Harvard University Area

HUA IRB Newsletter - March 2021

News & Important Reminders

New Phase for Resumption of In-Person Research

The resumption of in-person research at Harvard University has occurred in phases with timing based on governmental policies and the state of the disease, the health care system, and society at large. Beginning on February 15, 2021, Harvard University entered Phase HSR1.3. Phase HSR1.3 outlines the following permissible activities:

- Non-Harvard affiliated study participants for on-campus research
- Participants without known COVID-19 medical risk factors (as per CDC guidelines) can be on Harvard campus
- Participants with known COVID-19 medical risk factors (as per CDC guidelines) who have been fully vaccinated with recommended wait periods can be on Harvard campus

- Documentation of any close contact >15 minutes (i.e. nature and estimated time) in resumption request highlighting specific risk mitigation.
- Additional protection (e.g. face shields, better fitted mask), in addition to ASTM rated face masks, worn by study team members for times of close contact
- Maximum number of study team members (3, only 2 <6ft of participant)
- Frequent testing (at least weekly) of researchers engaged in human subjects research where there is close contact
- Research with subjects who cannot wear masks (e.g. toddlers) reviewed on case by case basis
- Up to 10 participants to interact with a study team member per week when close contact <6 feet
- Research in community settings reviewed on case by case basis.

More information as well as additional resources for researchers may be found here.

Don't forget that a 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 in -person research. These plans are subject to their School/Departmental review and approval. No in-person research can begin until a researcher's plan receives School/Departmental approval.

Coming Soon! New Agreements Tool – WAIT

Confused about what type of agreement might be needed for your collaboration with others? **WAIT** no more! Funded by NCURA and developed at Harvard, WAIT is a *Web-based Agreement Identification Tool* designed to assist the research community with the accurate identification and routing of various agreements. WAIT is structured around a series of yes/no questions that will help researchers identify and route information for the following agreement types:

- Sponsored Research Agreements
- Material Transfer Agreements
- Non-funded Agreements
- MOUs

- Service Agreements
- Gifts
- Data Use Agreements
- Non-disclosure Agreements

Upon the launch of WAIT in early 2021, a link to the tool, demo video, and associated User Guide will be available on the OSP website, along with an announcement on OSP Research Administration Listserv.

URTP Training Dates

The Undergraduate Research Training Program (URTP) is a comprehensive platform to create better prepared undergraduate researchers. As part of the program, in-person training sessions are held at various dates throughout the academic year. The in-person training sessions are an alternative to the standard online CITI training. The sessions have been developed with students in mind: they are 90 minutes in length, interactive, and developed with enthusiasm and energy.

All Spring 2020 “in-person” sessions will be held by Zoom. Follow the links below to the Harvard Training Portal to sign up for a session. Sign up will close one business day before the session and a Zoom link will be sent by email to all confirmed attendees at that time.

Date: March 29, 2021 (Monday)
Time: 3:30-5pm
Location: Zoom (link to follow)
Please sign up for the March 29th training by clicking here!

Date: April 6, 2021 (Tuesday)
Time: 4-5:30pm
Location: Zoom (link to follow)
Please sign up for the April 6th training by clicking here!

Date: April 14, 2021 (Wednesday)
Time: 4:30-6pm

Location: Zoom (link to follow)
Please sign up for the April 14th training by clicking here!

Lifecycle Guide

We don't need to tell you how challenging, mysterious, confusing, or (insert adjective here), that submitting your first IRB submission can be. In our continued effort to de-mystify the IRB process for our research community, we have collapsed the many tips, tricks, and resources about the IRB submission process in our new website feature, the IRB Lifecycle Guide found here.

The IRB Lifecycle Guide presents information in a sequential fashion – from creating your IRB submission to closing your IRB submission and everything in-between.

Consider yourself an IRB expert? We encourage you to take a look – you might learn something that you didn't know!

Don't Forget to Manage Relationships!

We all know the importance of a healthy relationship. The same holds true for the relationship between the ESTR system and the Data Safety system. As you know, the Data Safety system was introduced almost a year ago and the Harvard Research Data Security Policy that support its use was implemented this past July.

So, what is this "Manage Relationships" thing? The overall system that includes ESTR, Agreements, and now Data Safety was developed to talk to each other. What this means is that when a certain submission has other associated records in Data Safety, ESTR, and/or Agreements, completing the Manage Related Projects activity will connect the records across the systems. By connecting the different records in the overall system, a reviewer

will not only have access to information in the other systems but will also know when a review is complete. Without this notification, submissions may just sit there, leading to delays.

Now that you know the importance of “Manage Relationships”, how do you do it? A comprehensive document has been created to guide you through the process which you can find here - just go to page 20 for all the details.

Do you Speak IRB? Exempt

Let’s start with some regulatory background about where exempt review fits in…

IRB review occurs on a continuum according to risk. Once an activity meets the definition of regulated research and involvement of human subjects, the level of review is determined. Exempt review is the lowest level of review which is then followed by Expedited review and then review by the Convened IRB/Full Board. See more about level of review in our IRB Lifecycle guide here.

Below are some common questions that we encounter regarding exempt review that we thought might be helpful.

Exempt research and not human subjects research mean the same thing, right?
Well, actually no. Unfortunately, terms used in the IRB world are not as straight-forward as one might think. The IRB’s use of the word exempt means that the research **does** involve human subjects however the activities that are part of the research fall into one (or more) of the federal regulatory designated exempt categories. Because of this, the research is *exempt* from the regulations.

What are the exempt categories?
The categories are activity focused. For example, exempt category 2 focuses on research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey

procedures, interview procedures or observation of public behavior. While exempt category 3 focuses on what are called “benign behavioral interventions”. You can find more information about some of the more popular categories on our website here.

Can I make my own exempt determination?
The federal regulations do not specifically state *who* should make exempt determinations however our federal regulators, OHRP, state, “OHRP recommends that, because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that human subjects research is exempt.” You can read more about OHRPs current guidance on exempt research here.

What if I need to make changes to my study that has determined to be exempt?
Most exempt submissions do not require a modification if the exempt determination does not change. You also do not need to submit a modification when study team members change.

When should an Exempt study submit a modification?

- If including children, prisoners, or other protected populations.
- Study procedures that fall outside the exempt category. For example, an intervention was initially going to take place in one sitting, but the research team decides to include longitudinal effects, so they implement a follow-up treatment.
- Increase in risk.
- Ancillary policy / regulations: GDPR, collection of sensitive information requiring a Limited IRB review, change in data security assessment.
- Change in Principal Investigator.
- Change in Faculty Sponsor.
- If there is new funding.

What about other changes?
If an exempt study is changing the design of the study or major revision to the procedures, a new exempt determination request should be submitted.

What template do I use for the consent process for my exempt study?
As studies that have been determined to be exempt are exempt from the regulations, the standard template for the informed consent form does not have to be used. Instead, you may use the “HUA Exempt Human Research Consent Script Template” (HRP-502-c in the ESTR Library). You will find the Exempt Script to be much shorter than the standard consent form but still include all of elements that are needed.

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

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