

# IRB NEWS

A monthly newsletter brought to you by the Harvard University Area IRB,  
Committee on the Use of Human Subjects



**JULY 2018**

## Three Burden Reducing Provisions & You

On June 18, 2018, we received official notice that the implementation date of the **Revised Rule** is scheduled for January 19, 2019 and that institutions may implement “three burden reducing provisions” between July 19, 2018 and January 19, 2019.

So, now that we have the option of implementing these three burden reducing provisions, **let’s chat about them.**

The three burden reducing provisions are actually items from the Revised Rule that are being implemented as an interim measure:

1. The revised definition of “research,” which deems certain activities not to be research  
[Provides clarification on what IS NOT research: scholarly or journalistic activities, public health surveillance, and research conducted by criminal justice agencies...](#)
2. The allowance for no annual continuing review for certain categories of research  
[This applies to research that receives an expedited determination and those convened IRB studies, where the only remaining activity is the analysis of identifiable data/biospecimens or activity to obtain follow-up clinical data.](#)
3. The elimination of the requirement that institutional review boards review grant applications  
[Yes, it’s true. IRBs are required to verify that what is included in the grant application matches what is in the IRB submission. You may not have known that this is happening, since we do not come across grant/IRB protocol incongruity very often.](#)

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The caveat for implementation of the above provisions is that if they are used on a study, that study must be in full compliance with the Revised Rule when it takes effect on January 19, 2019. This would mean that new consent elements would need to be in place, additional review criteria are met, and the study meets the proper review level imposed by the Revised Rule.

Given this complexity, we will be implementing the above provisions on a study-by-study basis.

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## URTP Summer Undergraduate Training Dates

In-person training sessions provide a great opportunity for undergraduate students to get engaged in a conversation about ethical research, learn about what types of research require IRB review, learn best practices for conducting ethical research, and uncover additional resources that may be helpful.

We hope to see you at one of our upcoming sessions:

**Tuesday, July 10**

5:00 p.m. - 6:30 p.m.

William James Hall, Room 305

**Thursday, August 9**

4:00 p.m. - 5:30 p.m.

William James Hall, Room 305



## Do you speak IRB?

### "About whom"

We've heard from various parts of the campus that you are not conducting human subjects research if a researcher is interacting with a person but not collecting identifiable information.

Actually, this scenario would be considered human subjects research.

The definition of a human subject is comprised of two parts: actual intervention/interaction with a living individual and collection/receipt of identifiable information.

**Here's the first part of the definition that deals with intervention or interaction with an actual person:**

*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:

#### 1) Data through intervention or interaction with the individual

*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

*Interaction* includes communication or interpersonal contact between investigator and subject. This definition does not mention identifiability, rather, it focuses on an intervention/interaction that collects/obtains data that is "about whom". We interpret "about whom" to mean "any information from the person that is about them". This could be personally identifiable information, their opinion, their biometric data, etc.

When we ask an individual about something else, for example, about a company or a process, they are telling us about something that does not pertain to "them" but about that other thing; it is not their opinion, it is a fact that exists beyond them.

**Here's the second part of the definition that deals with collection/receipt of identifiable information:**

#### or 2) Identifiable private information.

*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, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable

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(i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

It is the second part to the human subjects definition that specifies identifiability and largely pertains to data collection that does not involve intervention or interaction. For example, observation of behavior, obtaining data from records or datasets, etc.

Also, to help illustrate, OHRP has provided a decision chart that includes “research” and “human subject” – note where identifiability comes in: [Click here for the chart.](#)

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