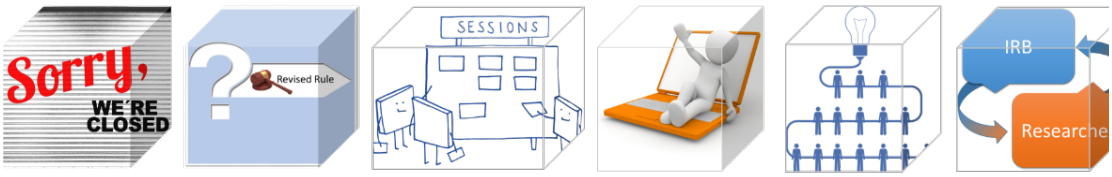
IRB NEWS

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

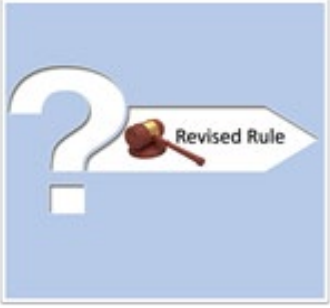


January 2019 – The Early Edition

IRB Office Closed - December 24, 2018 - January 1, 2019

Just a reminder that the IRB office will be closed for the Harvard Winter Break from Monday, December 24, 2018 through Tuesday, January 1, 2019. We will be back in the office on Wednesday, January 2, 2019. Have a lovely Winter Break!

Major Changes with the Revised Rule



The Revised Rule which takes effect on January 21, 2019 brings some changes to our regulated research landscape. Here are some of the more notable ones. Of course, if you are interested in learning everything there is to know about the upcoming Revised Rule, please visit our resource page here.

Continuing Review - No longer required for most minimal risk research, including studies where the only remaining activity is the analysis of identifiable data/biospecimens or obtaining follow-up clinical data.

Exemptions - New categories and clarification of existing categories. Conducting a "Benign Behavioral Intervention"? Well, we've got a new category for you! All in all, this is where most of the Revised Rule changes are taking place.

Informed Consent - A new "Key Elements" section and a rearrangement of content is designed to facilitate a potential subject's decision to participate or not. Don't worry, these additional elements have been included in our consent template since January 2018, so you're already compliant!

Single IRB-of-Record (sIRB) - IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB (commercial, academic, or hospital-based) starting January 20, 2020. Of course, NIH-funded studies must already adhere to the sIRB requirement. Didn't know about that? Check out our NIH-funded study resource page here.

Revised Rule Presentation Dates

Still need more Revised Rule?

Attend one of our 1-hour information sessions!

- Monday, January 7, 2019, Noon - 1:00 p.m., Lamont Library Forum Room
- Wednesday, January 16, 2019, 3:00 p.m. - 4:00 p.m., Lamont Library Forum Room
- Thursday, January 24, 2019, 10:00 a.m. - 11:00 a.m., Lamont Library Basement Room B-30

Revised URTP Process

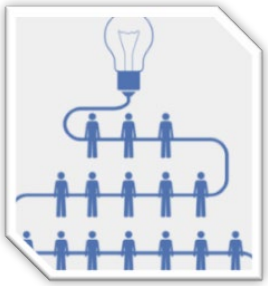
The Undergraduate Research Training Program (URTP) is a comprehensive platform to create better prepared undergraduate researchers. The URTP is comprised of research ethics training sessions, a student-focused curriculum, and an online decision form that assists students in determining whether their project requires IRB review.

Beginning in January 2019, the URTP will see some revisions. We will be implementing the Revised Rule changes into the URTP curriculum and in-person training, as well as streamlining the Decision Form to make for a more concise and efficient determination. If there is uncertainty about whether IRB review is needed, students will be required to submit an abbreviated application through our online submission system, ESTR.

Should a student require IRB review, they are one step closer to gaining approval, and should they not require IRB review, they will have an official document from the IRB for that determination.

Questions? Please contact the IRB office at 617-496-2847 or cuhs@harvard.edu

Recruiting Staff/Lab Members as Study Participants



But I'm just using study staff members in my lab to generate some data….

If you are conducting regulated research and are using individuals from your lab or even just people that you know, they are considered human subjects. In fact, these individuals may be considered a vulnerable population. Why? These individuals may feel that they have to participate or that taking part in the research is part of their job.

A central tenet of the human subject protection regulations is that those that take part in research decide to do so by making a voluntary and informed decision to participate. This includes not only providing enough information to make a decision but also providing an environment that is free from coercion or undue influence.

So now that we know that study staff may be considered a vulnerable population, how can researchers ensure that they are taking the appropriate steps for voluntary participation? Some suggestions to take into consideration:

- Should someone other than the Principal Investigator request participation?
- Is it possible to mask who takes part and who does not?
- Are individuals provided with enough information to make an informed decision?
- Have you ensured that all potential participants understand that participation is completely voluntary and not participating has no effect on their employment?

You may also wish to check out our federal regulators thoughts on the topic here.

Do you speak IRB?

"**Legally Authorized Representative**" (**LAR**) is one of the new definitions that is part of the Revised Rule:

Legally authorized representative *means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue,* ***legally authorized representative*** *means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.*

Yes, that's right, a **LAR** may provide consent on behalf of an individual who is not capable of providing consent for themselves. Allowing a **LAR** to provide consent has always been part of the human subject research regulations, so why is it being added as a new definition to the Revised Rule?

Our federal regulators submit the following points as to why **LAR** is now included as a definition in the Revised Rule:

- "As there is no federal legal standard as to who, or what entity, is authorized to serve as a **legally authorized representative** to provide consent to a subject's research participation, the issue of who can serve as a **legally authorized representative** has been determined by the laws of the jurisdiction in which the research will be conducted."
- "Some states have no law specifically addressing the issue of consent by a surrogate in the research setting, and some states have no applicable statutes, regulations, or common law specifying when an individual can provide consent for another to medical treatment."
- "SACHRP and the Presidential Commission for the Study of Bioethical Issues have raised concerns that the definition of **legally authorized representative**

may be inappropriately hindering the conduct of research with subjects who lack capacity to consent."

Okay, so I see why the feds would include this as a new definition in the Revised Rule, but what about Massachusetts – don't we have a rule about who can be a **LAR**?

Found in Massachusetts law as well as in our IRB SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013):

I. Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a legally authorized representative.
II. When research is conducted in Massachusetts, the following individuals meet these definitions:
    a. For research that involves medical treatment:
        i. A "health care agent" as defined in M.G. L. c. 201D. with authority to make health care decisions pursuant to a health care proxy; or
        ii. In instances in which no health care proxy has been executed, a "responsible party" designated by a health care provider under common law principles.
        iii. A "guardian" as defined in M.G.L. c. 190B § 5-101; however, the health care decision of a health care agent takes precedence over that of a guardian.
    b. For minimal risk non-medical research:
        i. A "guardian" as defined in M.G.L. c. 190B, § 5-101. ("a person who has qualified as a guardian of a minor or incapacitated person pursuant to court appointment and includes a limited guardian, special guardian and temporary guardian, but excludes one who is merely a guardian ad litum.")
        ii. In light of existing statutory and case law, it is unclear whether the IRB may approve a study that involves consent by a legally authorized representative for an incapacitated adult to

participate in non-medical research in Massachusetts that presents more than minimal risk.

iii. For all such determinations, before approving the study, the IRB should consult with legal counsel to determine that the individuals proposed to serve as legally authorized representatives meet the federal definition of "**legally authorized representative**."

So, there you go, everything you wanted to know about **LARs**!

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

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

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

HUA IRB (CUHS) Website

Unsubscribe