



How will this affect your research?

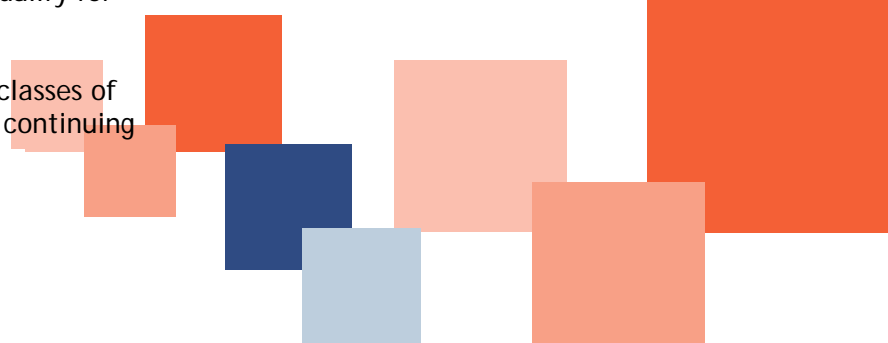
Burden Reducing Provisions

As we technically already apply the “not research” exclusions and the grant congruency check is a “behind the scenes” process, researchers will notably gain benefit by the removal of the continuing review requirement for special classes of research.

As studies that employ these provisions are required to be fully compliant with the Revised Rule on January 21, 2019, we are being selective about which studies are transitioned during the delay period.

Revised Rule

While there are a number of revisions that are included in the Revised Rule, the most notable are:

- **Revised Exempt Categories**
The Exempt categories have been expanded to be more inclusive of standard research methodologies so much so that many research studies that are now reviewed as Expedited will qualify for Exempt status.
 - **No Continuing Review**
Expedited and other special classes of studies will no longer have a continuing review requirement.
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- **Single IRB requirement**
Starting in January 2020, all federally funded studies will be required to have only one IRB provide review for multi-site studies. As the Harvard IRB strives to reduce duplicate review of any study that involves multiple institutions, researchers will feel little impact by this new regulation.
- **New Informed Consent Elements**
Luckily, we have already integrated the new consent elements into our current consent templates. So, if you are using a template from January 2018 or onward, you are already in compliance!

QUESTIONS? WE'RE HERE TO HELP!

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An Overview of the Upcoming IRB Regulation Changes

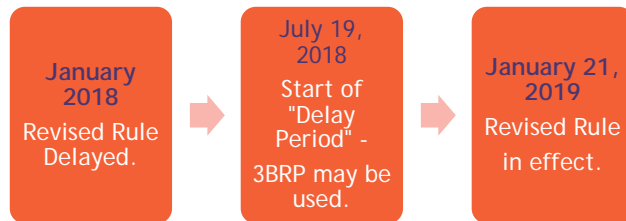
And how it affects your
research....

How did we get here?

Our federal regulators announced in January 2018 that the revised federal regulations (aka, “Revised Rule”, “2018 Requirements”, “New Rule”) would not go into effect and that the implementation date of January 19, 2018 would be delayed by another six months to July 2018.

In April 2018, a proposal was put forth to further delay the implementation date of the Revised Rule to January 21, 2019 along with an option for institutions to implement three “burden reducing provisions” between July 2018 and January 2019.

On June 19, 2018, we received official notice that the implementation date of the Revised Rule will be January 21, 2019 and that institutions may implement three burden reducing provisions (3BRP) between July 19, 2018 and January 20, 2019 (aka, “delay period”).



So, now that we have the option of implementing three burden reducing provisions during the delay period, let's talk about what those are -

3 Burden Reducing Provisions (3BRP)

The three burden reducing provisions are items from the Revised Rule that are being implemented as an interim measure from July 19, 2018 through January 20, 2019.

So, what are the 3BRP?

- *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...
- *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.
- *The elimination of the requirement that IRBs 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. With this provision, this will no longer be necessary.

What's included in the Revised Rule?

So, what are some of the new regulations that we can expect on January 21, 2019?

Does this new regulation apply to all studies? How about those studies that were in place before January 21, 2019?

- All studies submitted on or after January 21, 2019 will be reviewed under the Revised Rule.
- Existing studies (expedited and convened IRB) will be transitioned on a case-by-case basis at the time of continuing review. Existing exempt studies (submitted before January 21, 2019) will not be transitioned to the Revised Rule.

So, what's new?

- New definitions for “clinical trial”, “written or in writing”, and “public health authority”.
- Revised definitions for “Legally Authorized Representative”, “Human Subject”, and “Research”.
- New and revised exempt categories.
- No continuing review for expedited studies submitted after January 21, 2019 and for select existing studies.
- No continuing review for some convened IRB studies.
- Single IRB requirement is still slated for January 20, 2020.
- New informed consent requirements including the addition of new “key elements” and a re-arrangement of content designed to facilitate understanding.
- New informed consent waivers.

