



HUA IRB Newsletter - June 2021



Important Regulatory Items

IRB Lifecycle Guide – Your Lifeline for All Things IRB

Navigating the IRB approval process can be challenging, especially if you are a new researcher. As there are myriad regulations that may apply to your research, federal, state, local, and even institutional, as well as different levels of IRB review, knowing what to do or what to expect can seem daunting.

The HUA IRB office has broken this process down into manageable bite-size pieces according to the stages of IRB review – whether you are just starting to think about a research project, wondering what comes after IRB approval, or not certain what your responsibilities might be as a Principal Investigator. Check out our IRB Lifecycle Guide here - <https://cuhs.harvard.edu>

Informed Consent & You

A popular saying in the IRB community is that “consent is more than just a form, it’s a process”. In fact, the IRB regulations that govern informed consent highlight several requirements that speak to the consent process. For brevity, we will only dive into a couple of these requirements. For more information on the elements of informed consent, see the complete regulation at 45 CFR 46.116 here - <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116>

- “Before involving a human subject in research..., an investigator shall obtain the legally effective informed consent of the subject or the subject’s legally authorized representative.”

Obtaining informed consent from a study subject is the default in the federal regulations. If informed consent is not obtained, the reason needs to be justified. For example, think about a research study that involves the secondary analysis of data obtained from educational records. The research may involve analyzing thousands of records. How could a researcher possibly obtain informed consent from all these individuals? When there is no consent, there are four criteria that must be justified; one of which is “the research could not practicably be carried out without the requested waiver or alteration” meaning that it would not be possible to conduct the research without the waiver in place. Note that a waiver is not valid for researcher inconvenience or hassle.

If your research study qualifies for an exempt determination (see here for more information on exempt determinations - https://cuhs.harvard.edu/revised-rule-exempt-categories-0?admin_panel=1) certain exempt categories do not require a “consent” process. The reason for this is that research that has been determined to be exempt means that the research is “exempt” from the full breadth of the federal regulations. An important thing to note is that although exempt research does not require a full informed consent form (you know the one – that multi-page document with all the template language), most exempt research does require that study subjects be informed of some key aspects of the research. This is where the Exempt Research Consent Script fits in (see **HRP-502c-HUA Exempt Research Consent Script** in the ESTR Library). The use of this Script is required when your research falls under the new Exempt category, Category 3, Benign Behavioral Intervention. And, if your research involves either deception or incomplete disclosure a very specific statement alluding to the deception or incomplete disclosure must be included (see more on what deception and incomplete disclosure are here - https://cuhs.harvard.edu/topics-guidance-secondary-data-data-security-contracts-and-collaboration-0?admin_panel=1)

- “The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.”

So, what good is providing information to a prospective study subject if they can't understand it? Each research study may have different requirements for what is "understandable". A research study that involves Ivy League graduates may not require a thorough vetting by the Flesch-Kincaid Grade Level Readability Formula however a research study that includes those who have not finished high school will have different readability needs. To account for the wide variability of reading levels that may be found in the community, IRB's expect that a study's informed consent form should read at the 8th grade reading level. In fact, all our informed consent templates (including the Exempt Research Consent Script) has been written with this mind.

Do You Speak IRB?



118 Determination

The "118 Determination" is based in the Common Rule regulation 45 CFR 46.118, a special carve-out for a type of grant (institutional or training grants), cooperative agreement, or contract, and when the specific activities of the research have not yet been determined because there is significant activity that is needed prior to involving human subjects. The National Science Foundation has also recently acknowledged this type of determination, "pursuant to 45 CFR 690.118, NSF can accept a preliminary approval from an IRB that establishes a limited approval period, requires the PI to submit an amendment or new IRB application prior to the expiration date, and stipulates that no work with human subjects, including recruitment, may be conducted until full IRB approval is obtained."

While the 118 Determination has historically been requested by various areas of the university through a secret knock on the IRB door, there has never been an established process to request and document this determination. To that end, we implemented a Standard Operating Procedure ([HRP-095-HUA 118 Determination](#)) and submission form ([HUA 118 Request Template](#)) both of which may be found in the ESTR Library to make

this process more transparent.

Some things to keep in mind with the 118 Determination:

- A 118 Determination may be the way to go if you need to access your funding but there is ample work to do before you involve human subjects.
- Not all agencies accept the 118 Determination. It is commonly used by federal agencies although some private funders may accept it.
- The 118 Determination **IS NOT** an IRB approval. It is merely an acknowledgement that there are activities that need to take place before the project involves human subjects.
- Before human subject activities occur, IRB review and approval is required. You will need to submit a new application; not just a modification to the 118 Determination in ESTR.

From all of us at the HUA IRB, Be Well and Stay Healthy!

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