Guidance for Obtaining and Documenting Informed Consent during COVID-19 Pandemic

This document serves as guidance for how investigators and teams can navigate the regulatory requirements during this difficult time when signed consent forms cannot be obtained due to potential contamination, and it has been crafted after review of the policies at other benchmark institutions and guidance from regulatory agencies[1]. This document is intended solely for use in COVID-specific research.

Please note, this document is not meant to address the changes that may need to occur to the consenting process for non-COVID-19 related projects that are able to open or reopen under the Office of Research Reactivation Plan. For ongoing non-COVID-19 related research, it is likely that a signed consent form (either electronic or in-person) could be obtained by methods already acceptable under MCW policy and federal regulations that align with the recommendation to limit contact with subjects. While the options detailed in this document are not disallowed for non-COVID research, there are likely methods for obtaining consent that would present fewer challenges to researchers than the methods detailed in this document. Research teams should review the Consent Decision Tree to determine when this guidance should be consulted.

The regulations and Belmont Report make clear the requirements to obtain and document informed consent for research projects involving greater than minimal risk not only to protect subjects but also to uphold their right to autonomy. For this reason, the MCW HRPP cannot endorse the elimination of the regulatory requirement to obtain and document consent for projects involving greater than minimal risk.

For projects involving no greater than minimal risk, the option of requesting a waiver of consent should be pursued whenever appropriate. When waiving consent is not appropriate (e.g. when biospecimens are collected for research or when the IRB submission is classified as a bank), the suggestions for projects involving greater than minimal risk can be followed.

For projects involving greater than minimal risk, the following options are suggested and described in greater detail on the following page:

CONSENT CAN BE OBTAINED:

- Electronically
- Via phone call or video conference

CONSENT CAN BE DOCUMENTED:

- Electronically
- By photographing the signed form
- Via confirmation from the impartial witness and investigator

[1] Please visit the following websites for specific FDA guidance on the topic of informed consent:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic

- By recording the conversation

If a potential subject or a subject's legally authorized representative (when appropriate[2]) is not able to provide consent or documentation of consent in accordance with the options above or typical practice, the subject would not be able to participate in research as the regulatory requirements would not be met. In addition, these requirements cannot be waived or appealed.

Obtaining Informed Consent

The process for consent should be described thoroughly in the project application and documented in the research records.

1. Electronically
   Example – this method could include sending a consent form via email, obtaining e-consent utilizing an iPad, or utilizing a cloud-based system for delivery and communicating in-person with subjects.
2. Phone Call or Video Conference
   Example – this method could include utilizing the phone in the subject's room or utilizing video conferencing services such as WebEx, Skype, etc.

Regardless of the method utilized, a consent form must be provided to the subject either in person by health care staff or electronically.

If consent cannot be obtained electronically or in person, it is required that an impartial witness[3] be present or the conversation be recorded. When a witness is being utilized, the following must occur:

1. The witness must be present for the entire consent discussion and confirm that the potential subject's questions have been answered.
2. The investigator must confirm that the potential subject is willing to participate and sign the consent form with the witness present (via phone or teleconference).
3. The potential subject must confirm that he or she wishes to participate and has signed and dated the consent form.

Documenting Informed Consent

1. Electronically

[2] For information on when the use of a legally authorized representative is acceptable, please see the MCW HRPP Policy titled *Informed Consent Process for Human Subject Research*.

[3] An impartial witness is defined as a person, who is independent of the project, who cannot be unfairly influenced by people involved with the project. The witness may not be part of the research team or a family member of the potential subject.

Example – The consent form can be signed, scanned, and sent via email or fax from the subject to the team. In addition, electronic signatures can be utilized.

2. Photograph
   Example – The subject or research team can photograph the entire signed consent form by camera, cellular phone, etc. and send the picture to the research team. The picture can be taken from outside of the isolation area as long as the signed consent form can be seen clearly.
3. Confirmation
   Example – The impartial witness present for the consenting process can attest that the subject confirmed the he/she wished to participate in the project and signed the consent form.
4. Recording
   Example – A phone call or video conference is utilized for the consenting process, and a witness is not present. If this method is utilized, the recording must be done in a manner compliant with regulatory and Sponsor requirements,, and all parties involved must agree to being recorded. In addition, the study records should include the audio or video recording and a signed and dated attestation by the individual obtaining consent indicating why the informed consent form signed by the subject was not retained.

The method of obtaining informed consent should be included in study records along with the signed consent form (if available). If a signed consent form is not available for the reasons outlined in this document, the study record should include an explanation of which method was used for confirming that the subject signed the consent form as well as the explanation of why the originally signed consent form could not be filed.