Harvard University Area

HUA IRB News

A monthly newsletter brought to you by the Harvard University Area IRB

January 2020

AAHRPP Tip Sheet #1

Our national accrediting agency, AAHRPP (Association for the Accreditation of Human Research Protection Programs), developed "Tip Sheets" that are designed to "help Organizations write Human Research Protection Program policies, procedures, and other supporting documents that help them meet the Accreditation Standards." Starting with this newsletter, we'll be going through the most salient Tip Sheets each month to provide an overview of the regulatory requirements and best practices that are used by accredited IRBs.

Tip Sheet #1 encompasses the criteria for approval that must be met for research studies that are reviewed at the Expedited Review level or reviewed by a Convened IRB. Criteria include such items as consideration of the risk to study participants, measures taken to ensure privacy and confidentiality, what needs to be included in an informed consent form, as well as other aspects that an IRB should take into account.

You can check out Tip Sheet #1 here.

Single IRB Requirement for All Federally Funded Studies in Effect January 20, 2020

The Revised Rule (aka "2018 Requirements") that took effect on January 21, 2019 requires that all federally funded research that involves multiple institutions must have only one IRB provide review. Also known as "Single IRB" (or "sIRB" – a cool new IRB word, by the way), this requirement follows the NIH's implementation of a similar policy way back in 2017. With the NIH policy, only those

studies funded by NIH and meeting the definition of a "clinical trial" required sIRB review. This current requirement applies to all federally funded "Cooperative Research". This is different because cooperative research does not need to be a clinical trial; the research only needs to involve more than one institution.

There are some exceptions (insert a sigh of relief here). The following types of studies DO NOT need to follow the sIRB requirement (as stated by the Feds):

1. Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB initially approved the research before January 20, 2020.
2. Cooperative research conducted or supported by NIH if either:
    - the NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or
    - NIH excepted the research from its single IRB policy before January 20, 2020.

One Year After the Implementation of the Revised Rule

It's been almost one year since the implementation of the long-awaited Revised Rule to our federal regulations. Included below are some of the more notable changes that might have garnered your attention.

No Continuing Review

The Revised Rule includes a provision that an annual check-in is NOT required for those studies reviewed at the Expedited Review level. Since we only started applying this provision a year ago, it will be a couple of more weeks before we start to see the impact.

Exempt Studies

The Revised Rule also gave us a new Exempt Review category and an expansion of an existing one.
Exempt category 3 is specific to "benign interventions" involving adults. This new category also allows for deception under certain conditions. Data collected under this category may be sensitive and identifiable as long as a "limited review" is conducted by the IRB. Before the Revised Rule, this type of research was reviewed at the Expedited Review level, a higher review level where the entirety of the regulations applied.

Exempt category 2 was revised and now includes clarification that data collected under this category may involve visual or audio recording as well as a carve-out that allows for the collection of sensitive, identifiable data to be collected as long as a "limited review" is conducted by the IRB. Before the

Revised Rule, this type of research was reviewed at the Expedited Review level, a higher review level where the entirety of the regulations applied.

Exempt Review Rumor

We are also aware that there were some rumors floating around that the Revised Rule allowed researchers to make their own Exempt Review determinations. Rather, the Revised Rule states that exempt determinations can be made either by 1) using a tool that is designed in such a way that if the person using the tool inputs accurate information about the study, the tool would produce a determination of whether the study is exempt. The tool would also record responses so that they may be audited for accuracy. Or, 2) if institutions chose not to use the tool, they are required to have such determinations made by an individual who is knowledgeable about the exemption categories and who has access to enough information to make an informed and reasonable determination. The regulations states that investigators would not be allowed to make exemption determinations for themselves (other than with the assistance of the tool) due to considerations of a conflict of interest.

So, where is this tool? Harvard took part in a pilot study to determine the effectiveness of an exempt tool a year or so ago with limited success. Moreover, the new exempt categories include "limited review," which requires an IRB member to conduct the review. Given this, and our federal regulators statement regarding a potential conflict of interest for researchers to make their own determinations, as an institution, Harvard has chosen to have the IRB office make exempt determinations for the research community.

