



HUA IRB Newsletter - June 2020

Re-Starting Research at Harvard

Since March, research studies that involve face-to-face interaction have been on “pause” (see [here](#)). With national and local leaders beginning to move forward with phased re-openings, Harvard Leadership has been working tirelessly to create a plan to re-start research at Harvard University. The plan, which may be found [here](#), is meant to, “...establish clear and consistent guiding principles for the conduct of research in the era of COVID-19, to define operational protocols and precautions that minimize risk of viral transmission in a laboratory/research environment, and to provide examples of how the physical and temporal space of laboratories might be organized to enact these protocols in accord with these principles.”

More information on when the re-start of research will occur will be shared soon. Don't forget to check back often for up-to-date information!

What to Submit and Not to Submit to the IRB, that is the question

With the upcoming re-start to research at Harvard, many researchers might be wondering if COVID-related procedures that are being implemented for the safety and well-being of study subjects need to be included in their IRB application. The answer is, “it depends”.

A general rule of thumb is that if procedures are being put in place to prevent transmission of COVID-19, these procedures are not considered “study procedures” and do not need to be approved by the IRB. For example, if all study subjects are screened prior to arriving for the study visit and data from this screening is not retained other than for the purpose of health and safety, this procedure does not need to be approved by the IRB. On the other hand, if a research study is implementing a screening procedure and are also retaining the data to analyze along with the study data, then this screening would be considered a study procedure which requires IRB review and approval.

More information about what COVID-related procedures need to be submitted to the IRB may be found on our website [here](#).

ESTR Release – what to expect from the upgrade

ESTR, our online IRB submission system, has been offline for the past couple of days while some major upgrades were taking place. Wondering what was keeping you from accessing the system while it was down? Check out some of these highlights:

- Integration with Office365 for easier viewing and editing of submission-related documents in Word, Excel, and PowerPoint.
- Modernized SmartForm design with updated navigation and reviewer options; and
- Updates to support new Data Safety requirements related to IRB submissions.

A complete list of items included in this upgrade can be found in the Release Notes [here](#). Should you run into problems, please feel free to contact the [ESTR Help Desk](#) with any questions or concerns.

Submitting a Comment versus Submitting a Response – what’s the difference?

Like many things in the IRB world, a word may make all the difference. Such is the case with submitting a **comment** versus submitting a **response** in ESTR. They appear to mean the same thing, but they don’t.

When you **submit a comment**, think of this as a type of correspondence; the ESTR version of an email. Comments are used for informal reminders, general questions, and the like - a quick and easy way to communicate in the system. Detailed information about submitting a comment may be found [here](#).

When you **submit a response**, you are moving the submission from one state to another state in ESTR. What does this mean? If we take a deeper look at how ESTR works, the IRB review process is a series of “states” (check out this cool graphic, below) -

When a study moves through the IRB review process, the study first moves through the Pre-Review *state* where there might be some minor clarifications requested by the IRB Reviewer to get things in order. To do this, the IRB Reviewer will send the submission back to you in the “Clarifications Requested” *state*. You make the necessary changes and then send the submission back to the IRB by “**submitting a response**”. This volley from *state* to *state* moves the submission from Pre-Review to IRB Review to Post-Review and then, voila - Approval! More information on submitting a response may be found [here](#).

When a response is submitted instead of a comment, this moves the submission into a *state* that it might not be ready for. This is a bit of a headache for ESTR, so please be careful about what you are submitting.



Do you Speak IRB? De-Identified, Coded, and Anonymous

Who knew data had so many classifications according to identifiability! Below is a simplified guide of data terminology that are sometimes misused in IRB protocols.

“Anonymous” data

Definition: The research team does not collect, nor store any identifying data that would link (either directly or indirectly) back to participants’ identities

Examples:

- Large scale polling data (if online, IP addresses are not collected)
- Study-specific processes that do not require obtaining personally identifiable information

Case study: A researcher walks up to someone on the street, obtains verbal consent (not documented), and asks whether s/he prefers coffee or tea. No names or other identifiable information is collected.

“De-identified” data

Definition: Data that were originally identifiable at the individual level but from which those identifiers were removed.

Examples:

- Online surveys, where IP addresses, names, and other identifiers have been permanently removed
- In-person interviews that have been transcribed, and identifiers have been permanently removed
- Secondary analysis of data that has been stripped of all indirect and direct identifiers by the data provider before transferred to the research team. There is no link to identities.

Case study: A researcher conducts a survey with a small population of students in one dorm about their alcohol use. In order to prevent the participants from being identified based on their responses, the researcher removes any personally identifiable information (e.g., dorm name, ethnicity, religion) in order to minimize the risk of re-identification of participants.

“Coded” data

Definition: Identifiers were removed from the dataset, but a unique code is used for each participant, which links data to a key containing participants’ identities.

Examples:

- Longitudinal studies, where identifiers are removed and replaced with unique codes in order to link responses over time. A key linking the codes and names are stored separately from the data.
- Secondary analysis of data that has been provided by a data provider in a coded manner. A crosswalk/key exists to which the research team may or may not have access.

Case study: A researcher is conducting a longitudinal study of participants’ work history and will conduct multiple survey waves to compare responses over time. The researcher needs to maintain identifiable information in order to match the responses from each survey wave. A code is used to allow the researcher to link the identities (or contact info) of these participants with the data, but still maintain the datasets in a “de-identified” state. The key for the codes is maintained

separately from the data.

Did you realize that “identifiable” wasn’t included? Check out our discussion of what is identifiable in our June 2018 newsletter [here](#).

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

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