

MEMORANDUM

Date: April 10, 2020
From: Protection of Participants, Evaluation and Policy Branch, OPCRO, DAIDS
To: DAIDS MGX, DAIDS MOs, NLGPOs, OCSO, DAIDS Clinical Trials Network Leadership, NICHD, DMID, CTU PIs, CRS Leaders, HANC
CC: DAIDS OPCRO, DAIDS Clin Trials Group
Subject: OHRP Guidance on COVID-19

Background:

DAIDS is sharing the guidance OHRP released on April 9, 2020 on the applicability of 45 CFR part 46 to actions taken by institutions and investigators in response to the COVID-19 pandemic. Please review the full guidance document for examples and complete information: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html>.

Summary of OHRP's Guidance:

In the current circumstances, OHRP encourages the research community to prioritize public health and safety and reassures the community that it will take into account the specific circumstances and be appropriately flexible and offers the following guidance:

(i) Public Health and Clinical Activities:

Actions taken for public health or clinical purposes (such as mandatory COVID-19 screenings) do not require institutional review board (IRB) approval.

a. Excluded Public Health Surveillance Activities: Some types of public health surveillance activities, including collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority (such as COVID-19 tests), are explicitly excluded from the Revised Common Rule (2018 Requirements) [45 CFR 46.102(l)(2)]. Exception: FDA regulations may apply if this involves use of an investigational in vitro diagnostic device.

b. Legally Required Reporting: When required by law to provide information related to an individual's COVID-19 test results to a public health authority, including individually identifiable information about research subjects, the HHS protection of human subjects regulations do not prevent investigators/institutions from fulfilling this requirement (even if doing so would be inconsistent with statements made in the study's consent form). Similarly, the existence of a Certificate of Confidentiality does not alter an investigator's ability to disclose a research subject's COVID-19 test results when required by federal, state, or local laws.

(ii) **Research Changes to Eliminate Apparent Immediate Hazards:** Investigators may implement changes to approved research prior to IRB review and approval, if the changes are necessary to eliminate apparent immediate hazards to the subject [45 CFR

46.108(a)(3)(iii) under the 2018 Requirements and 45 CFR 46.103(b)(4)(iii) under the pre-2018 Requirements].

(iii) Proposing and Reviewing Study Changes: Investigators may submit any proposed changes to previously approved research to the IRB at any time. The IRB may use an expedited review procedure to review and approve minor changes [45 CFR 46.110(b)(1)(ii) under the 2018 Requirements and 45 CFR 46.110(b)(2) under the pre-2018 Requirements].

(iv) Whether Suspensions of Research Must be Reported: Please note that only IRB suspensions or terminations of approved research are required to be reported to OHRP. If an investigator or an institutional official suspends or terminates approved research, such actions are not required to be reported to OHRP under 45 CFR 46.113.

Per OHRP, the FDA guidance issued on March 18, 2020 and as updated on April 2, 2020 (see <https://www.hhs.gov/ohrp/sites/default/files/fda-covid-guidance-2apr2020.pdf> - PDF), is consistent with the HHS human subjects protection regulations at 45 CFR part 46, even when the research is not FDA regulated.

Additionally, OHRP's May 14, 2018 guidance, "Effects of Disasters on Human Research Protections Programs," would be applicable to the COVID-19 outbreak (See <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/effects-of-disasters-on-human-research-protections-programs-guidance/index.html>).

Institutions and investigators are encouraged to contact OHRP for questions about the applicability of 45 CFR part 46 in response to the COVID-19 pandemic. OHRP is available by telephone at 240-453-6900 or 866-447-4777, or by email at ohrp@hhs.gov.