



Harvard University Area IRB Monthly Newsletter

September 2022



Welcome to Harvard!

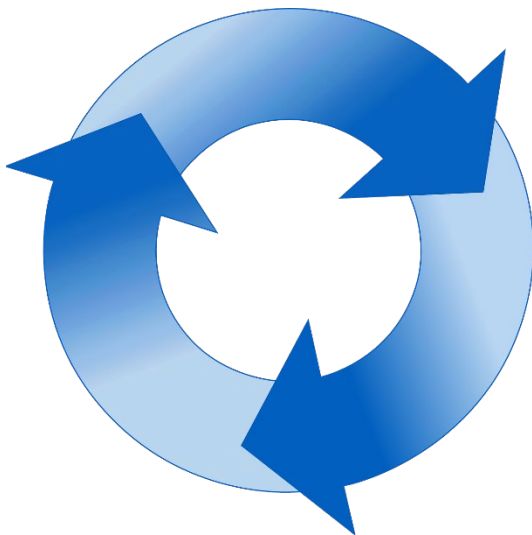
With the start of a new academic year, there are a lot of new faces on the Harvard campus. Navigating a new campus can be daunting as is knowing what resources are available to you. The Harvard University Area IRB is here to help.

The Harvard University Area IRB provides IRB review for the Harvard Faculty of Arts and Sciences, Harvard Graduate School of Education, Harvard Kennedy School, Harvard Divinity School, Harvard Business School, Harvard Law

School, Harvard Graduate School of Design, the Harvard School of Engineering and Applied Sciences, Harvard University Health Services, and the Radcliffe Institute for Advanced Study. The IRB of record for the Harvard University Area is referred to as the Committee on the Use of Human Subjects (CUHS).

The HUA IRB administrative office is responsible for managing the day-to-day operations and support of the IRB. The HUA IRB office staff perform a variety of functions in addition to supporting the IRB such as providing IRB determinations, reviewing studies on behalf of the IRB, assisting researchers with IRB-related questions, and providing training and outreach.

The HUA IRB staff are assigned a portfolio according to Schools and their Departments. The HUA IRB team is here to help. You can locate your go-to IRB staff member [here](#). Or, for a staff directory, you can go [here](#).



IRB Lifecycle Guide – Your Lifeline for All Things IRB

Navigating the IRB approval process can be challenging, especially if you are a new researcher. As there are numerous regulations that may apply to your research as well as different levels of IRB review, knowing what to do or what to expect can seem intimidating.

The HUA IRB office has broken this process down into manageable, bite-size pieces according to the stages of IRB review – whether you are just starting to think about a research project, wondering what comes after IRB approval, or you are not certain what your responsibilities might be as a Principal Investigator. Check out our IRB Lifecycle Guide [here](#).



What type of data is this?

The level of identifiability of data that you use in your research makes a difference in how your research is reviewed or whether you need review at all.

Here are common terms and definitions (in lay speak) that are used to describe the identifiability (or non-identifiability) of data.

De-Identified: De-identified data are data that were once identifiable but have been stripped of any potentially identifying characteristics. De-identified data fall into two buckets:

- **Coded:** Coding data is one way to remove identifiers. When data are coded, identifiable variables are replaced with a code. This is common in research studies that involve multiple data collection points. Instead of using a study participant's name, their code number can be used instead. With coded data, there is a "crosswalk" document that connects the code with their identity.
- **Anonymized:** Anonymized data are data that have been stripped of anything that could possibly be identifying. It is not coded. There is no way to know to who the data might belong.

Identifiable: Identifiable data are just that – identifiable. The data may contain a study participant's name or other identifying information such as social security number or medical record number. This leads us to two different aspects of what is considered "identifiable":

- **Directly identifiable:** These data contain variables that point explicitly to study participants. Examples include names, addresses, ZIP and other postal codes, telephone numbers, including area codes, Social Security numbers, other linkable numbers such as driver's license numbers, certification numbers, etc.
- **Indirectly identifiable:** These data contain variables that can be used together or in conjunction with other information to identify study participants. Examples include detailed geographic information (e.g.,

state, county, province, or census tract of residence), organizations to which the study participant belongs, educational institutions (from which the study participant graduated and year of graduation), detailed occupational titles, place where the study participant grew up, exact dates of events (birth, death, marriage, divorce), detailed income, offices or posts held by the study participant.

Note that there are some regulations that have a higher threshold for what is considered identifiable. These include HIPAA, GDPR, and PIPL, among others.

And while we are talking about data, Harvard has a great website to help you manage your research data, “Research Data Management at Harvard”. You can access the website [here](#).

**Do You Speak
IRB?**



Debriefing

A central tenet of the regulations and ethical guidelines that govern human subjects research is that participants are fully informed of the true nature of the research. This includes a description of the procedures as well as the risks and benefits that may occur should an individual choose to participate.

Sometimes, particularly in behavioral research, investigators may plan to withhold information about the real purpose of the research (i.e., incomplete disclosure or withholding of information) or even to give participants false information about some aspect of the research (i.e., deception). This means that the participant's consent may not be fully informed.

In behavioral research involving deception or incomplete disclosure, especially if the research may induce psychological stress, guilt, or embarrassment, it is often suggested that participants be "debriefed" after their participation. Debriefing gives the investigator an opportunity to explain any incomplete disclosure or deception involved and to help the participants deal with any distress caused by the research. The debriefing should disclose the full or true purpose of the research and allow the participant to indicate that their data not be used in the study.

In rare instances, such debriefing may not be helpful, it may even be harmful. This may be when disclosure of the information may cause more distress to participants than if not disclosed or when disclosure may bias the scientific integrity of the study. For example, some participants may not benefit from being told that the research found them to be willing to inflict serious harm to others or possess negative characteristics. The IRB must be sensitive to

possible harms, and use good judgment when evaluating the potential risks caused by incomplete disclosure or deception on a case-by-case basis.

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