

Obtaining Informed Consent by Phone or Videoconference: Guidance for Human Subjects Research

COMIRB must approve the consent process for any study. For research in which signed consent is not a requirement, COMIRB can approve a phone or videoconference consent process relatively easily. However, if the research requires signed consent, the study team must provide additional detail about the consent process in the IRB application.

Obtaining signed consent using a phone or video consent process may be allowed with the following constraints. The IRB application, Section L, should address these issues:

- The prospective subject must have a written copy of the approved consent form “in-hand” at the time of the informed consent discussion.
- The discussion should begin with identification of who is participating on the call/video, and an inquiry to confirm that the potential subject has a copy of the consent form.
- For FDA-regulated research, an impartial witness must be involved in the phone consent process. If the subject agrees to participate, the witness should sign the copy of the consent form. Include the following under the signature line for the witness: “The subject’s questions were answered, and the subject agreed to participate.” The additional language must be approved by COMIRB.
- A copy of the signed consent form (and HIPAA Authorization) must be received by the study before any research procedures are conducted on the subject. The IRB application must address how this will be ensured.
- If the research involves one of our affiliate health care systems, hospital policies regarding uploading the signed consent form to the medical record must still be followed.

HIPAA Compliant Videoconferencing Tools

The University has formally approved the following audio/video applications for use with highly confidential/HIPAA data: [Zoom](#), [Skype for Business](#), [Microsoft Teams](#).

In addition, our affiliate health care systems each have telehealth systems (*e.g.*, Vidyo) which may be used for patient-facing encounters. If you are using a telehealth system with one of our affiliate health care systems, be sure this use is in compliance with health system policies.

If you have questions or a request for a different application for use for research, please [contact the OIT for an assessment](#).

FAQs:

Q: My protocol currently requires written consent, can I obtain consent during a telehealth session?

A: Contact COMIRB if you wish to discuss whether conducting a consent process over telehealth is feasible. COMIRB approval would be required before implementing the new consent procedure.

Q: Do I need COMIRB approval to permanently move study visits from in-person to over videoconferencing?

A: Yes, COMIRB approval would be required before implementing these changes to make sure risks are minimized. Carefully consider any changes before implementing them. For example, moving study visits from a clinic to the subject's home, in the current environment, would need to involve new screening procedures for the subjects, the household members, and for your research staff. Such a change may also require additional staff training and protective gear, which is in very short supply at this time. Moving study visits from clinical locations to campus non-clinical locations is not advisable. Contact COMIRB if you wish to discuss whether some study procedures could be moved to new locations.

Q: The website for a videoconference application I want to use says on its website that it is HIPAA compliant. Can't I use it?

A: No, a videoconference application is not HIPAA-compliant alone. In particular, it is not HIPAA-compliant without a legally-binding Business Associate Agreement (BAA) with the University or with one of our affiliate health care systems. [Contact the OIT for an assessment.](#)