Hello everyone, and welcome back to a new semester! We have a lot of projects underway, which we're excited to share with you in upcoming messages over the next several weeks. But first and foremost on everyone's mind is, of course, the pandemic. Below are some questions we've been fielding.

COVID-19 FAQS and Information

What needs an amendment?

As researchers gradually resume in-person research, you may be wondering how the health precautions intersect with your IRB procedures, and whether IRB approval (i.e., an amendment) is needed for the changes.

No amendment needed: Changes to your procedures **solely** related to social distancing, sanitization, COVID-19 symptom screening, and personal protective equipment are public health precautions and **don't** need to be approved by the IRB.

Amendment needed: Changes to research activities themselves **do** require IRB review and approval. Examples include:

- Requesting approval for remote consenting procedures (see below for options).
- Modifying in-person activities so they can be conducted virtually.
- Eliminating or modifying activities that require close contact with individuals, such as drawing blood.
- Changing eligibility criteria to exclude individuals considered to be high risk due to the pandemic.

How can I obtain informed consent remotely?

There are several options for obtaining consent remotely. You can use one or offer a combination of methods, depending on the specifics of your study.

1. Request a waiver of documentation of consent. You still provide the consent information to participants (mail, email, online, verbal, etc.) but are not required to collect a signature. The fact that they complete the study procedures can be taken as indication of their consent.
    - This waiver can be granted if your study is 1) minimal risk, and 2) doesn't have any procedures where written consent would be required outside the research context.
    - This option **cannot** be used if your research involves accessing FERPA- or HIPAA-protected records. A written signature is required under those regulations.
2. Have participants sign and return a consent form to you, either electronically (print/sign/scan) or hard copy via mail.
    - Consider whether all your participants have the ability to print and scan materials before choosing this as the sole option.
3. Have participants sign an electronic consent form in Qualtrics, using the Signature question type.
    - Insert your consent information as a static text question, then insert additional questions for participants to type their name and to electronically sign on their device.
    - Remind participants to print or save the screen if they wish to keep a copy of the consent for their records.

- DO NOT collect any study data in this survey. If you are collecting data via Qualtrics, you may include a link to a separate survey on the second page after they sign.
- Consider whether all your participants have access to a device and internet before choosing this as the sole option.

Do I need to list the risk of COVID-19 in my consent document for in-person research?

The IRB discussed this question at a recent meeting. They came to the conclusion that the risk of contracting COVID-19 is a risk of daily life and so widespread that it doesn't need to be specifically mentioned in consent forms. While the IRB did acknowledge that asking participants to meet in person does potentially increase this risk, they felt that including it in every consent form is unnecessary.

If we're asked to give a participant's name for contact tracing purposes, is that a breach of confidentiality?

In the vast majority of cases, no. Identifying who you've been in contact with doesn't necessarily identify what study they were involved in, and in any case does not link their identity to the research data. Few of our studies involve such a sensitive topic that harm can arise simply by someone knowing they participated in the study. We encourage researchers to cooperate fully with university and public health officials in contact tracing efforts.

If you do have a study where the topic is so sensitive that even identifying who you met with would potentially cause harm, it would be best to explore alternate methods of data collection (e.g. virtual) or postpone conducting the research altogether.

Participant Handout

If you would like a handout to distribute to in-person research participants about what to expect at their research visit, feel free to use and modify the attached document. Many thanks to the Center for Cognitive Medicine at Vanderbilt University Medical Center and the University of Arizona for creating and sharing it.

To learn more

For more details, please see our COVID-19 Guidance page on our website. Can't find the information there? Email or call our office (irbinfo@uwm.edu / 414-662-3544). As always, we're happy to help!

Your friendly IRB Administrators,
Melody & Leah