Harvard University Area

HUA IRB Newsletter - January 2022

Things to Know

ESTR Unavailable 1/13 – 1/14

The research administration and compliance suite of applications which includes ESTR will be unavailable from Thursday, January 13 at 7:00 pm ET until Friday, January 14 at 1:00 am ET to complete minor updates. A complete run-down of the changes that will be made can be found here.

IRB Office Remote Again

With the rise in COVID-19 cases due to the highly transmissible Omicron variant, the IRB office will transition to a remote work environment beginning on Monday, January 3rd. Should you have any questions about your submission or anything else, the best way to reach us is by email. For general questions, please contact the HUA IRB at cuhs@harvard.edu. You may also contact any of our excellent staff here.

PIPL Data Considered Sensitive

China's new Personal Information Protection Law, known as PIPL, took effect on November 1, 2021. PIPL is like the European data security law, GDPR, however, there are important differences. See comparison here.

Personal Information under PIPL is considered **sensitive** research data and must be treated accordingly per the Harvard Research Data Security Policy and Enterprise Information Security Policy. As such, data collected under PIPL will be required to be maintained at minimum data security level 3.

As we await more guidance on the impact of the PIPL on research, the HUA IRB has begun notifying research teams of the next steps that are needed.

If your research study has already been approved (or received a determination, including not human subjects research), and you are CURRENTLY collecting data from those in China, either locally or abroad, you are required to create a submission in the Harvard Data Safety and Security System AS SOON AS POSSIBLE. Instructions on how to do so may be found here - https://ras.fss.harvard.edu/files/ras/files/safety_submission_guide.pdf

If your research study has yet to be submitted or is under review, a submission in the Harvard Data Safety and Security System is required. Instructions on how to do so may be found here - https://ras.fss.harvard.edu/files/ras/files/safety_submission_guide.pdf

You can learn more about the PIPL on the *Research Data Management @ Harvard* website here.

Changes to Documentation for GDPR

The European Union (EU) adopted the General Data Protection Regulation (GDPR) in May 2018 that affects how data is collected and used in the European Economic Area (EEA) and the United Kingdom.

For any data collected or used from individuals residing in the EEA and the UK, data may be used for research only with the, "freely given, specific, informed, unambiguous, express

consent of the individual data subject."

Since May 2018, documentation of this permission has been through a signature or the marking of a check box on the GDPR Addendum that accompanies a study's informed consent form. Recently the HUA IRB office learned of some flexibility to how GDPR permission is documented from the Office of the Vice Provost for Research (OVPR).

If GDPR applies, and the Harvard University researcher is responsible for collecting consent (as opposed to a 3rd party or retrospective data, etc.), then:

1. For studies that do not involve *Special Categories* (see note about Special Categories below), verbal consent is appropriate if there is some sort of documentation of the agreement, whether that be a signature, marked "x", video/audio documentation, written notation on notes/transcription, or otherwise.
2. For studies that do involve *Special Categories*, verbal consent is not permissible without an exception from OVPR.

***Note** - The Special Categories are comprised of personal data about racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic or biometric information, health information (mental or physical, regardless of source), and sex life or sexual orientation. Personal data relating to criminal activities are similarly restricted.*

Note that by oral consent, this means that the GDPR Addendum would be read to the individual.

More information about the GDPR may be found in the Harvard GDPR Guidance document here.

Do You Speak IRB?

Exculpatory

To kick-off the new year, we will revisit one of the best (and one of the most fun to say) terms used in the IRB world, **exculpatory**.

According to the federal regulations that protect human subjects (45 CFR 46.116), “No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.”

The central purpose of the informed consent form is to provide enough information for an individual to make an informed decision about whether they wish to voluntarily participate in a research study. An informed consent form should not give the impression of a legal agreement or include any statements that the individual may lose or “give up” something if they participate.

As an example, the HUA IRB has encountered some research submissions that include a Term of Service (TOS) agreement or other binding agreement that is meant to substitute for an informed consent form. This is not permissible. Or the study may involve an informed consent form and a TOS for the use of a service, such as a mobile phone application. In these instances, the researcher must draw a line in the sand between what is research and what is not. And, to convey this line to the study participant.

Here are some examples of exculpatory language according to our federal regulators:

- “By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.”
- “I waive any possibility of compensation for injuries that I may receive because of participation in this research.”

From all of us at the HUA IRB, Happy 2022! Continue to Be Well and Stay Healthy!

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