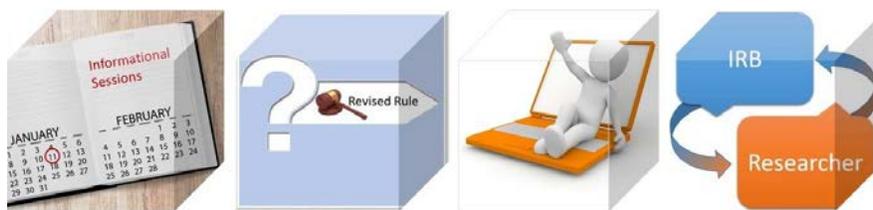


# IRB NEWS

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



## How can you prepare for the Revised Rule?



**Revised Rule Overview Presentations** are being held throughout the month of January. We have added some dates in February too. All presentations are held in the Lamont Library Forum Room.

- Thursday, January 11: 1:00-2:30 pm
- Friday, January 19: 2:00 -3:30 pm
- Wednesday, January 24: 1:30-3:00 pm
- Thursday, February 1: 9:00-10:30 am
- Monday, February 5: 3:30 – 5:00 pm

Can't make it to one of our presentations? You can access our presentation slides [here](#).

**ESTR Upgrade Overview Sessions** that provide an overview of the ESTR system changes and how they affect IRB submissions and review will be held over the next several weeks. The sessions will be held at 6 Story Street in the first floor conference room on the following dates:

- Tuesday, January 16, 2:00 pm
- Monday, January 22, 3:00 pm

To sign up for one of these sessions, please visit [this webpage](#).

## What can researchers expect from the revised rule?



The upcoming Revised Rule reflects the first change in the federal regulations since 1991!!! The rationale for these revisions is to not only strengthen human subject protections but to reduce administrative burden and get up to speed with the technological advances (electronic records, big data, genetic research, to name a few) that have taken place over the past 27 years.

While the revisions are robust, researchers will most likely notice a change in how minimal risk research is reviewed:

- Research that was previously reviewed under an expedited category may now receive an exempt determination.
- No continuing reviews will be required for expedited category research.
- Clarification on what is and what is not “regulated research” that requires IRB review.
- Re-organization of informed consent form information as well as some new elements that need to be included.

The Harvard University Area IRB office has been preparing for these revisions and is here to help.

Here is how:

- We've revised our main IRB application to include questions geared toward the revised regulations.
- We've updated the informed consent templates that includes new required consent elements and a re-organization of information.
- We will be implementing an updated Standard Operating Procedures (SOP) manual that outlines our processes and policies.
- We will also be implementing an Investigator Manual that provides guidance and additional information on the how, what, and why of the IRB submission process.
- Questions? IRB staff have received extensive training to provide you with answers.

---

## Attention all undergraduate researchers - have we got a training program for you!



Launched in December 2016, the Undergraduate Research Training Program (URTP) is a comprehensive program to create better prepared undergraduate researchers. The URTP is comprised of research ethics training sessions, a student-focused curriculum, and an online decision form that will assist students in determining whether their project requires IRB review. Interested in learning more? Visit the URTP web port.

---

## Do you speak IRB? Deciphering Multi-site versus Single-site



You may have heard terms such as “ceding review,” “IAA,” or “reliance agreement” in the context of studies involving collaborative research. These terms refer to the type of arrangement in which one IRB agrees to serve as the reviewing IRB for the agents of another institution involved in the research, and the other IRB agrees to rely on the reviewing IRB for review of its agents' activities, in order to prevent duplication of review effort. The impetus to engage in these agreements has been underscored by the Single IRB initiative – complementary federal policies in which certain types of federally-funded studies that involve multiple institutions are *required* to use a single IRB to accomplish IRB review.

When most people think of a “site,” they think of a geographical location. While it is important to know where a study is taking place, questions regarding “multi-site” research instead revolve around **who** is taking part in the research, and **what** they are doing. If collaborating investigators are not affiliated with Harvard University Area and are interacting or intervening with a human subject, obtaining consent, or obtaining or analyzing private, identifiable information, then the study may be suitable for a reliance agreement (and indeed may be required to have a single IRB, under certain circumstances related to receipt of federal funding).



**Multi-site:** Conducting a study where there are multiple institutions are involved? If yes, then you are conducting a multi-site study. Each of these “sites” may be doing different activities, for example, data analysis, intervention with subjects, or coordinating study activities. Or, each of the sites may be doing the same research activity, as is common in a standard “clinical trial”.



**Single-site:** If there is only one institution involved, your study is a single-site study. For example, if your study involves Harvard University Area researchers conducting a survey in a high school in Oregon, where no other researchers are taking part, this would be a single-site study.