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# IRB NEWS

A monthly newsletter brought to you by the Harvard University Area IRB,  
Committee on the Use of Human Subjects



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## AAHRPP Accreditation - the IRB gold standard



The Harvard University Area IRB is seeking accreditation!

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) is a national organization whose primary purpose is to “accredit high-quality human research protection programs to promote excellent, ethically sound research.”

AAHRPP accreditation shows that an institution is committed to providing the most comprehensive protections for research participants.

### What does AAHRPP accreditation entail?

AAHRPP accreditation involves more than just standard operating procedures (SOPs), however having a comprehensive set of SOPs provides a good foundation. With the implementation of our [Toolkit](#) in January 2018, we’ve crossed this requirement off the list but what’s next? AAHRPP accreditation also requires that an institution have a robust human research protection program (HRPP).

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### What is a HRPP?

The [HRPP](#) is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The HRPP is based on all individuals in this Institution along with key individuals and committees **fulfilling their roles and responsibilities** as described in the HRPP plan. The HRPP demonstrates the commitment of the entire organization, not just the IRB. This is where we need your help.

As we will be working on the accreditation process during fiscal year 2019, we will be providing you, our research community, with information about accreditation in this newsletter, in-person HRPP training sessions, online resources, and other documents to assist in developing a robust and comprehensive HRPP. **Stay tuned!**

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### GDPR is coming!



The European Union (EU) General Data Protection Regulation (GDPR) which takes effect on May 25, 2018 is “designed to harmonize data privacy laws across Europe, to protect and empower all EU citizens’ data privacy and to reshape the way organizations across the region approach data privacy.”

The GDPR applies to all individuals, organizations, and institutions that collect personal data from individuals residing in the EU.

While the GDPR may appear to not be applicable to researchers in the United States, here are some aspects of the GDPR that may affect you and your research:

**Increased Scope:** The GDPR protects the personal data of those that reside in the EU. However, the location of those that are collecting the data extend beyond the EU boundaries. For example, if you are conducting an online survey that collects data from EU residents, you may be subject to GDPR.

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**Consent:** GDPR requires that consent be “clear and distinguishable” and provided in an “intelligible and easily accessible form, using clear and plain language.” The GDPR goes on to say that, “It must be as easy to withdraw consent as it is to give it.”

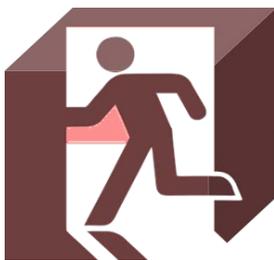
**Right to Access:** The GDPR requires that individuals from whom personal data are collected have a right to know that their data was collected, where and how it was collected, and for what purpose. Individuals also have the right under the GDPR to request a free electronic copy of the data that was collected from them.

**Right to be Forgotten:** The “right to be forgotten” also known as “Data Erasure” has become the hallmark characteristic of the GDPR. The GDPR provides individuals the right to have data that was collected from them to be erased, to cease their data from being further distributed, including third parties that may have received their data.

Harvard University has formed a working group to outline GDPR issues and provide guidance on how to navigate the GDPR and its impact on the University. More information will be coming soon but in the meantime, you can find out more about the GDPR [here](#).

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## Leaving Harvard?



All active and ongoing research involving human subjects that is expedited or greater than minimal risk requires continual oversight by an IRB. But what if you are leaving Harvard? What do you do with your research studies?

There are a couple of options available to you:

**Transferring your studies to another institution** – The Harvard IRB will work with your new institution to ensure that there is continued coverage for your research study. As soon as possible, please let your [IRB Reviewer](#) know that you are leaving Harvard and that you wish to have your study transferred to your new institution.

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**Transfer to another PI** – If taking your study with you is not an option, the study may remain open if another Harvard University Area PI is identified. The first step is to determine if the identified individual is “[PI eligible](#)”. If not, you will need to also identify a Faculty Sponsor for this individual. Once the new PI is ready, you will submit a modification to change the PI on your study. Information on how to submit a modification to change the PI may be found [here](#). Of note, to change the Principal Investigator on an approved study, select the “Other parts of the study” Modification scope.

**Close the study** – If you are not interested in continuing with your study or are just not able to carry on for various reasons, you will need to close your study. If your study is funded, it is always a good idea to check in with your funder about whether closing your study is possible. You will also want to think about what you will do with the data that has been collected. And a friendly reminder – if the data are identifiable, it is not permissible to analyze these data without current and active IRB approval. Information on how to close an IRB study may be found [here](#).

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## Do you speak IRB?



**Exculpatory (ik-skuhl-puh-tawr-ee) tending to clear or charge from guilt.**

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 a sufficient amount of information for an individual to make an informed decision about whether they wish to voluntarily participate in a research study.

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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. The 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. 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, it is imperative that the researcher draw a line in the sand between what is research and what is not and 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.”

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<http://calists.harvard.edu/mailman/listinfo/huairb>

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