



HUA IRB Newsletter - October 2021



Things to Know

Who is an Agent of Harvard?

The Harvard University Area IRB (also known as HUA IRB) is responsible for the review and oversight of Human Research conducted by its agents. Its oversight applies regardless of whether the Human Research is conducted at a HUA school, another institution, in another country, and/or in collaboration with non-Harvard affiliates. An agent may be an employee, a student, or a volunteer that is affiliated with the HUA. An agent is a person who has been specifically authorized to conduct human research on behalf of the institution.

Individuals cannot self-identify as being affiliated with the HUA; their affiliation must be recognized by the University. For example, a research lab has enlisted the assistance of a local college student. This student would not be considered an agent of HUA just because they are working in the lab. In contrast, if the student were to become a member of the lab, even as a volunteer, and were vetted by the research lab's department, then this person would be considered an agent of the HUA.

If an individual is an agent of the HUA and they will have contact with human subjects,

have access to data that is identifiable, or are responsible for the design, conduct, or reporting of the research, then this individual should be listed in **item 1** of the Study Team Members section of the ESTR SmartForm.

If an individual is NOT an agent of the HUA, and they will have contact with human subjects, have access to data that is identifiable, or are responsible for the design, conduct, or reporting of the research, and the HUA IRB will provide review for their activities through a reliance agreement, then this individual should be listed in **item 2** of the Study Team Members section of the ESTR SmartForm.

Note that individuals who are affiliated with Harvard Medical School, Harvard School of Dental Medicine, or the Harvard T.H. Chan School of Public Health are not considered agents of the HUA and should not be listed in item 1 of the Study Team Members section of the ESTR SmartForm. If members of the Harvard Longwood community will receive review from the HUA IRB, they should be listed in **item 2** of the Study Team Members section of the ESTR SmartForm.

For more information about agency, engagement, and other regulatory fun things when you are working with non-affiliates, please see our monthly newsletter from April 2021 found here - https://cuhs.harvard.edu/files/cuhs/files/hua_irb_newsletter_april_2021.pdf

Personal Information Protection Law

Personal Information Protection Law (PIPL), China's newly passed privacy regulation, will take effect on November 1st, 2021. PIPL closely resembles GDPR, the privacy law that governs data in the European Economic Area (EEA) since May 2018. Like GDPR, PIPL applies to any "company" that processes the personal data of Chinese citizens regardless of whether that happens in China or outside the country. PIPL also gives individuals the right to access, request, correct, delete, transfer, and restrict the collection and use of their personal data.

More information and guidance about PIPL and how it may affect research will be coming soon.

What it Means to Be a Faculty Sponsor

For individuals who are not eligible to be a Principal Investigator, a Faculty Sponsor is required. A Faculty Sponsor must be eligible to be a Principal Investigator and is willing to accept the same responsibilities of a Principal Investigator. So, what does this mean? The Faculty Sponsor must confirm that they will oversee the research and ensure that the listed Principal Investigator complies with all IRB requirements.

The Faculty Sponsor must also confirm that they will follow all responsibilities in the Faculty Sponsor Assurance document including ensuring that there are adequate resources to carry out the research safely, ensuring that Research Staff are qualified, submit to the IRB any reportable new information within five business days, as well as other responsibilities.

You can find the full list of Faculty Sponsor responsibilities in the ESTR Library under the tab “Ancillary Review and Other Reference”.

What’s New on Our Website

Prospective IRB Member Information

Interested in becoming an IRB member? We’re always on the look-out for interested and talented individuals willing to devote time and effort to the protection of human subjects. To find out more on what it means to be an IRB member, check out our new webpage here - https://cuhs.harvard.edu/become-irb-member?admin_panel=1

Change in the Location of our Quarterly Metrics

We are always looking for ways to improve our website. Recently, we moved the location of our metrics to a more prominent location, our main landing page - <https://cuhs.harvard.edu/> Just go to the heading “HUA IRB Information” and you will find our IRB metrics link. On a laptop or desktop, this heading is found on the right side of the page. On a mobile device, just keep scrolling!

Thank an IRB Staff Member

Has an IRB staff member gone the extra mile to provide assistance or complete your submission quickly due to a funding deadline or other time crunch? If you would like to express your thanks, for any reason, we've created an easy way to do so. Like the other new items on our website, just go to the heading "HUA IRB Information" and you will find our "Thank an IRB Member Staff Member" link.

Do You Speak IRB?



Coercion and Undue Influence

The Belmont Report defines "coercion" as occurring "when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance." Coercion may be direct or indirect. For example, conducting research at institutions that provide services to subjects may be perceived or as a direct threat that receiving these services is dependent upon participation in the research.

According to Office for Human Research Protections (OHRP), "undue influence" is defined as occurring "through an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture to obtain compliance." For example, the amount of monetary compensation provided to a research participant may involve undue influence, especially if excessive.

There are other factors that may make individuals vulnerable to undue influence, coercion, or increased risk. These factors can include the relationship of the participant to the researcher (e.g., student/professor), economic circumstances (e.g., under

housed/homeless), among others. The IRB considers what measures should be taken to mitigate any factors that could impact the voluntariness of the research and/or increase overall risk of participation as result of potential vulnerabilities. For example, in the case of a researcher who uses their own students as the participant population, someone other than the researcher could obtain consent of the students for participation. This would assist in students feeling free to decline participating. Another way to mitigate this risk would be the inclusion of a sentence ensuring participation would not impact their grade or status in the course. This would help students from feeling compelled to participate because of their relationship with the researcher.

From all of us at the HUA IRB, Be Well and Stay Healthy!

Harvard University Area IRB

44-R Brattle Street, Suite 200 (2nd floor)

Cambridge, MA 02138

Email: cuhs@harvard.edu

Phone: (617) 496-2847

Web: <https://cuhs.harvard.edu/>