
IRB NEWS

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



Burden Reducing Provisions Now in Effect!



As you are aware, the much-awaited revisions to the federal human subject protection regulations that were to occur in January 2018 have now been delayed until January 2019. However, our federal regulators have provided institutions with the option of implementing “three burden reducing provisions,” which we have lovingly named “3BRP”.

So, what is 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.

- **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.

How will this affect your research?

We technically already apply the “not research” exclusions and the grant congruency check is a “behind the scenes” process. However, 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.

Here is an overview of all the studies that are eligible for 3BRP:

BRP item	Type of Submission	Restrictions
Not research	Initial	None – all studies
No Continuing Review	Initial	Only studies that are Expedited 5
	Continuing Review	Only convened IRB studies that are in data analysis only and/or are only accessing follow-up standard of care clinical data, and studies that are Expedited 5 or Expedited 8.
No grant check	Initial	Only studies that are funded by a federal agency and Expedited 5.

Translation:

Expedited Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Expedited Category 8: Continuing review of research previously approved by the convened IRB as follows:

- 1) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
- 2) where no subjects have been enrolled and no additional risks have been identified; or 3) where the remaining research activities are limited to data analysis.

More information on the 3BRP as well as the upcoming Revised Rule may be found on the IRB website [here](#).

Accreditation Spotlight



Did you know that as the upcoming Revised Rule will be in place on January 21, 2019, our accreditation will be based on these new regulatory standards?

The first step in the accreditation process is to conduct a self-assessment. What this entails is a review of our review “toolkit” (standard operating procedures, investigator manual, worksheets, letter templates, etc.) to ensure that the domains, standards, and elements contained in the AAHRPP Evaluation Instrument are included. However, since the Revised Rule will not take place until early next year, we are evaluating our toolkit with the documents that *will be* implemented in January 2019 and not currently in use.

While this sounds potentially confusing, we are optimistic that working between two sets of toolkits and regulations will result in us being better prepared for the Revised Rule and the accreditation process overall.

What can the research community expect? We will be sharing revised documents with you on a rolling basis as well as holding outreach sessions to review the new regulations and how it will impact current and upcoming research. Stay tuned!



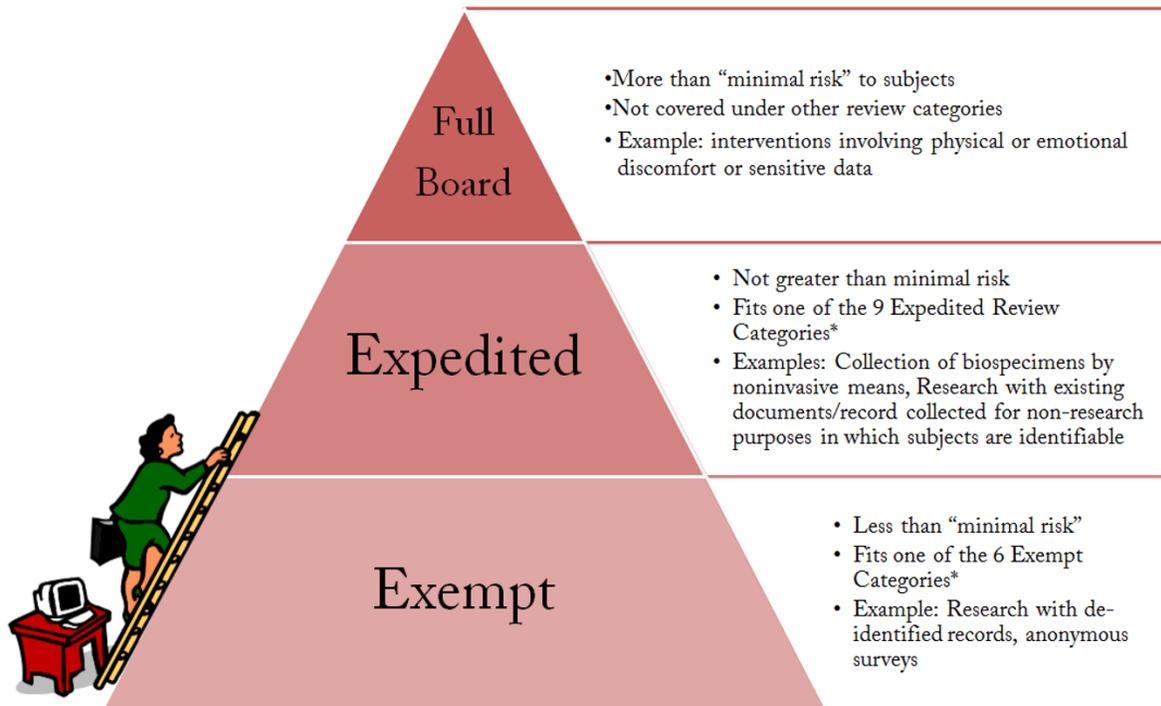
Do you speak IRB?

"Exempt"

Let's start with some regulatory background about where exempt review fits in...

IRB review occurs on a continuum according to risk. Once an activity meets the definition of regulated research and involvement of human subjects, the level of review is determined. **Exempt** review is the lowest level of review which is then followed by Expedited review and then review by the Convened IRB/Full Board.

Levels of IRB Review



*Defined by federal regulation (45 CFR 46)

*From the Office for the Protection of Research Subjects, University of Southern California (USC)

Below are some common questions that we encounter regarding **exempt** review that we thought might be helpful.

Exempt research and not human subjects research mean the same thing, right?

Well, actually no. Unfortunately, terms used in the IRB world are not as straight-forward as one might think. The IRB's use of the word **exempt** means that the research **does** involve human subjects however the activities that are part of the research fall into one (or more) of the federal regulatory designated **exempt** categories. Because of this, the research is *exempt* from the regulations.

What are the exempt categories?

Currently, there are six **exempt** categories. The categories are activity focused. For example, **exempt** category 2 focuses on research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. While **exempt** category 4 focuses on research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.

Can I make my own exempt determination?

The federal regulations do not specifically state *who* should make **exempt** determinations however our federal regulators, OHRP, state, "OHRP recommends that, because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that human subjects research is **exempt**." You can read more about OHRP's current guidance on **exempt** research [here](#).

However, this may change with the Revised Rule. The Revised Rule does not restrict or set requirements for how or whom determines if research is **exempt** by the institution. With this upcoming change, some institutions are exploring alternate methods on how to make an **exempt** determination. An initiative that is gaining traction is the **Exempt Wizard** led by the Federal Demonstration Project (FDP). The **Exempt Wizard** is online tool that will allow investigators to determine if their IRB protocol is **exempt** from full IRB review. More information on the **Exempt Wizard** may be found [here](#).

Will there be any changes to the exempt categories or how exempt determinations are handled with the upcoming Revised Rule?

Yes, there will be a number of changes. The Revised Rule includes revision to many of the categories and adding some new ones. One notable change is the expansion of the **exempt** categories to include "benign behavioral interventions". The Revised Rule describes a benign behavioral intervention as:

“...brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions include having the subjects play an online game, solve puzzles under various noise conditions, or decide how to allocate a nominal amount of received cash between themselves and someone else.”

Currently, research that meets the definition of a benign behavioral intervention receives an expedited review meaning that ALL of the federal regulations are applied (i.e., consent requirements, continuing review requirements, as well as the complete set of review criteria). The addition of this **exempt** category will be a huge win for the Harvard research community.

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