Harvard University Area

HUA IRB Newsletter - September 2021

Things to Know

New GDPR Guidance Document - Just Released

Hot off the Harvard Office of the Vice Provost for Research (OVPR) website:

"GDPR, effective as of May 25, 2018, is a far-reaching regulation applicable to organizations with European Economic Area ("EEA") based operations and certain non-EEA organizations that process the Personal Data of individuals in the EEA. For purposes of GDPR, Personal Data refers to any information that relates to an identified or identifiable natural person (i.e., an individual, not a company or other legal entity), otherwise known as a "data subject." OVPR developed the GDPR Research Guidance to support Harvard researchers in their engagement with Personal Data and European collaborators."

The new GDPR Research Guidance document provides a succinct overview, definitions, sample scenarios, a flowchart to help in determining whether GDPR applies, as well as

links to important resources. All in all, a great document that provides a simple, yet comprehensive, overview of GDPR. Check it out here.

What's New on Our Website

Quarterly Report

As part of our reporting requirements to the Harvard Human Research Protection Program, we are providing the report shared with the Harvard University Area Advisory Committee to the larger Harvard research community. Quarterly metrics, operational updates, and outreach efforts may now be found on our website here. Just click on "Contacts" in the ribbon and choose "HUA IRB Operations/Metrics".

Online Scheduling for IRB Office Hours

We have created a new online scheduling tool to schedule meetings with IRB staff as well as reserve a space for an upcoming IRB Office Hours for your School. We will be using our online scheduling tool for all meetings beginning today. To schedule a meeting, go to our main website here – and click on the link in the section "BOOK YOUR OFFICE HOURS APPOINTMENT". Or, you can also access the direct link to our booking system here.

Things to Know When Your Harvard Research Study Will Involve MGB

The following guidance was created to inform the Harvard University Area Research Community of the evolving policy and procedural changes taking place at all Mass General Brigham (MGB) Institutions. The MGB "Institutions" include Mass General Hospital, Brigham and Women's Hospital, Mass Eye and Ear, McLean Hospital, among others. The complete listing of all affiliates may be found here.

This guidance applies regardless of which IRB is providing a review, for example, whether

the Harvard IRB is the Reviewing IRB or the Relying IRB.

Of note, a Reviewing IRB is when an Institution's IRB provides the primary IRB review. A Relying IRB is when an Institution relies on another Institution's IRB to provide the primary IRB review.

If your research study activities are taking place at an MGB Institution

Activities may include intervention or interaction with an individual at an MGB Institution, accessing data from a medical record, or consenting individuals to take part in your study.

- MGB requires that MGB affiliated individuals be part of the research study and oversee the activities that are taking place at the MGB Institution. This person would be the MGB Principal Investigator ("MGB PI")
    - **Note.** If an MBG affiliated individual is not part of the overall research study, activities at an MGB Institution are limited to the distribution of study flyers.
- Some Harvard affiliates are also MGB Affiliates. In this circumstance, the individual will be considered a Harvard affiliate and an MGB Affiliate; it is not possible to only conduct a study as a Harvard Affiliate when involving MGB in a collaborative research study.
    - While a Harvard PI may also act as the MGB PI in this circumstance, it is preferred that a person other than the Harvard PI fill the MGB PI role. If this is not possible, it is imperative that the Harvard PI understand that they are filling two roles, Harvard PI and MGB PI. Each role has distinct responsibilities including responding and communicating to the MGB IRB and the Harvard IRB.
- The individual acting as the MGB PI must submit a separate submission to the MGB IRB in addition to the Harvard IRB.

Collecting Data at an MGB Institution

Data collection at an MGB institution may include accessing data through an MGB patient's medical record, interaction, or intervention, with an MGB patient, staff member, or physician (or other MGB affiliate or individual at an MGB Institution) including conversation, self-report information, surveys, or interviews, regardless if health-related.

- Data collected at an MGB Institution will most likely be considered HIPAA Private Health Information (PHI).

