MEMORANDUM

Date: April 8, 2020

From: Protection of Participants, Evaluation and Policy Branch, OPCRO, DAIDS

To: DAIDS MGX, DAIDS MOs, NLGPOs, OCSO, DAIDS Clinical Trials Network Leadership, CRS Leaders, NICHD, DMID, CTU PIs, CRS Leaders

CC: DAIDS OPCRO, DAIDS Clin Trials Group

Subject: Use of Alternative/Remote Informed Consent Process during the COVID-19 Pandemic

Background:

The COVID-19 national emergency has impacted clinical trials and participants. This memo provides DAIDS' guidance for documenting informed consent during the COVID-19 national emergency.

DAIDS' guidance is based on the recently published guidances: FDA Guidance and EMA Guidance which include alternatives to in-person informed consent processes. Additional information on electronic Informed Consent can be found in the joint OHRP/FDA guidance, Use of Electronic Informed Consent; Questions and Answers, which discusses a variety of methods for obtaining 21 CFR part 11 compliant electronic signatures, such as using computer-readable ID cards, biometrics, digital signatures, and username and password combinations.

DAIDS' Guidance:

1. Alternative/Remote consent processes should be designed and conducted to maintain the privacy, safety, and confidentiality of the participant and meet all usual informed consent requirements.
2. Electronic informed consent should be obtained using validated and secure electronic systems, compliant with all applicable requirements.
3. Sites should consult the IRB/EC of record as early as possible regarding changes to the informed consent process and documentation of IRB/EC decision should be maintained. The IRB/EC of record has the final authority to approve or reject any alternative informed consent process.
4. Each site's informed consent process SOP should be revised to capture any new procedures.
5. It is especially critical that participant identity be verified and documented when using an alternate/remote consent process.
6. The U.S. OHRP and FDA regulations as well as ICH E6(R2) require that the participant be provided new information obtained during the course of the trial that may affect their continued participation, this new information should be presented, per the Secretary's Advisory Committee on Human Research Protections (SACHRP), "… using the least burdensome approach for the participant".

NOTE: The FDA and EMA guidances referenced above are only in effect during the current declaration of a national emergency.