Informed Consent Form Key Information

The Revised Rule changed the way our informed consent forms were formatted such that a new "Key Information" section was included. The purpose of the Key Information section is to "assist a prospective subject in understanding the reasons why one might or might not want to participate in the research." This new element is unique because it cannot be waived by the IRB. While the intent of this new section makes sense, the addition of this new section added more text and redundant information.
Thankfully, our federal regulators have recently provided clarification that if the information in the "Key Information" section is already covered in full in the remainder of the document, there is no need to duplicate the information. To this end, the IRB office is working to include guidance in the current consent form template to guide researchers on how to remove redundant information and remain compliant with this regulation.

You can check out an overview of the gifts provided to us by the Revised Rule here.

NEW! Harvard IRBs Master Agreement

Are you a Harvard University Area researcher who is collaborating with a Harvard Medical School researcher? Have you ever wondered why a reliance agreement is needed when you work with another Harvard researcher? It's almost like we are two separate institutions! Well, we are, or at least in regard to how the Harvard IRBs are set up. Since the Harvard IRBs work independently of each other, if a Harvard University Area researcher (Cambridge and Allston campus) is working with a Harvard Longwood Campus Area researcher, it **is** like being at separate institutions. When you are working across two separate institutions, each collaborator may either seek IRB review from their home institution or have their institution "rely" on another institution's IRB review.

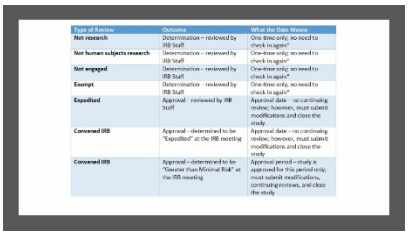
Here at Harvard, we seek to prevent duplication of effort (really, it's true!). In order to achieve this, your Harvard IRB would request that you into enter what is called a "reliance agreement". This agreement allows one IRB to provide review for another IRB. In the case of Harvard collaborations, a researcher would need to create an IRB submission in ESTR as well as request a reliance agreement in the online IRB reliance system, SmartIRB. Yes, that's right, two separate submissions!

For some time now, the Harvard IRBs have been working to find a way to simplify this process. While it is a requirement to have Harvard researchers complete an IRB submission in ESTR, we have uncovered a way to bypass the SmartIRB reliance request process.

May we introduce to you, the Harvard IRB Master Agreement. So, what is the Master Agreement? The Master Agreement is a standing document between the Harvard IRBs that acts like a permanent reliance agreement: it outlines the conditions for reliance, the responsibilities for each researcher, as well as the general terms and conditions of the reliance. But the best part about the Master Agreement is that you do not need to create a separate reliance request. Just submit your respective ESTR submission and that's it - no need for a separate SmartIRB reliance request submission.

The Harvard Master Agreement and process will become effective on Monday, January 20, 2020. But what if you forget about this brand-new process when submitting to a Harvard IRB? Or maybe you go ahead and complete a SmartIRB request? Don't worry, the folks at the Harvard IRB office will let you know and guide you to the right path.

Do You Speak IRB? IRB Determination and Approval Dates



The dates that are included on your IRB letter mean different things according to the type of review that your study received. In short, there are two different types of IRB actions: 1) Determinations and 2) Approvals.

Determinations

A determination is given to those studies that do not require IRB review using the entirety of the federal regulations either because they do not meet the various federal definitions or they are determined to be "Exempt" from the federal regulations. With these types of determinations, once they are given, they are good for the entirety of the study activity. However, an important thing to note is that if the activity changes, the determination may no longer be valid. That's right – the determination is only good as long as the activity stays within the determination's boundaries.

Approvals

You will receive an Approval if your study received IRB review at the Expedited Review or Convened IRB level. An approval means that the entirety of the federal regulations was satisfied. With the change in the federal regulations last year, studies that were reviewed at the Expedited Review level during or after January 2019 will receive an "Approval Date" (the date that you can begin your study) but no end date is provided – that means that there is no need to submit a continuing review on a yearly basis. Something to keep in mind: If your study was initially reviewed before January 2019, your study is most likely still being reviewed under the "old regulations" which require an annual check-in (continuing review).

A lot of information to digest? Click on the above graphic for an overview.

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