



HUA IRB Newsletter - February 2021



Remember!

Reminder about Review Timeline

The time-to-completion for a submission is calculated as the time that a submission enters our e-submission system, ESTR (Electronic Submission, Tracking, and Reporting), until the time that a determination is made. Time-to-completion may be affected by the time taken by the IRB or the time taken by the study staff, by the type of review (e.g., convened IRB review takes longer as there is only one meeting per month), or by the difficulty of the submission (e.g., a modification that involves substantial changes to an IRB submission versus a modification to add a study team member).

Given the multiple variables involved for any one IRB submission, the HUA IRB recommends that researchers submit their submissions at least six weeks before they plan to start their research. If you are uncertain about where to start or how to submit an IRB submission, check out our IRB Lifecycle to gain insight into the IRB review process. Our IRB Lifecycle may be found on the homepage of our website here - <https://cuhs.harvard.edu>

Reminder about School/Department Approval for In-Person Research

Don't forget! During the current COVID-19 pandemic, studies involving face-to-face interaction require approval by the School or Department that you, as the researcher, are affiliated with. This applies to research where the Harvard researcher has direct contact with study participants as well as those studies where the research will take place at other locations.

Each School or Department has a process and criteria for the resumption of in-person research for their researchers. The principal investigator (PI) of a research program/study is required to craft a plan outlining the COVID-19 precautions that will be undertaken for their research. No research can begin until a researcher's plan receives School or Department approval.

For more information including answers to common questions, check out the IRB webpage here - <https://cuhs.harvard.edu/questions-about-covid-19-and-your-research> - as well as our handy resumption of research study decision aid found here - https://cuhs.harvard.edu/files/cuhs/files/resumption_of_research_study_decision_aid.pdf

Funding Deadline? Other Sensitive Deadline? Leave a Comment!

We understand that there are circumstances when you don't have a lot of time to get IRB review and approval. This may be due to a Just-in-Time award or other pending commitment. If you find yourself in this situation, leave a comment in ESTR to let us know. Not sure how to leave a comment? See below.



Communicating with Staff During Review

During review (and after), you can complete the Add Comment activity to:

1. Post a note to the submission history that all individuals with access to the submission may view, and
 2. If selected, send a notice to:
 - PI/PI Proxy and Primary Contact
 - Study Team Members and/or
 - The assigned IRB Coordinator (If the IRB Coordinator box is selected and there is no assigned IRB Coordinator, a notice is sent to all members of the IRB office.)
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Do you Speak IRB? Exculpatory

Exculpatory (ik-skuhl-puh-tawr -ee) tending to clear or charge from guilt.

According to the federal regulations that protect human subjects (45 CFR 46.116), “No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.”

The central purpose of the informed consent form is to provide a sufficient amount of information for an individual to make an informed decision about whether they wish to voluntarily participate in a research study.

An informed consent form should not give the impression of a legal agreement or include any statements that the individual may lose or “give up” something if they participate. The IRB has encountered some research submissions that include a Term of Service (TOS) agreement or other binding agreement that is meant to substitute for an informed consent form. This is not permissible.

We realize that there may be times when a study may involve an informed consent form and a TOS for the use of a service, such as a mobile phone application. In these instances, it is incredibly important that the researcher make apparent what is research and what is not.

Here are some examples of exculpatory language according to our federal regulators and what NOT to include in an informed consent form:

- “By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.”
 - “I waive any possibility of compensation for injuries that I may receive because of participation in this research.”
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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/>