



HUA IRB Newsletter - April 2020

- Working Remotely Edition -

New Situation, Same Regulations

With the rapid escalation of COVID-19, we have seen that adapting to changes in our daily life, working remotely, and doing our best to stay healthy and optimistic, is challenging - there is no doubt about it.

The IRB office staff have been doing their best to support the Harvard research community by prioritizing research related to the COVID-19 as well as modifications to existing studies to adhere to COVID-19 restrictions. For example, studies are moving procedures to online or virtual venues instead of face-to-face interaction.

Even though we are doing our best to navigate through this unprecedented situation, the regulations that govern human subjects research have not changed; the IRB office must follow all regulatory standards just as we did before the COVID-19 pandemic. We know that this can be frustrating especially when a research team is looking to implement a change to their research as quickly as possible.

Here is how you can help the IRB office to review incoming submissions compliantly and efficiently:

- When submitting a new submission, whether that be an initial submission or modification, place the text "COVID-19" as a comment. More information on

submitting a COVID-19 modification may be found here -

<https://cuhs.harvard.edu/how-do-i-submit-modification>

- While we are doing our best to expedite review of COVID-19 related research, we need you to provide us with the same level of information as you would during non-COVID-19 times. Incomplete submissions require more back-and-forth between the IRB and researchers than complete submissions.
- If you are submitting a modification that includes COVID-19 procedures, ensure that these procedures pertain to the existing study. Take into consideration whether these new procedures should instead be a new study. Submitting a modification that includes procedures that are discordant with an existing study does not save time; in fact, it may lengthen the review process.
- Check out our COVID-19 webpage for up-to-date information - <https://cuhs.harvard.edu/questions-about-covid-19-and-your-research>

Delay of the HRDSP

The implementation of the revised Harvard Research Data Security Policy (lovingly referred to as “HRDSP”) has been delayed until July 15, 2020. But don’t let this delay prevent you from using the slick, new Data Safety system. Harvard researchers can submit and maintain the following items through the online system:

- review of data management plans,
- communication with reviewers and select Harvard resource teams, and
- details about use of data, including project / data access team members.

You may also access a copy of the approved but not implemented policy here -

https://vpr.harvard.edu/files/ovpr-test/files/02.05.20_hrdsp_guidance.pdf

Do you speak IRB? Written Documentation of Consent

As well all know, the regulations require that “informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.” (45 CFR 46.117)

While we are accustomed to thinking that documentation of consent is an in-person inked signature, there are many alternatives that satisfy these requirements as technically, the regulations that govern human subjects research and other state, local, and institutional laws, policies, and guidance do not directly outline what is considered acceptable documentation of an informed consent form. What they do require is that certain guidelines are followed. Here is what those guidelines are:

There must be a mark made by the study subject. Typically, this mark is the individual's signature but in the case where a person does not read or write, this mark may be an “X”, thumbprint, or other mark.

The study team should have a reasonable way to verify the identity of the individual (“study subject”) signing the informed consent form. If a consent process occurs in-person, verification of the identity of the person is straight-forward but what if the consent process is taking place remotely? Here are some ideas: 1) A virtual meeting or teleconference where the Study Team witnesses the signing of the informed consent form by the study subject; 2) Using technology that supports an electronic signature; 3) Verification of state-issued identification or other identifying documents, or use of personal questions, biometric methods, or visual methods.

An important note - Our most applied set of regulations realizes that it may not always be possible to verify that the person signing the informed consent is the study subject and therefore encourages a risk-based approach to the consideration of subject identity. For example, for some research, if the consent form was mailed (either by postal mail, email, fax, etc.) directly to the individual it may be sufficient verification if the signed informed consent form is sent back to the study team via the same method. In these instances, it is recommended that the study team seek advice from the IRB.

A copy of the informed consent form must be provided to the study subject. The

various federal, state, local, and institutional laws, policies, and guidance do not specify the required medium of the form and indicate that the copy provided to the subject can be paper or electronic and may be provided on an electronic storage device or via email. The federal regulations go on to state that, "If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion."

And, Massachusetts Law states that, "You must not use software or security settings that would prevent the recipient from printing or saving a document that the recipient has been asked to sign electronically." (see M.G.L. c. 110G § 8(a)).

The Study Team must retain the study document for their records. While the federal regulations at 45 CFR 46 (the "Common Rule") do not specify a research records retention period, other federal regulations such as FDA and HIPAA do. Moreover, Massachusetts state law and Harvard policy require a retention period for said documents.

Exception! As the above guidelines demonstrate the flexibility in what is considered valid documented consent, there are certain regulations that require strict security requirements. As an IRB, we have determined that because of this, there are certain types of studies that require an in-person, inked signature as the only allowable method of documentation. These include studies that are regulated by the FDA and fall under 21 CFR 312 (drugs and biologics) and 21 CFR 812 (devices) and therefore require Part 11 compliance, as well as those studies regulated under HIPAA that require an individual authorization for research use/disclosure (45 CFR 164).

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

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