- If the HIPAA PHI will leave the MGB Institution, a data use agreement (DUA) is required. The DUA will outline the security provisions for the continued use of the data at Harvard or any other non-MGB Institution.
    - Although the data will no longer be covered by HIPAA as the data have left the MGB HIPAA "Covered Entity", MGB requires that these data be retained at HIPAA data security standards (i.e., Harvard "Sensitive" data designation/ Data Security Level 4 (DSL-4)).
    - DSL-4 requires a data management plan and data security review by your Harvard School's Data Security Officer.
        - **Note.** DSL-4 data security requirements may limit how you store your data and the type of technology that you use to collect the data.
- If you will be collecting data by way of various technology (FitBit or other wearable devices, Smart Phone application or other application, etc.) and this technology is used on the premises of an MGB institution, a separate technology review will be conducted by the MGB Research Information Security Office (RISO).
    - **Note.** If the Harvard PI is also the MGB PI, the technology review by RISO will occur regardless of where the technology is used.
- As the Harvard IRB does not act as a HIPAA Privacy Board for other institutions, the MGB IRB will provide the MGB PI with a stand-alone HIPAA Authorization Form for the collection of PHI at the MGB Institution.
    - Note. If it is not possible to obtain HIPAA Authorization, the MGB IRB will determine if a HIPAA Waiver of Authorization is appropriate. This determination will be provided to the MGB PI. It is imperative that this HIPAA Waiver of Authorization also be provided to the Harvard IRB as soon as it is received.
- If the informed consent process for your study will take place at an MGB Institution, the MGB will require that the MGB RedCap system be used.
    - **Note.** Harvard and MGB each have required institutional language that must be placed in the informed consent form. It is important to work with the Harvard IRB and MGB IRB to facilitate the inclusion of this language in the informed consent form that will be used.
- **The overall research study cannot commence until all regulatory requirements at the MGB IRB and the Harvard IRB are fulfilled.**

Fees Associated with the Use of the MGB IRB

- When the MGB IRB will be the Reviewing IRB for a research study and the overall study is funded by an external source, a fee will be assessed and charged to the MGB PI.

- When the MGB IRB will be the Relying IRB for a research study, a fee will be assessed and charged to the MGB PI only when the overall study is industry-sponsored.

Do You Speak IRB?

DoD Research Regulations

We are all familiar with the Common Rule (also known as 45 CFCR 46), our main set of federal regulations that we apply to all research regardless of funding. But there are also other sets of regulations that might apply to your research. This might be because of a funding award, or other circumstances.

One such regulation is the *Department of Defense Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and Supported Research*. With this regulation, any research supported by the DoD (which also includes the Army, Navy, Air Force, and Marine Corps), or recruitment of DoD personnel requires compliance with this regulation.

Here are some main points about the DoD regulation:

- Scientific Review: New research and substantive modifications to approved research must undergo scientific review prior to or at the time of IRB review.
- Research Monitor: For studies involving greater than minimal risk, the appointment of an independent research monitor is required.

- Consent Issues:
    - Stricter requirements regarding research-related injury.
    - If the research subject of a study funded by the DoD or its components meets the definition of “experimental subject” then a waiver of consent by the IRB is prohibited unless a waiver is obtained from the Secretary of Defense.
    - Research involving consent by a legally authorized representative is only permissible if the research is intended to be beneficial to individual subjects.
- If using DoD Personnel:
    - For research involving more than minimal risk and involving military personnel, the officers and senior non-commissioned officers cannot be present at the time of recruitment into the research.
    - When compensating personnel: Individuals may receive compensation for research activities if the research activities take place outside of scheduled work hours, and Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw, among other restrictions.
- Additional Reporting Requirements for Investigators and the IRB
    - Investigators conducting DoD funded research must promptly report (within 30 days) to the DoD research protection officer: 1) When Significant changes to the research protocol are approved by the IRB, 2) The results of the IRB continuing review, and 3) Change of reviewing IRB
    - The IRB must promptly report (within 30 days) to the DoD research protection officer when they are notified by any Federal department, agency, or national organization that any part of the human research protection program is under for cause investigation of a research protocol involving a DoD support.

This is only a snapshot of the regulation. You can check out our Worksheet that goes over the entirety of items to consider, HRP-318-WORKSHEET-Additional Federal Agency Criteria, found in the ESTR Library. Just scroll to the section on DoD in the worksheet.

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

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