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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Find your IRB Contact

Have you ever wondered how helpful it would be to have a single point of contact in the IRB office? Have you been looking for a contact person that you could establish rapport with? Have you wished for someone that understands the intricacies of your research portfolio? Well, you are in luck!

Beginning on **March 1, 2018**, IRB staff have been assigned to be the point of contact for specific Harvard Schools and Departments. Please see “Find Your IRB Contact Person!” on our website at https://cuhs.harvard.edu/find-your-departments-irb-contact-person

IRB Protocol Spotlight: How do I answer this?

How do I answer the question "Will the data be physically housed at Harvard or stored remotely under the management of Harvard Researchers?"

You may have wondered why the IRB is asking this question and what it means. The reason why this question is being asked is because the IRB is responsible for assigning a data security level per the Harvard Research Data Security Policy (HRDSP).

But what does it mean? Only data that is housed at Harvard or under the management of Harvard researchers fall under the HRDSP.

So how do I answer this protocol question?

Answer **"Yes"** if the data will be stored at Harvard (in an office, lab, dorm-room, etc.) or under the management of the Harvard research team (on personal/ home devices, email accounts, cloud services, etc.). This means that the Harvard research team is responsible for the storage and security of data. For example:

1. A Harvard researcher collects visual data of children playing games and stores it on a camera and their department's computer in the lab.
2. A Harvard researcher uses the Qualtrics platform to conduct surveys and stores the data on Qualtrics and their laptop.

Answer **"No"** if the data will be stored at a non-Harvard institution or under the management of a non-Harvard affiliated team member. This means that a non-Harvard researcher or institution is responsible for the storage and security of data. For example:

1. A Harvard researcher collaborates with a local non-profit to conduct surveys of the non-profit's clients. The data will be maintained securely by the non-profit at their institution; Harvard researchers will only access the data via VPN into the servers.
2. A Harvard researcher conducts data analysis on a large dataset. The data was collected by an outside institution. In order to access the data, the researcher must travel to the institution and conduct all analyses at that institution—the data cannot leave that institution.

Do you speak IRB?

How to decide which consent form is right for your study.

Long form, short form, or information sheet? How to decide which form is right for your study? We are hopeful to clarify what these various forms are and provide you with information on how to decide which form is right for your study.

"Long Form" Informed Consent Form: The "long form" is the informed consent form that you are probably the most familiar with. The long form contains all of the elements of consent, is a couple of pages long, and is the form that one uses with most research studies. The long form is used for all studies that meet the definition of human subjects research: studies that are minimal risk and receive an expedited review or are greater than minimal risk and are reviewed by the convened IRB. It is generally not used for studies that receive an exempt determination (see below). The default for most investigators is to use the long form.

***"Short Form" Informed Consent Form*:** The "short form" is the informed consent form that is typically used when you expect that you may enroll participants that do not speak English and there is not enough time to translate the English version of the approved consent document. The short form is **not** to be used as a substitute for a translated document. If you will be recruiting from a population that is largely Spanish-speaking and you know this, an investigator should use a translated document, not the short form.

What is a short form? A short form is a brief summary of the regulatory elements of consent. It is used in conjunction with a written summary. Typically, the written summary is the long form that is used with other participants in the study.

When is it appropriate to use the short form? If you will be recruiting from a location where there may be multiple languages and you are uncertain what those languages may be, the short form may be right for you. For example the short form may be useful if you are recruiting from an inner-city hospital waiting room where there may be many languages spoken.

Please know that there is a very specific process that must be followed when using the short form. In short (no pun intended), the investigator must:

- Prepare the short form using the short form template found here.

- Prepare a written summary that describes the research. Usually, the written summary is the long form consent form that is used with other participants in the study.
- Read the written summary and short form to the participant.
- Have a witness present when you are reading the written summary and short form to the participant. The witness cannot be the same person who is obtaining consent. The witness should be fluent in both English and the language of the participant. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.
- The short form will be signed by the participant and the witness.
- The written summary will be signed by the witness and the person actually obtaining consent.
- A copy of the written summary and the short form will be given to the participant.

***Information Sheet*:** The information sheet is used for studies that receive an exempt determination. It is also referred to as the *Exempt Research Consent Script.* According to the regulations, when a study is "exempt", it involves human subjects however the procedures are of such low risk that our federal regulators consider this research "exempt from the regulations". What this means is that the regulations do not apply and because of this, an informed consent process is not required. However, the ethical principles outlined in The Belmont Report, namely, respect for persons, emphasizes the importance of ensuring that participants are fully informed. Therefore, a "consent process" is recommended when exempt human research involves an interaction with human subjects.

All consent form templates may be found here. If you are still unsure what form to use, contact us!

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

Harvard University Area IRB, Committee on the Use of Human Subjects (CUHS)

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