

Is the Principal Investigator a licensed physician or dentist with clinical privileges at OHSU OR a nurse practitioner or physician's assistant at OHSU providing procedures within the scope of licensure? ☐ Yes

☐ No [Clear](#)

Is the Principal Investigator qualified to conduct research at OHSU?

☐ Yes ☐ No [Clear](#)

For clarification, see the [investigator eligibility requirements](#).

Rights

In this section you need to declare what rights this individual has on the study (only this study, this does not affect their rights on any other study).

* ☐ Yes ☒ No [Clear](#) **Edit rights** - Allows the person to edit forms (e.g. IRQ, CRQ, Modification), upload and delete documents associated with the study, read all information associated with this study. **Principal Investigators must have edit rights in order to submit forms.**

* ☒ Yes ☐ No [Clear](#) **Read rights** - Allows a person to read all information associated with a study including uploaded documents. They may not, however, edit anything related to the study.

No rights - It is possible in certain situations that a person is a member of the study team, but is not allowed to read, or edit anything associated with the study. For example, if certain staff are blinded you may not allow them access to information that would potentially unblind them. To give a person no rights, select "no" to both the Edit and Read rights questions above. **If you do not give a person read or edit rights, they will not receive emails regarding this study.**

OHSU Student

☐ I am an OHSU student.

Non-OHSU Personnel

Check that person is not affiliated with OHSU, that there is an '3. Other' type of agreement, and that agreement is an MOU.

Indicate that OSU has a conflict of interest policy and that the OSUIRB Staff has completed RCR training.

Then click 'OK':

Non-OHSU Personnel

Check if this person is not affiliated with OHSU?: ☒

The following questions only pertain to those individuals who are not employees of OHSU.

What type of agreement is in place?:

3. Other

If 'other' agreement please explain:

MOU

Is there a conflict of interest in research policy in compliance with PHS regulations 42 CFR Part 50, Subpart F, and 45 CFR Part 94 in place at the person's institution?
☒ Yes ☐ No [Clear](#)

If No:
A current OHSU Conflict of Interest in Research disclosure for Outside Investigators is required. This disclosure form is completed online at: <http://bigbrain.ohsu.edu/coi/>

Has this person completed responsible conduct of research (RCR) training at his/her institution or at OHSU?
☒ Yes ☐ No [Clear](#)

If Yes , Please upload an electronic copy of the certificate showing RCR completion. If your RCR compliance history can be found via the "**Visual CoIR RCR**" link you do not need to upload evidence of completion.

If No , Please complete the OHSU RCR training at <https://bigbrain.ohsu.edu/>

Participation Dates (Read-Only)

Start Date:

Stop Date:

* Required

OK

OK and Add Another

Cancel

Don't add OSU IRB to either list of Notifications!

Customize E-mail Notifications

Please use the tables below to customize the e-mail notification settings. Individuals specified in the Full Set of Notifications table will receive all e-mail notifications and individuals specified in the Limited Set of Notifications table will only receive e-mail notifications related to major actions taken upon a study. If you would like to exclude an individual from receiving any e-mail notifications, simply remove that individual from both of the tables below.

★

Full Set of Notifications:

<input type="text"/>			<input type="button" value="Add"/>
First Name	Last Name	E-Mail	
Kathryn	Schuff	schuffk@ohsu.edu	<input type="button" value="Remove"/>

Limited Set of Notifications:

<input type="text"/>			<input type="button" value="Add"/>
First Name	Last Name	E-Mail	
There are no items to display			

HELP TEXT