






Study Team Member JHM SOM IRB Application

Discover how to include new study team members and learn how to agree to participate once added.





How to Add a Study Team Member

Adding a Study Team Member: Johns Hopkins Affiliates

1. Ensure that the individual has logged into [eIRB](#) at least once with their JHED credentials to establish their profile.
2. Confirm completion of the mandatory [IRB compliance training](#).
3. Add the study team member by creating a "Change in Research" (CIR) application under "Further Study Actions".
4. Once CIR is created, add investigator to Section 1, question 25. The PI should never be listed as a study team member section 1 question 25.
5. Use the "Request Study Team Participation" activity to have the system send an email requesting the study team member(s) agree to be added to the study team.
6. Confirm their agreement to participate by checking the History Log in the CIR.
7. PI should Submit the action in eIRB.
8. Wait for IRB approval before new study team members can conduct any research or research-related tasks.

Adding a Study Team Member: non-Hopkins affiliates

Individuals not affiliated with Johns Hopkins should not be added as study team members within the eIRB application.

If a non-Hopkins investigator will not have access to PHI, they are not considered engaged in human subjects research (HSR) and do not have to be added to the study team.

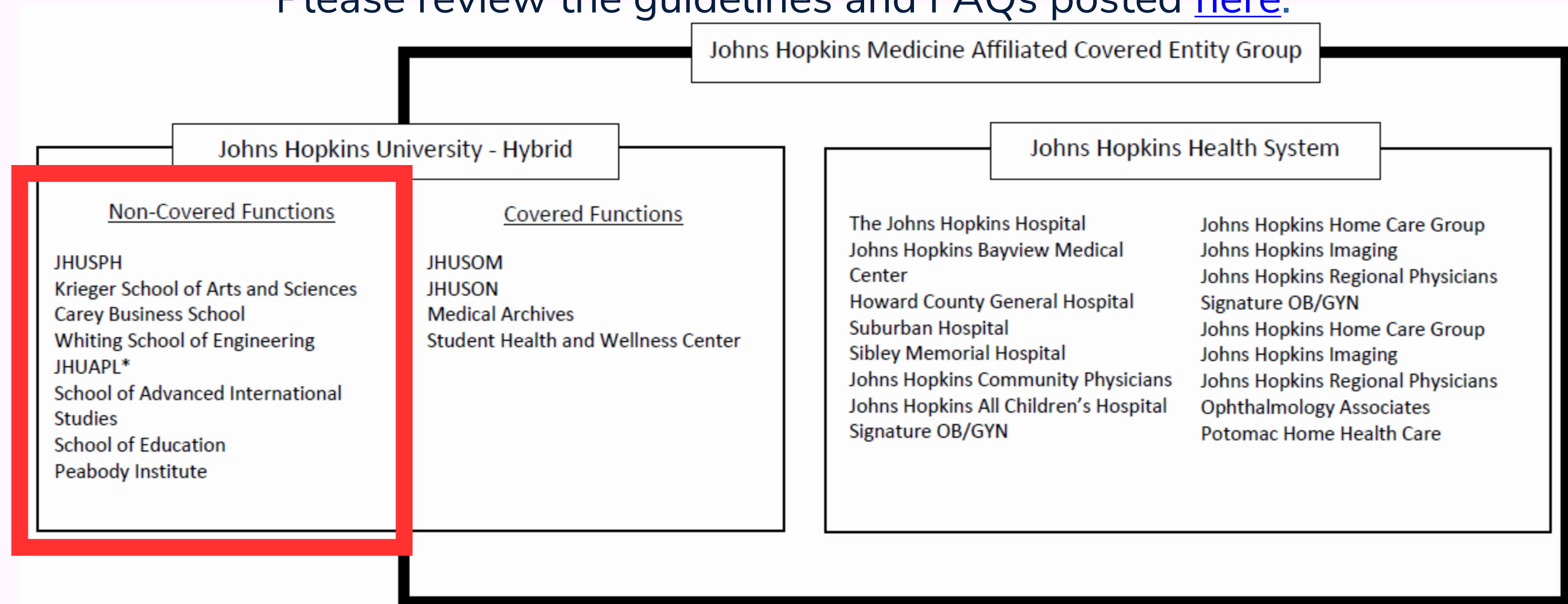
A reliance agreement may be required if a non-Hopkins investigator is engaged in HSR. A reliance request survey must be submitted and our Reliance team will review the request to determine if a reliance agreement is needed.
Visit our [website](#) for more information.

Outside the Covered Entity

Individuals affiliated with a school under the “Non-Covered Functions” square are considered outside the Johns Hopkins Medicine covered entity and may require further review before being added to the study team.

https://intranet.insidehopkinsmedicine.org/privacy_office/about_hipaa/index.html

Please review the guidelines and FAQs posted [here](#).



* JHUAPL is outside of the JHM Covered Entity Group, however, there is a standing Business Associate Agreement, which permits them and their workforce to have access to PHI to perform services (but not to conduct research) on behalf of any of the entities within the JHM Covered Entity Group



Agree to Participate

Request Study Team Participation

- PI Selects “Request Study Team Participation” from the Current Activities section.
- This opens the Request Study Team Participation Window.
 - PI will Click OK to send a courtesy email to everyone on the study team.

Current Status
Researcher Prep

Project Editor

View/Edit

Print Friendly

View Differences

Current Activities



Request Study Team Participation



Submit IND Safety Reports



Agree to Participate

Agree to Participate

- Study team members may complete the “Agree to Participate” activity without having received the courtesy email notification.
 - Select the “Agree to Participate” activity from the Current Activities section of the left navigation bar.
- This opens the Agree to Participate window.



