

# IRB NEWS

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



## Transition Existing Studies to the 2018 Requirements

The Office of Human Research Protections (OHRP), our federal regulators and creators of the 2018 Requirements, have stated that if a study that was approved prior to the January 21, 2019 implementation date is transitioned to the 2018 Requirements, the study must meet the “entirety of the 2018 Requirements.” This sounds intimidating, even to a seasoned IRB professional, but what does it mean?

To determine what the “entirety of the 2018 Requirements” is, we will explore what is different about



these new regulations and how these differences may affect existing studies. These items do not include every change; these are the ones that would most affect studies that would be transitioned.

**Clinical trial posting requirement.** If your study is federally funded and meets the definition of a “clinical trial” (see below), one IRB-approved informed consent form used to enroll subjects must be posted on a publicly available Federal website. The informed

consent form must be posted after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

*Clinical trial means 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.*



**New waiver criterion (this applies when you have a complete waiver of consent).**

If your research involves using identifiable private information or identifiable biospecimens, the IRB (or IRB staff) must document how the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

**New waiver for screening, recruiting, or determining eligibility.**

If your research will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject, and (1) You will obtain information through oral or written communication with the prospective subject, or (2) Your research will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens, the IRB (or IRB staff) must document a waiver for this purpose.

**New criterion for not documenting consent (this applies when you obtain consent but you don't obtain a signature):**

If your research will not involve documenting consent and 1) if the subjects are members of a distinct cultural group or community in which signing forms is not the norm, 2) the research presents no more than minimal risk of harm to subjects, and 3) provided there is an appropriate alternative mechanism for documenting that informed consent was obtained, the IRB (or IRB staff) must document a waiver for this purpose.

*Should we pause here? Maybe get a cup of tea?*

*We know this is a lot of information! If not, let's carry on.*





**New informed consent elements [these are items that must be included in an informed consent form (unless formally waived by the IRB or the IRB staff) – and, don't worry, we've already included all of these items in our current informed consent form template.]**

*Key Information:* Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This element is unique because it cannot be waived.

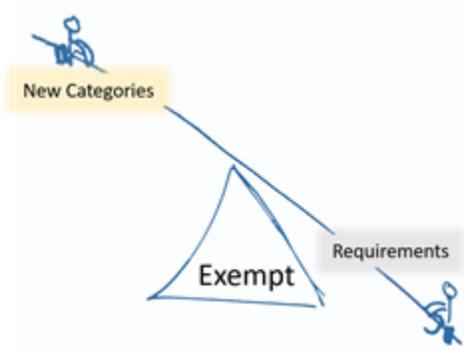
*Sharing of data:* A statement about future sharing of data or whether identifiers will be removed for any research that involves the collection of identifiable private information or identifiable biospecimens. We've been seeing a lot of researchers removing this element from their informed consent form even when it's applicable. Please know this language is NOT an option and must be included in the consent form or formally waived.

*Commercial Profit:* If applicable, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

*Return of Results:* If applicable, a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

*Whole Genome Sequencing:* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**New exempt categories and requirements.** We've got some new and revised exempt categories, two of which include some additional requirements:



*Prospective agreement:* If your research involves a ‘benign behavioral intervention’ (exempt category three - see our spotlight on this exempt category under the “Do You Speak IRB” heading below), subjects are required to prospectively agree to participate. This means that there needs to be a document to demonstrate this prospective agreement.

*Limited IRB review:* If your research falls under exempt category two (i.e., survey and interview procedures) or exempt category three (i.e., benign behavioral intervention) and data that are collected are identifiable and sensitive, there must be a limited IRB review. Does this mean that the study must be reviewed by the Convened IRB? No, not at all. Since IRB staff are also IRB members, limited IRB review may be conducted by IRB staff. A limited IRB review is a process by which the IRB (or IRB staff) ensure and document that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. In essence, this follows the IRBs designation of a data security level according to the Harvard Research Data Security Policy which you can check out [here](#).

There are also some additional limitations that must be considered:

- The FDA and DOJ have not signed on to the entirety of the 2018 Requirements therefore we will not be transitioning studies that fall under their regulatory authority.
- ESTR will only transition existing studies over at the time of continuing review. So, just keep in mind that there may be a delay in transitioning your study over if it qualifies.
- Studies that had the Burden Reducing Provisions (BRP) applied will be manually moved over to the entirety of the 2018 Requirements. If your study was BRP'd, you will be receiving a note from your IRB reviewer about the steps they will take to ensure everything is a-okay with your study.



Oh boy! There are certainly a lot of changes to consider. This is the reason why we are limiting the types of existing studies (remember – those that existed before January 21, 2019) that may be transitioned to the 2018 Requirements.

So, *what* are we transitioning?

- Certain expedited studies to take advantage of no continuing review.

Studies that are approved under an expedited category (categories 1 through 7) and are 1) not considered a clinical trial, 2) no longer enrolling subjects, and/or are 3) no longer receiving identifiable data may be transitioned. *Why?* By using these criteria, it prevents many of the 2018 Requirements from being applied to the study *and* the study can still take advantage of the new ‘no continuing review’ bonus.

