We're Moving!

Starting May 14th, we will be located on the 2nd floor of 44-R Brattle Street. This is the cozy little building situated next to Harvest Restaurant and the first-floor location of our favorite ticket seller, Harvard's Outings and Innings.

Receive a Lapsed Approval Notice
If you received a lapsed approval notice from ESTR regarding your study that was determined to be “not human subjects research” then you are not alone!

During our recent upgrade late last month, ESTR became a little confused and sent notices to a subset of studies that were determined to be not human subjects research. We have identified these studies and have left a comment explaining the issue and how we are fixing the problem. Serenity now!

External IRB Process Update

Working with another institution or are you part of a multi-site study? Will an external IRB provide review instead of the Harvard University Area IRB?

If so, we will need to obtain the IRB approval letter and ancillary documents prior to finalizing our internal review.

As the Single IRB (also known as “sIRB”) environment is becoming more and more popular (and a regulatory requirement for NIH-funded clinical trial studies and federally funded studies beginning in January 2020), we are required to provide greater detail of the nature of this review, including review type, whether there is a continuing review date, and other regulatory details.

Should you forget one of these items, don’t worry, we’ll remind you during the review process. And, check out more information about sIRB below.
Do you speak IRB?

External IRB Review – The Terms You Need to Know

You may have heard terms such as “ceding review,” “IRB Authorization Agreement”, or “reliance agreement” in the context of studies involving research when more than one institution is involved.

These terms refer to the type of arrangement in which one IRB agrees to serve as the reviewing IRB for all institutions involved 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.

While this all seems straightforward, there are some complexities involved in how various terms are used and what the implications for review may entail. Here are some of the more popular terms:

**Multi-Site Research Study:** This type of study involves multiple institutions and each of the sites is doing the same research activity. This is quite common in a standard “clinical trial”.

**Collaborative Research Study:** This type of study involves multiple institutions and each of the “sites” may be doing different activities, for example, data analysis, intervention with subjects, or coordinating study activities.

**Single-Site Research Study:** 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 research study.

**Cooperative Research Study:** Cooperative research projects are those projects that involve more than one institution. Cooperative Research does not specify whether each site is doing the same activity or different activities; it casts a wider net. For example, your study may be a *cooperative* study and a *collaborative* study. If you receive funding from a federal agency and are engaged in cooperative research, a sIRB is required. Our federal regulator, OHRP, has indicated that the sIRB requirement for this type of study is effective January 20, 2020.

**Clinical Trial:** “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.” Although both HHS and NIH have adopted this definition, only NIH has outlined specific additional requirements, including the use of a sIRB. You can find out about these additional requirements [here](http://calists.harvard.edu/mailman/listinfo/huairb).

Is your head spinning? Yep, our head is spinning too. We can help you navigate this increasingly complex regulatory environment starting with our webpage [here](http://calists.harvard.edu/mailman/listinfo/huairb).

---

**Know someone who would be interested in subscribing to our newsletter?**

It’s easy! Just share this link with them: [http://calists.harvard.edu/mailman/listinfo/huairb](http://calists.harvard.edu/mailman/listinfo/huairb)

---

Harvard University Area IRB, Committee on the Use of Human Subjects (CUHS)

Smith Campus Center, 1350 Massachusetts Ave, Suite 935 Cambridge, MA 02138

*Copyright © 2019 Harvard University Area IRB, All rights reserved.*