Agree to Participate Window

Clicking OK below is the electronic equivalent of a signature.

- I have read the protocol and this application.
- I agree to perform the role(s) assigned to me by the PI.
- I certify that I am trained and qualified to perform my role(s) in the study, or will undergo the training that the PI will provide to qualify me to perform my role(s).
- I will familiarize myself with the standard operating procedures for this study before beginning to perform my role(s).
- I will conduct the study procedures in accordance with local, state, and federal laws and regulations, the terms of the JHM IRB approval, and institutional policy.
- Your use of eIRB is governed by all applicable Johns Hopkins policies. eIRB contains information that is confidential and proprietary. Your use of eIRB may be subject to audit. DO NOT submit individually-identifiable information about research participants in eIRB applications. You are responsible for removing all such individually-identifiable patient information from any documents that you upload to eIRB.
- I certify that I have reviewed the terms of the [Data Protection Attestation](#) and agree to be bound by its terms as applicable for this study.

*** I agree to the above:**

Yes No [Clear](#)

*** I wish to receive all study related notifications from the IRB:**

Yes No [Clear](#)

I am a physician-investigator or mid-level provider who will be consenting participants for this study.

Yes No [Clear](#)

*** Do you (or your spouse, domestic partner or dependent children) have a financial interest or fiduciary relationship that -- could be affected by the research, or -- is in an entity that could be affected by the research?**

Yes No [Clear](#)

Click OK below to complete.

Please review all bullet points and the Data Protection attestation before responding to each question. Once you have answered each question, click "Ok" to proceed.

**Ensure your response to the question "I am a physician-investigator or mid-level provider who will be consenting participants for this study" aligns with section 1, question 25.5. If you are uncertain, consult your PI/Study Coordinator to confirm if they have designated you as a physician-investigator or mid-level provider in section 1, question 25.5.*



Agree to Participate Error

Error Message

An error message (similar to the one below) is received when there is an inconsistency in answering the question in section 1, question 25.5 and during the Agree to Participate process.

Could not execute the Submit activity due to one or more errors:

Please ensure that the study team member profile information re: Physician/Mid-Level Provider consent (Section 1, Question 25, Sub-question 5) is consistent with the Agree to Participate response for all study team members. If a study team member is not obtaining consent, the answer in their Agree to Participate response for Question 3 should be no.

Example

The PI/Study Coordinator selects if the study team member will consent in section 1, question 25. The study team member selects if they are consenting in the “Agree to Participate” function. The highlighted boxes below need to be consistent. If not, the PI will receive an error when they try to submit. If the study team is uncertain if they are consenting, they should consult their PI/Study Coordinator to confirm.

Section 1, question 25.5-PI/Study Coordinator selects

Add Study Team Member

Study Team Information

1.0 * Study Team member:

Jessica Jones ...

2.0 * Study Team role:

Co-Investigator ...

3.0 * Primary Affiliation:

Surgery - Broadway ...

4.0 * Will this study team member be consenting participants for this study?

Yes No [Clear](#)

5.0 Is this study team member a physician-investigator or mid-level provider who will be consenting participants for this study?

Yes No [Clear](#)

Agree to Participate-Study team member selects

* I wish to receive all study related notifications from the IRB:

Yes No [Clear](#)

I am a physician-investigator or mid-level provider who will be consenting participants for this study?

Yes No [Clear](#)

* Do you (or your spouse, domestic partner or dependent children) have a financial interest or fiduciary relationship related to this research? This applies to current interests/relationships and those within 12 months.

A financial interest or fiduciary relationship is one that could reasonably appear to be related to the proposed research. Examples include, but are not limited to:

- consulting, advisory, or speaking services (paid & unpaid)
- fiduciary role (e.g., officer, member of board of directors),
- remuneration/income for services (e.g., honoraria, consulting fees),
- ownership of equity, including stock, stock options, etc., and/or
- entitlement to royalty.

Example

The two questions highlighted below need to match. The left question is in section 1, question 25.5 when the individual is added to the study team, and the question on the right is in the agree to participate function. In this case, the user needs to go back to the agree to participate activity and select “no” to this question.

25. Study Team Members:

Click **Add** to add new Study Team members. Click **Update** to modify existing Study Team member information.

	Last	First	Degrees	JHED Dept	Primary Affiliation	Role	Consenting Hopkins participants	Consenting Physician- Investigator/ Mid-Level Provider	Agree Consenting Physician-Investigator/ Mid-Level Provider	Receive Notifications	Agree To Participate
<input type="button" value="Update"/>	Freets	Jean		Education and Proj Mgmt	Other - Affiliation Not Listed	Co-Investigator	no		no	yes	yes
<input type="button" value="Update"/>	Hanson	Senya		Education and Training	Other - Affiliation Not Listed	Co-Investigator	no		no	yes	yes
<input type="button" value="Update"/>	Keith	Brandon	PharmD	Specialty Clinical Coordinators	Other - Affiliation Not Listed	Co-Investigator	yes	no	yes	yes	yes
<input type="button" value="Update"/>	Wascher	Molly	n/a	Specialty Clinical Coordinators	Other - Affiliation Not Listed	Co-Investigator	yes	no	no	yes	yes
<input type="button" value="Update"/>	Wright	Sai		Residents	Other - Affiliation Not Listed	Co-Investigator	yes	no	no	yes	yes

Resolution

To resolve this, the study team member will need to “Agree to Participate” again. If they do not have this function, the PI will need to remove them from section 1, question 25 and then add them back on. This should then open up the “Agree to Participate” function to start again.

**Contact the IRB
[Help Desk](#)
with any questions.**