



HUA IRB Newsletter - October 2020

AAHRPP Site Visit – We Did It!



Our Site Visit took place on September 28th and September 29th. We had over 40 individuals from across Harvard that contributed to the success of this visit – individuals from research administration, research compliance, researchers, research staff, IRB members, and IRB staff. This Site Visit truly took a village, and we thank everyone for taking part.

So, what's next? We will receive a Site Visit report within the next 30 days. The report will be based on the Site Visitor's very minor observations. Our response to this report will be reviewed at the December 2020 Council on Accreditation meeting. At this meeting, the Council on Accreditation makes a decision about accreditation based on the draft Site Visit report, our response, and the evaluation of the response.

We'll keep you updated on how things progress!

What Do I Need to Submit to the IRB during the COVID Pandemic?



As we re-start research at Harvard University, research studies that involve human participant interactions will often include screening procedures prior to contact with participants, as well as the use of Personal Protective Equipment (PPE) to minimize the risk of contracting or spreading COVID-19. Studies may also be modifying study procedures to move from in-person visits to remote visits or revising study inclusion criteria to decrease the risks for some vulnerable populations.

So, what does and does not need to be reported and/or submitted to the IRB? The following list includes some examples of when you need to be in touch with your friends at the HUA IRB.

Topic	DOES NOT Require IRB Review	DOES Require IRB Review
Public Health and Clinical Activities	<p>Actions taken for public health or clinical purposes, and not for research purposes, are not research procedures and do not require IRB approval before being implemented.</p> <p>For example, if a research study implements mandatory clinical screening procedures related to COVID-19 for all people who come to their lab, these screening procedures do not need to be reviewed by an IRB before they may be implemented. Further, as these activities are not research procedures, the research team does not need IRB review in order to share the screening results with a public health authority or the research</p>	<p>If those actions taken for public health or clinical purposes are also part of the research procedures (“dual purpose”) such that the data will also be part of the study data collection, IRB approval is required before being implemented.</p> <p>For example, if a research study implements mandatory clinical screening procedures related to COVID-19 for all people who come to their lab, and those screening procedures become a variable in the data analysis for the study, these screening procedures would now be considered study data and need to be reviewed by an IRB before they may be implemented.</p>

	<p>subjects, although other permissions or notice may be necessary under applicable law or policy.</p>	
<p>Legally Required Reporting</p>	<p>When required by law to provide information related to an individual's COVID-19 test results to a public health authority, including individually identifiable information about individuals who are research subjects, the regulations do not prevent investigators or institutions from fulfilling this requirement (even if doing so would be inconsistent with statements made in the study's consent form). The existence of a Certificate of Confidentiality does not alter an investigator's ability to disclose a research subject's COVID-19 test results when required by federal, state, or local laws.</p> <p>For example, if a research subject tests positive for COVID-19, an investigator may provide this test result to a public health authority if required to do so under applicable state or federal law. In such circumstances, investigators should inform the participant of the required reporting of results.</p>	<p>Not applicable.</p>
<p>Proposing and Reviewing Study Changes</p>	<p>If you have a study that offers direct therapeutic benefit and/or stopping the</p>	<p>As most studies at the Harvard University Area do not offer direct therapeutic benefit and/or stopping the</p>

	<p>procedures would cause harm to study subjects, researchers may implement changes to approved research prior to IRB review and approval, if the changes are necessary to eliminate apparent immediate hazards to the subject.</p> <p>For example, if researchers need to cancel or postpone non-essential study visits instead of in-person visits to reduce COVID-19 transmission risks, these changes may be implemented without prior IRB approval, but the researcher still needs to report these changes to the IRB within five business days.</p>	<p>procedures would not cause harm to study subjects, it is assumed that ALL changes to study procedures would need to be submitted to the IRB for review and approval before implementation. Please note that pauses to research because of the pandemic do not need to be reported to the IRB.</p> <p>As there are some intricacies about modifications depending on the study's review type, say, exempt studies, it is recommended to check-out "Submitting a Modification" in the FAQ's here - https://cuhs.harvard.edu/how-do-i-submit-modification</p> <p>For example, if researchers change study procedures from in-person visits to telephone or Zoom visit to "un-pause" a study, the researcher needs to submit a modification to the IRB for review and approval prior to implementation. Or, if a researcher modifies the inclusion criteria for a study so that only health volunteers are included, this change would need to be submitted to the IRB too.</p>
<p>Whether Pauses in Research Must be Reported</p>	<p>Research that has been paused because of the pandemic does not need to be reported to the IRB.</p> <p>For example, all Harvard research studies that involved direct contact with study subjects have been paused. This pause was not required to be reported to the IRB.</p>	<p>Although a study pause does not need to be reported, if something that is not unanticipated happens -as a reminder- all UPIRTSO's (Unanticipated Problems Involving Risk to Subjects or Others) must be reported within five days to the IRB as a Report of New Information (RNI). See here for how to report a RNI - https://estrsupport.fss.harvard.edu/rni-smartform</p> <p>If the IRB suspends or terminates an approved research study as the result of such an RNI, the IRB is required to report to the federal agency, OHRP.</p>

		For example, if a research study has found that study procedures result in severe increased risk to participants, the IRB may decide to suspend the study until more information about the risk is uncovered. This suspension must be reported to the federal agency.
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You can find this as well as more information about how COVID-19 may impact your research on our website [here](#).



Do you Speak IRB? *Institutional Official*

The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution in matters of human subjects protection. The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects.

The University Chief Research Compliance Officer, Ara Tahmassian, Ph.D., is designated as the Institutional Official/Organizational Official (IO/OO) for the Harvard University HRPP.

The IO/OO has the authority to:

- Create policies and procedures related to the HRPP.
- Suspend or terminate research approved by the IRB.
- Disapprove research approved by the IRB.
- And, a lot of other authority – check out the [HRPP Plan](#) for the complete listing.

The IO/OO also has many responsibilities in the HRPP, including (but not limited to):

- Oversee the review and conduct of Human Research under the jurisdiction of the HRPP.
- Periodically review the HRPP plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirements.
- Ensure that the research review process is independent and free of coercion or undue influence and ensure that officials of the Institution cannot approve research that has not been approved by the IRB.
- And, a lot of other responsibilities – check out the [HRPP Plan](#) for the complete listing.

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

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