# Harvard University Area

# Harvard University Area IRB Monthly Newsletter
December 2023



## Winter Recess Reminder

Just like you, we're counting down the days on our (advent) calendar to a much-needed break. This year the Harvard Winter Recess will run from Friday December 22, 2023, through Monday January 1, 2024.

Please know that IRB staff are busy trying to ensure that submissions already in review are attended to before the recess. For those items submitted during the month of December, we will do our best to wrap them up; however, this may not be possible in all cases, and we appreciate your flexibility and patience.

- The last Convened IRB meeting of the year will take place on Thursday, December 14. As the deadline for this meeting has passed, any studies that qualify for Convened IRB review (i.e., those studies with an uncertain risk or greater than minimal risk) have already been assigned to the December meeting. Any further studies requiring Convened IRB review will be assigned to the agenda for the January meeting.
- If there is an emergency such as an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) or other unexpected event, please submit a Report of New Information (RNI) to the IRB within five business

days. An overview of this process may be found <u>here</u> – just click on the tab "RNI – review of new information."

- If you are pursuing a Second Year Policy Analysis (SYPA) as an HKS student, or a Winter Writing Project as an HLS student, please submit as soon as possible if you intend to conduct new research during the recess!

---

## How to Zoom (and Not the Meeting Kind)



The HUA IRB office has developed a webpage with 6 tips for speeding up the review of your IRB application. Explore the webpage <u>here</u> and learn more about how to navigate the review process in an expeditious way.

---



Do You Speak IRB?

I Speak IRB!

# Identifiability

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 who the data might belong to.

**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, 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.

More information on how this definition may impact your need for IRB oversight may be found here under "Is it Human Subjects?" If you believe your research does not involve human subjects, perhaps because the information is not

identifiable, but you require a formal determination from the IRB, please submit the *Not Human Subjects Research Request Determination* form found in the Templates and Forms section of the Library in ESTR.