Harvard University
Area

HUA IRB Monthly Newsletter

February 2022

Important Things to Know

Useful tips, resources, and helpful items to know to make your research more manageable.

Is it human subjects research? We have a form for that!

Just a friendly reminder that if you are conducting not human subjects research, we have a special form that you can use that will save you some time and effort.

Here's how to find it - In the ESTR Library, under the tab "Templates and Forms", scroll to "HRP-213-FORM-Not Human Subjects Research Request Determination" (be sure to be logged in to ESTR to access this document).

Remember, it is not a federal regulatory requirement to receive a “not human subjects research” determination however if you are uncertain, it is always a good idea to check. Note that your funder or other agencies that you are working with may require such a determination.

You may also carry out your own assessment by using the worksheet “HRP-310-WORKSHEET-Human Research Determination” (be sure to be logged in to ESTR to access this document).

If Scheduling Your IRB Office Hours Using the Online Booking Tool, Check Your Spam/Junk Folder

Our new online appointment scheduler has made booking an IRB office hour so much easier! You can see staff availability, receive a confirmation of your appointment, as well as a reminder of your upcoming meeting. One downside that we recently uncovered is that the appointment scheduler may send these confirmations and reminders to your spam and/or junk folder. So, if you find yourself wondering why you didn’t receive a confirmation or reminder – check your spam and/or junk folder!

What type of data is this?

The level of identifiability of data that you use in your research makes all the difference in how your research is reviewed or whether you need review at all. Here are some common terms and definitions (in lay speak) that are often 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: Anonymizing data is data that has 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 is 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. Which leads us to two different aspects of what is considered "identifiable":

Directly identifiable: These are variables that point explicitly to study participants or units. Examples include names, addresses, including 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 are variables that can be problematic as they may 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.

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.

From the Office for Human Research Protection (OHRP) also known as our federal regulators - Free Webinar Series on the Basics of the Common Rule. Register Now!

Are you new to the IRB world and looking to gain a basic understanding of the Common Rule? Are you a researcher struggling to determine whether your research involves human subjects? Do you work at an institution looking to establish or update your human subjects protection program? Have basic questions and don't know where to turn? Register for OHRP's free three-part introductory webinar series on the regulatory framework for human research protections. Don't forget to tell your colleagues!

Nothing basic about it, but we'll try to make it so – Common Rule ABCs with OHRP

Friday, February 18, 2022, 12 to 1 PM EST

This presentation will explain why we have regulations to protect research participants, how they function, and who needs to comply with them. It is intended for anyone who needs to know the general framework for how the review and approval process works for human research protections and is perfect for those who are new to the field!

Each webinar requires a separate registration. Click here to register for this webinar.

What is research, what isn't, and, who is a human subject anyway? – Explaining Common Rule terms in plain language

Friday, February 25, 2022, 12 to 1 PM EST

This presentation will explain when an activity is or is not 'research', and who is or is not a 'human subject' according to the Common Rule. It is intended to help IRB administrators, researchers (including student researchers), reviewers, grant administrators, institutional leaders, and anyone who works in an area related to human research understand how the Common Rule functions.

Each webinar requires a separate registration. Click here to register for this webinar.

The ABCs of 104: Understanding exemption categories

Friday, March 4, 2022, 12 to 1 PM EST

This presentation will help attendees understand what exemption to the Common Rule means, conditions for the different exemption categories, and when human subjects research may qualify for an exemption according to the Common Rule. IRB administrators, researchers, reviewers, grant administrators, institutional leaders, and anyone who works in an area related to human research would find this presentation helpful.

Each webinar requires a separate registration. Click here to register for this webinar.

Do You Speak IRB?

Regulatory topics broken down into easy to understand concepts and words

Human Subjects Research

The federal regulations define a human subject as a "A living individual about whom an investigator conducting research obtains (1) information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens" (45 CFR 46.102(f)(1)(2)).”

We thought it might be easier to break this down into common terms rather than "regulatory speak" -

Living individual refers to data (information or specimens) collected from living subjects. For example, research using data from the 1880 Census would not be human subjects research.

About whom refers to the fact that the information collected must be personal information about an individual. For example, a survey that collects data about the activities of an organization, rather than its members, is not human subjects research.

Intervention includes physical procedures and manipulations of the subject or the subject's environment for research purposes. For example, taking a saliva or blood sample from a subject or having a subject view a video would be considered a research intervention.

Interaction refers to communication between the researcher and the subject. For example, research that includes face-to face, mail, internet, and phone

interactions (e.g., surveys), as well as other modes of communication would be considered an interaction.

Identifiable private information or biospecimen means the identity of the subject is or may be readily ascertained by the researcher or others or associated with the information. For example, research with a de-identified data set is not research with human subjects because the data are not individually identifiable.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable to be considered information to constitute research involving human subjects. Examples of private information include medical or academic records or personal journals.

Still have questions? Check out our IRB Lifecycle Guide that covers all of the nuts and bolts of human subjects research. You can access the IRB Lifecycle Guide on the front page of our website here.

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