

ORARC Tip Sheet: STUDENT RESEARCHERS NEEDING IRB REVIEW – WHERE TO START?

The purpose of this Tip Sheet is to assist student researchers from Harvard Longwood Campus (HLC) Schools (HSPH, HMS, HSMD) in determining if they need to submit an HLC IRB application for their research project.

As a student researcher, it may be confusing to know where to start to obtain IRB approval if you have more than one institutional affiliation and/or if multiple institutions are involved in the research project.

Researchers commonly have multiple roles that relate to their research (academically, professionally, personally). The IRB likes to use the metaphor of comparing these roles to the many different types of “hats” researchers wear.

The Multiple “Hats” That Researchers Wear



Harvard hat



Hospital hat



Home institution hat



Volunteer hat



Consultant hat



Unicorn hat

Despite the many “hats” a student researcher may wear, they should ask themselves...

1. Is the research I am conducting in fulfillment of a HLC-related course, degree program, and/or academic requirement (e.g. capstone, thesis, dissertation, practicum, etc)?
2. Will I represent myself as a HLC-affiliate while conducting the research (e.g. use Harvard’s logo on study materials, list Harvard on consent forms/recruitment materials, tell participants you are from Harvard, etc.)?

If **YES TO EITHER**, you are wearing your Harvard “hat”; HLC IRB review is required.

If **NO TO BOTH**, you are not wearing your Harvard “hat”; HLC IRB review is not required.

But wait...it doesn’t stop there!

Regardless of if you are/are not wearing your Harvard Longwood Campus “hat” – IRB review at the institutions where you wear other “hats” **may still be required**. You **must check in** with every institution you are affiliated with to ensure their IRB requirements are met.

What if I need more than one IRB review?

In some instances, where multiple IRBs are involved in a research project, IRBs can agree to “rely” on one single IRB for review. This is common when:

- The research project is ongoing and is led by a non-Harvard PI
- You will be, or have been, added as a study team member to that project

Harvard is willing to consider reliance agreements with other institutions if:

- The institution is within the US
- The human research is non-exempt
- The reliance agreement meets [Harvard’s eligibility criteria listed in the HLC HRPP Plan](#)

More information on reliance agreements can be found here: [ORARC Reliance Support webpage](#)

Additional ORARC Toolkit Materials:

- Additional information on this topic can be found on HLC IRB Tip Sheets: [Agent of Harvard](#) & [Dual Affiliation](#)
- [Human Research Protection Plan](#)

**See below for Harvard Longwood Campus IRB Review Requirements
(assuming an HLC School is involved in the project)**

Research Type	Activities Involved/ Examples (not exhaustive)	Is IRB Review Required?	Can I make my own determination?	What IRB application do I fill out?	I'm collaborating with individuals external to Harvard, is a reliance agreement appropriate?
Not Research & Not Human Subjects Research	<ul style="list-style-type: none"> Activities that do not meet the regulatory definition of research (e.g. Program evaluation, quality improvement, journalism, literature review, analysis of policies, facility data) Activities that do not meet the regulatory definition of research involving "human subjects" (e.g. Utilizing de-identified data/specimens; Studies of the deceased) 	No. NR/ NHR do not require IRB review/approval. Determinations are provided as a courtesy to investigators who require documentation.	Yes, researchers can self-determine using the following HLC IRB resources: <ul style="list-style-type: none"> Investigator Manual guidance regarding when an IRB application is required Worksheet: Human Research Determination IRB Decision Tool Getting Started FAQ website 	Create an ESTR application ; complete and upload the Not Human Subjects Research Request Determination Form	Reliance ineligible for such activities. External collaborators should check in with their home institution/IRB to follow necessary requirements, if any.
Exempt Human Subjects Research	Research activities within one of the Exempt categories listed in §46.104 (e.g. Survey, focus group, interview with adults; Secondary analysis of medical records)	Yes. Researchers must submit an application in ESTR for IRB review (irb.harvard.edu)	No, only the IRB has the authority to approve human subjects research.	Create an ESTR application ; complete and upload the HLC Research Protocol Template	Reliance ineligible for such activities. External collaborators should check in with their home institution/IRB to follow necessary requirements, if any.
Expedited Human Subjects Research	Research activities within one of the Expedited categories listed in §46.110 (e.g. Research with children, pregnant women, or prisoners; Prospective/identifiable specimen collection; Body measurements; Data collection using smartphone, app, or wearable)	Yes. Researchers must submit an application in ESTR for IRB review (irb.harvard.edu)	No, only the IRB has the authority to approve human subjects research.	Create an ESTR application ; complete and upload the HLC Research Protocol Template	Reliance eligible. Contact HLC Reliance Specialist Julie Chamberlin to discuss HLC reliance process.
Human Subjects Research Requiring Review by Convened IRB	Research activities not listed above; Research activities that pose greater than minimal risk to participants (e.g. Investigational studies on drugs, devices, biologics; Randomized clinical trials; Interventions; Research on alternatives to standard of care; Some vulnerable population research (e.g. undocumented persons))	Yes. Researchers must submit an application in ESTR for IRB review (irb.harvard.edu)	No, only the IRB has the authority to approve human subjects research.	Create an ESTR application ; complete and upload the HLC Research Protocol Template	Reliance eligible. Contact HLC Reliance Specialist Julie Chamberlin to discuss HLC reliance process.

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