- Certain expedited studies that now qualify for exempt review.

Studies that involve a ‘benign behavioral intervention’ and were required to be reviewed at the expedited level will be the biggest winner in this transition category. However, please be aware that your IRB reviewer may need to conduct a limited IRB review if the data are sensitive. They will also confirm that there is a document to capture prospective agreement. And, if your study involves deception, there will be some additional language that needs to be included. All in all, not a heavy lift for a potentially big pay off! And by “pay off” we mean that continuing review is not required, and if any changes you make to your research do not disqualify it from being exempt, there are no modifications to submit. Yahoo!

What are we are *not* transitioning?

- Exempt studies as there would be little to no benefit.

Studies that are actively enrolling, receiving identifiable data, and do not qualify under an exempt category. As mentioned, transitioning these studies would require a great deal of work to meet the entirety of the 2018 Regulations.

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## Do you speak IRB?



Along with the many revisions and additions that were included in the “2018 Requirements,” one of the most striking was the implementation of a new exempt category.

As a reminder, exempt research *is* research with human subjects. As the IRB reviews according to level of risk, exempt determinations are the lowest level of review. In IRB lingo, an exempt determination means that the human subjects research is *exempt* from the full breadth of the Federal regulations.

Exempt category 3 provides us with a spiffy new term “[Benign Behavioral Intervention](#).” While this may seem straight-forward at first, it includes a hefty set of caveats and regulatory parameters.

Ready to know more? Well then, here we go!

We will start by breaking down this exempt category into several “bite-size” pieces. We will do so by introducing the actual regulatory text and then an explanation of what it means.

If you want to check out the regulatory text in its entirety, you can do so by clicking [here](#) (just be sure to scroll down to #3).

### 1. **Who may take part?**

Here is what the regulation states:

*Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:*

As this is a two-part section, we are going to pause here and review what this section entails:

- May only include adults.

- Individuals must prospectively agree to participate, and it must be “meaningful.” Our handy-dandy *HUA Exempt Human Research Consent Script Template*, which may be found in the ESTR library, is perfect for this.
  - Those adults must have adequate decision-making capacity. This is an inherent criterion if one is to have a meaningful agreement.
2. **And, there was mention of data collection too.**

Data collection is limited to:

- Verbal (oral) or written responses by the subject,
- Data entry by the subject, or
- Observation of the subject, including audiovisual recording.

3. **How can data be recorded?**

Here is what the regulation states:

*(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;*

*(B) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or*

*(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §\_\_.111(a)(7).*

You’ve got some choices here. You can either collect information that is not identifiable (can be sensitive or not), collect identifiable data but it must not be sensitive, or you can collect data that is sensitive and identifiable. But if you collect data that is sensitive and identifiable, there must be a limited IRB review. Remember our friend “limited IRB review”? If not, scroll back up to the beginning of this email. Or, if you don’t feel like it, a limited IRB review is a process by which the IRB (or IRB staff) ensure and document that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

What is meant by sensitive? There has been a great deal of conversation about this in the IRB world with a great deal of variability in interpretation. Because of this, we decided to go to the source and

ask OHRP what they meant by sensitive. Here is what they said:

*“The essence of the matter regarding ‘sensitive’ as described in the preamble of the revised Common Rule is related to potential harm upon disclosure.*

*The limited IRB review requirements are designed to provide privacy safeguards to reduce the chances that the disclosure of identifiable private information will occur and lead to harm.”*

So, “sensitive” really means sensitive!

#### **4. What types of interventions/data collection is allowed?**

Here is what the regulation states:

*“For the purpose of this provision, benign behavioral interventions are 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 would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.”*

The types of interventions that are included are limited but may include:

- Communication or interpersonal contact with the subject,
- The performance of a cognitive, intellectual, educational or behavioral task, or
- Manipulation of the subject’s physical, sensory, social, or emotional environment.

Some additional caveats:

- The intervention or the methods used to collect data may not introduce risks of harm, physical or emotional discomfort, offense, or embarrassment.
- Physical interventions are not allowed. For example, physical (bodily) tasks or physical manipulations (e.g., range of motion activities, physical exercise) are not allowed UNLESS these are minor activities that are incidental to the behavioral intervention and do not increase risk.
- The intervention must be brief in duration. What does this mean? Well, the intervention should last a few minutes to a few hours. While it does not have to occur in a single session, the entire intervention should occur on a single day and not exceed a few hours in total.

## 5. Deception is okay? Really?

Here is what the regulation states:

*If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.*

Yep, deception is allowed in this exempt category but (yes, there is a “but” here) only when the subject agrees to participate in research following disclosure that he or she will be unaware of or misled regarding the nature or purpose of the research. Say what? In ordinary speak this means that you must inform the subject that, “We’re not going to tell you everything and we may tell you something that isn’t true.” Simple as that. This language is also included in our *HUA Exempt Human Research Consent Script Template* that may be found in the ESTR library.

And, as usual, debriefing after the intervention is the default unless by doing so you cause more harm or there is another reasonable reason to not do so. Not doing so because it is inconvenient is not a reasonable reason.

Got all that? If not, don’t fear! Your trusty [IRB staff member](#) is here!



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