



INFORMED CONSENT DURING THE COVID-19 PUBLIC HEALTH EMERGENCY

Description

During the COVID-19 public health emergency, the IRB realizes that investigators must plan for adjustments to the consent process and documentation of consent. This guidance will outline the additional considerations that should be made in light of the public health emergency with regard to the applicable regulatory requirements of informed consent. The University of Utah has devoted a page on the IRB website, [IRB COVID-19 Communications Center](#) which will be continually updated.

Informed consent is generally documented by use of a written consent document signed by the participant or Legally Authorized Representative (LAR). Under normal circumstances, the consent document is signed after the consent process takes place. During the COVID-19 public health emergency, there may be obstacles in obtaining documentation of the consent process.

Minimizing Coercion

Investigators should continue to minimize the possibility of coercion or undue influence. Minimizing the possibility of coercion can be accomplished in a number of ways. Often, investigators give the participant an opportunity to ask questions before providing consent, and give the participant enough time to consider being in the study. If conducting a consent procedure via telephone call or video call, consider how you to allow for opportunities to provide extra time for questions or a second call to allow for the participant to take time to consider participation.

Providing a Copy of the Consent Document

While a consent procedure may take place via telephone call or video call, a copy of the consent document will need to be provided to the participant prior to the consent procedure. Consider how the consent form will be given to the participant if there is no physical contact, e.g. electronic informed consent, fax, e-mail, etc. Investigators must describe the plan for providing a copy of the consent document to the participant.

Documentation of Consent and Returning the Consent Document

Investigators must provide a plan for documentation of the consent procedure. Investigators must consider how this will be accomplished if there is no physical contact with the participant. The University of Utah IRB has prepared a [COVID-19 Consent Process Worksheet](#) in order to properly document the consent process within the research record.

Options for participants to return the signed informed consent document to the investigator may include fax, scanned document, photo image, or electronically signed informed consent (eIC). Investigators should ensure that that the technology used to obtain an electronically signed consent is compliant with any requirements set forth by the sponsor, HIPPA Privacy Rule, or FDA, as applicable.

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FDA-regulated studies must adhere to the requirements for e-signatures (see the FDA guidance, [Use of Electronic Informed Consent in Clinical Investigations](#)). Although FDA regulations do not require that the subject's copy include a signature, FDA recommends that a copy of the signed informed consent form that includes the date when the eIC was signed be provided to the subject. The copy provided to the subject can be paper or electronic and may be provided on an electronic storage device or via email.

If a consent document also includes a HIPAA authorization for research, the signature must be a valid electronic signature under applicable laws and regulations. A copy of the signed authorization must be provided to the participant, even when authorization is obtained electronically.

Additional Considerations for FDA-regulated Research

The FDA issued recommendations regarding obtaining informed consent and a signed consent during COVID-19. Investigators conducting FDA-regulated research are advised to follow the [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#) which includes detailed recommendations for:

- Obtaining informed consent for patients in isolation
- Obtaining informed consent from legally authorized representatives
- Obtaining informed consent when electronic and paper forms cannot be provided

As mentioned above, FDA-regulated studies must adhere to the requirements for e-signatures. The FDA may require that a written attestation be made in certain circumstances, the University of Utah IRB has prepared written attestation pages that may be used. Investigators may find the written attestation pages on the [IRB COVID-19 Communications Center](#) page of the IRB website.

Points to Address

- New Study Application:**
- 1. Page 4. Study Information, Question 6:** Please indicate how the consent process will be conducted in the description of study procedures.
 - 2. Consent Process Page, Question 2:** This question asks for a description of the location(s) where consent will be obtained. It may include a description of where consent may be obtained in person, but should also describe any contingency for remote consent (e.g., via video conferencing technology). **Note:** a waiver of documentation of consent is **not** appropriate in cases of remote consent when the consent process will be documented and transmitted to the investigator through an acceptable method.
 - 3. Consent Process Page, Question 3:** This question asks for a description of the consent process, including whether there is a waiting

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period between the consent process and obtaining consent. If consent is obtained remotely, describe how the signed documentation of consent will be returned to the study team, and include description of the platform(s) being used for remote consent (telephone, video call, etc.). Describe plans for providing a copy of the signed consent to the participant, if applicable.

4. Consent Process Page, Question 4 and 5: If conducting remote consent, describe measures taken to minimize coercion or undue influence and describe the provisions made to allow adequate time for questions and to exchange information (e.g., providing the consent document to the participants prior to the consent process, scheduling a second call to answer questions or to allow time for consideration, etc.).

References & Links

*University of Utah IRB
COVID-19*

<https://irb.utah.edu/about/news/2020/irb-covid19-communications.php>

*Communications Center
FDA Guidance on*

*Conduct of Clinical Trials
of Medical Products
during COVID-19 Public
Health Emergency*

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency>

Use of Electronic

*Informed Consent in
Clinical Investigations –
Questions and Answers*

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers>

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