Important Regulatory Items

Conducting Research in Brazil

If you are conducting research in Brazil, approval from the Brazilian Government is required. CONEP (National Commission for Ethics Research) is the branch of the Brazilian Government (or one of its official designees) that provides ethical oversight for research studies that take place in Brazil. This is in addition to the IRB review that you receive from the HUA IRB.

Should your research involve indigenous Brazilian populations, be sensitive, or involve risks that are greater than minimal, additional review and requirements will be needed. For research that is benign in nature and determined to be no greater than minimal risk, there are several CONEP-certified IRBs in Brazil that are authorized to conduct this review.

If you will be conducting research in Brazil, reach out to your IRB Administrator as soon as possible to avoid any delays. We will assist you in navigating the process, including which Brazilian IRB is the most appropriate for your study.
MTurk ID’s – Yep, they are an “Identifier”

“Amazon Mechanical Turk (MTurk) is a marketplace for completion of virtual tasks that requires human intelligence. It has become popular among researchers as it provides access to a large, diverse, and on-demand workforce.” (see more here - https://www.mturk.com/worker/help)

Each MTurk worker receives a unique identifier known as a “worker ID”. At first glance, the worker ID appears to be a string of random letters and numbers however the MTurk worker ID is a unique identifier, much like a social security number or driver’s license number. MTurk worker IDs can easily be linked to an individuals’ Amazon profile. As such, the HUA IRB considers the MTurk worker ID to be an “identifier”. This means that researchers must be careful in deciding what information to collect from participants. The default should be that participants MTurk worker IDs not be collected. If it is necessary to collect worker IDs, then the researchers should ensure that worker IDs are kept confidential and secure.

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Things to Note!

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Policy on the Use of Harvard Names and Insignias

You just finished your IRB submission and have submitted it in the online IRB submission system, ESTR. Upon initial review, you receive a comment from the IRB Administrator that
according to the Policy on the Use of Harvard Names and Insignias, you must have approval to use the logo that was included in your study informed consent form. If you do not have approval, you must obtain approval to use the logo or it must be removed from your informed consent form. What? Why are they asking me to do this?

According to the Policy on the Use of Harvard Names and Insignias, “…the identification, statement, or display of Harvard's name in any way that may reasonably be interpreted as implying endorsement, approval or sponsorship by the University or one of its units” must receive specific approval.

In fact, the only instances where approval is not required are in the following circumstances:

- Stationery, business cards, and other materials used by the Schools or other units in the ordinary course of business;
- Official publications of the University (e.g., catalogues and related materials of the University and its various Schools and units, "home pages" on the World Wide Web, and similar electronic publications issued by Schools and other units, and the Harvard Alumni Directory);
- Journals in printed or digital form published by the University or any of its Schools or units where the University, School or unit involved retains sole editorial control (e.g., the Harvard Business Review and the Harvard Educational Review); and
- Materials prepared specifically for use in connection with courses conducted by the University (e.g., Harvard Business School Cases).


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**Leaving Harvard? Plan Ahead and Take Action Prior To Your Departure**

If you will no longer have a formal affiliation at Harvard, there are some important steps that you need to take before your departure. Why? Well, when you are no longer affiliated with Harvard, your Harvard IRB approval will no longer be active, the Harvard University
Area IRB will not be able to provide IRB review for you, and you will no longer be able to access ESTR to make any changes to your existing study. Here is what to do:

If you are closing your study at Harvard

ESTR requires creating a Continuing Review in order to close your study. You will be answering “no” to four questions about your study at Harvard, even if you will be transferring your research to another institution. These are the questions:

1. Study is permanently closed to enrollment OR was never open for enrollment
2. All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
3. Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
4. Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)

Important Fact! If your study received an Exempt or Not Human Subjects determination it does not need to be closed in ESTR.

Next, close your study at Harvard using these study closure instructions from the ESTR Support website - https://estrsupport.fss.harvard.edu/study-closure

If you are moving to a new institution and will continue your research

Contact your new institution’s IRB office for instructions on how to open your study there. It is important to ensure that there is no gap in approval for your study during this transition. We recommend that your study has approval in place (if possible) at your new institution prior to closing your study at Harvard.

Next, close your study at Harvard using these study closure instructions from the ESTR Support website - https://estrsupport.fss.harvard.edu/study-closure

If you plan to transfer your research to another Harvard Principal Investigator

Determine if the identified individual who will be the new PI is “PI eligible.” Check here to see - https://cuhs.harvard.edu/am-I-PI-eligible

If not, you will need to also identify a Faculty Sponsor for the new PI. To change the PI of your study, submit a Modification using these modification instructions from the ESTR support site - https://estrsupport.fss.harvard.edu/mod-smartform
From all of us at the HUA IRB, Be Well and Stay Healthy!

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