

# Telehealth/Virtual Research Visits (1)

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Use only telehealth/virtual platforms that are approved by NIH IT/your ISSO or the Clinical Center (if protocol is being conducted at the CC)

For virtual research visits in general: your plan should be described in the IRB-approved protocol:

- Describe if this is for new subjects only or ongoing/existing subjects
- Describe how and when you will communicate with the subjects
- State what procedures/treatments may be performed locally
- Describe how and when you will communicate with the local MD, if applicable
- Describe the new consent processes, if your consent process is changing as well

# Telehealth/Virtual Research Visits (2)

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If only temporary and for a few subjects, e.g. due to the pandemic, you can submit this on a single patient planned deviation request form, rather than as a protocol amendment.

- In this case, be sure to discuss what procedures/treatments may be omitted, if applicable, and how that affects the safety of the subject/scientific integrity of the study.
- If the protocol is under an IND, the plan needs to be approved by the IND sponsor prior to IRB submission.

# Describing the Consent Process in a New Protocol (1)

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Your planned consent process(es) should be described in your protocol. Please see required content in the approved NIH protocol templates. In addition:

- If you intend to use a remote consent process to communicate with some or all of the subjects, explain whether you will use telephone consent; consent using NIH-approved video conferencing platforms, e.g. MS Teams; or a web-based consent form, etc.
- Clarify for which group of subjects you will employ which technique (if different for certain groups)
- Describe how subjects will view the consent form, i.e. a paper copy, an electronic version, etc.

# Describing the Consent Process in a New Protocol (2)

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- Ideally, the consent process should mirror a traditional consent process as closely as possible, allowing for a real time exchange of information with the participant.
- If you do not intend to have a real time, oral discussion with subjects, i.e. you will only provide contact info if there are questions, you must provide sufficient justification to the IRB to support that there is no reasonable alternative to this approach and that this will not hinder subject understanding of the research.
- If you intend to collect subjects' signatures through an electronic platform, e.g. through Adobe Acrobat or iMedConsent, using a finger, stylus or mouse, please describe this.
- If you wish to request a “waiver of documentation” (waiver of signature) be sure to state that and justify using the applicable regulatory criteria

# Electronic Consent Process vs. E-Signature

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Not all electronic consent processes use an e-signature, but all consent processes using an e-signature are considered electronic consent.

Electronic consent refers to a consent process in which the informed consent document is presented to the prospective participant in an electronic format.

Electronic signature refers specifically to when the documentation of consent, i.e., the participants “signature”, is digitally generated by the program following the participant clicking on a field of the document.

A hand signature provided using a finger, stylus, mouse or equivalent is not considered an “electronic signature” and is acceptable. Having the subject type in their name in the signature field is NOT acceptable.

A true electronic signature currently will not be approved by the IRB, as NIH lacks the software and systems to assure compliance with required regulations.

# Describing the Consent Process in an Existing Protocol

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Your planned consent process(es) should be described in your protocol.

- If you are changing your approved consent process from in person to remote or changing the remote process significantly, you need to amend your protocol prior to implementing it (see slides 3 & 4).
- If you plan to use the NIH iMedConsent platform to obtain the signature but the consent will still be obtained in person, there is no need to submit an amendment to describe this as the *process* itself is unchanged.
- If your protocol already describes a remote process (e.g. telephone consent) and your process will be unchanged aside from the platform (e.g. you are now using MS Teams instead of a telephone to communicate with the subject), you do not need to amend your protocol.