# COVID-19 AND CONSENT FOR RESEARCH AT DUKE
# April 30, 2020

The purpose of this policy is to provide guidance from the DUHS IRB to Duke's research community regarding the consent process during the COVID-19 pandemic. The term "COVID subject" as used in this policy shall mean potential subjects who either have a confirmed diagnosis of COVID-19 or have been in close contact with someone who has received a COVID-19 diagnosis. All research subjects who do not fall under this definition should be consented in accordance with federal regulations and standard DUHS IRB policies. The processes described in this policy apply only to COVID subjects and will remain in effect until rescinded by written notification from the DUHS IRB.

**Temporary Halt to the Requirement for Initials in the Consent Footer**
In order to reduce exposure time between the COVID subject and the individual obtaining consent, the DUHS IRB is temporarily removing the institutional requirement for initials on the footer of each page of the consent form. This temporary practice also applies to a Legally Authorized Representative (LAR) who may be consenting on behalf of the COVID subject. Please note that options contained within the body of the consent form still require initials (e.g., sub-studies, future unspecified use, etc.). Written assent from minor COVID subjects 12 years old or older should still be obtained whenever possible.

Study teams implementing this practice are encouraged to keep a copy of this policy with the study record for future documentation purposes.

**Please keep in mind that OHRP and FDA requirements for waiver of consent or waiver of documentation of consent have not changed during this pandemic. Waiver requests must still be consistent with applicable federal regulations and obtain DUHS IRB approval.**

## I. FDA-Regulated Studies

During the pandemic, the FDA requirement for written consent for research is still in effect, and applies to COVID subjects. There are two goals when re-structuring the consent process because of the COVID pandemic: (1) avoid bringing potentially contaminated materials out of the hospital room/living quarters of the COVID subject; and (2) limit exposure for the person obtaining consent while ensuring that the COVID subject is given adequate information to make a decision about participation. The following approaches are acceptable to the DUHS IRB:

Obtain consent electronically while having the consent discussion with the COVID subject/LAR via phone/WebEx/Zoom in accordance with institutional guidelines. The platform used for electronic consent must be part 11 compliant, per FDA regulations (21 CFR 11). If using REDCap for consent, please consult with DOCR to ensure part 11 compliance. If using any other software platform, please submit a request for software review at: https://redcap.duke.edu/redcap/surveys/?s=D9AX7Y8H9R.

1) Ideally, this will be accomplished using the COVID subject's own laptop or tablet. Otherwise, there must be a plan for disinfecting the device after the consent process is complete.

2) If electronic consent is not possible, the consent form can be delivered to the patient's hospital room by a caregiver who enters the room regularly as part of clinical care. The consenter can then have the consent discussion with the COVID subject/LAR and an impartial adult witness via a three-way phone or software interaction. The impartial adult witness could be a member of the patient's clinical care team who has no relationship with Key Personnel on the study team.

In its March, 2020 guidance, the FDA recommended the following sequence for consent while in isolation:

- Identification of who is on the call;
- Review of the informed consent with the patient by the investigator (or their designee) and response to any questions the patient may have;
- Confirmation by the witness that the patient's questions have been answered;
- Confirmation by the investigator that the patient is willing to participate in the trial and sign the informed consent document while the witness is listening on the phone;
- Verbal confirmation by the patient that they would like to participate in the trial and that they have signed and dated the informed consent document that is in their possession.

FDA regulations require that documentation of each subject's signed consent be retained in the study records. When retrieving the signed consent from the COVID subject is not possible, the FDA is permitting two alternatives:

1) Dated attestations from both the consenter and the adult witness that the COVID subject agreed to participate and signed the document. In such circumstances, the study team should have on-hand a prepared statement ready for signature by the consenter and witness, with the actual date and time of consent to fill in once the consent process concludes;
   **OR**
2) A photograph of the COVID subject's signature on the consent document with an explanation in the study record as to how the photograph was obtained and a statement that it is a photograph of the document signed by the COVID subject.

When obtaining consent from an LAR, the DUHS IRB's regular LAR consent policies should be followed. If the LAR is considered high risk, then the study team should follow the COVID subject process described in this policy when approaching the LAR.

**II. Non-FDA Regulated Studies**

The DUHS IRB can approve either a waiver of documentation of consent or a waiver or alteration of consent in the case of a COVID subject consenting to a non-FDA regulated study, where appropriate. The DUHS IRB's decision regarding approval of a waiver will be made on a study-by-study basis and will depend primarily upon the complexity of the study and risks of the consent process to the COVID patient and study team. In order for a waiver to be granted, the investigator must demonstrate that the research:

- could not practicably be carried out without the requested waiver or alteration, and
- involves no more than minimal risk to subjects.

In re-structuring the consent process, investigators can use any of the following when consenting COVID subjects:

1) Electronic consent;
2) Consent by mail/email, following the DUHS IRB's posted policy;
3) Remote consent using the DUHS IRB's posted scripts;
4) Implied consent when the only study activity is an online survey.

In circumstances where the signed consent document cannot be retrieved, a memo of explanation should be added to the study regulatory documents.

As described in section I of this policy, the goals are to: (1) avoid bringing potentially contaminated materials out of the COVID subject's hospital room/living quarters; and (2) limit exposure for the person

obtaining consent while ensuring that the COVID subject is given adequate information to make a decision about participation.

These recommendations regarding consent for COVID subjects are not all-inclusive. If you have alternative proposals to safely obtain valid consent, please feel free to discuss them with the IRB Executive Director, Director of Research Review, or an IRB Chair. Email links can be found on the following page on the IRB's website: https://irb.duhs.duke.edu/about-us/staff-and-chairs.

Reference

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