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U.S. Department of Health & Human Services

Office for Human Research Protections

OHRP Guidance on COVID-19

Date: April 8, 2020

This guidance represents the current thinking of the Office for Human Research Protections (OHRP) on this topic. This guidance does not create or confer any rights for or on any person and does not operate to bind OHRP or the public. OHRP guidance should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word "must" in OHRP guidance means that something is required under the Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The use of the word "should" in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of 45 CFR part 46. OHRP is available to discuss alternative approaches by telephone at 240-453-6900 or 866-447-4777, or by email at ohrp@hhs.gov.

OHRP has received questions regarding how the HHS human subjects protection regulations (45 CFR part 46)[1] apply to actions taken by institutions and investigators in response to the COVID-19 outbreak.

Given the current circumstances, the research community is encouraged to prioritize public health and safety.

As a general matter, OHRP wants to reassure the research community that OHRP will take into account the specific circumstances that institutions and investigators are experiencing, and will use available flexibility in its decision making as institutions and investigators implement actions necessary to protect public health, while still appropriately protecting research subjects.

In response to questions from the research community, OHRP offers the following guidance regarding the regulatory requirements at 45 CFR part 46:

- **Public Health and Clinical Activities:** Actions taken for public health or clinical purposes, and not for research purposes, are not research procedures and therefore do not require institutional review board (IRB) approval before being implemented. For example, if a hospital implements mandatory clinical screening procedures related to COVID-19 for all people who come to that institution, including research subjects, these screening procedures do not need to be reviewed by an IRB before they may be implemented. Further, as these activities are not research procedures, the hospital does not need IRB review in order to share the screening results with a public health authority or the research subjects, although other permissions or notice may be necessary under applicable law or policy.

- **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^[2], are explicitly excluded from the Revised Common Rule (2018 Requirements) (45 CFR 46.102(l)(2)). However, note that FDA regulations may apply if this involves use of an investigational in vitro diagnostic device. The following is an example of an activity that could be conducted under 45 CFR 46.102(l)(2) as a public health surveillance activity.

- *Example:* If a public health authority authorizes general screening for COVID-19 for public health surveillance purposes, and requests that test results be shared as necessary with a public health authority to allow the public health authority to identify, monitor, assess or investigate the COVID-19 outbreak, an investigator may incorporate these activities into an existing research study visit without prior IRB review and approval.

- **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 individuals who are research subjects, the HHS protection of human subjects regulations do not prevent investigators or institutions from fulfilling this requirement (even if doing so would be inconsistent with statements made in the study's consent form). The existence of a Certificate of Confidentiality^[3] 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. For example, if a research subject tests positive for COVID-19, an investigator may provide this test result to a public health authority if required to do so under applicable state or federal law. In such circumstances, investigators should inform the participant of the required reporting of results.

- **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). For example, we expect that investigators are cancelling or postponing non-essential study visits or conducting phone visits instead of in-person visits to reduce COVID-19 transmission risks. In these situations, investigators may make such changes to the research to reduce risks without prior IRB approval, but they should report those changes to the IRB when possible.
- **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 those changes if the changes are minor (45 CFR 46.110(b)(1)(ii) under the 2018 Requirements and 45 CFR 46.110(b)(2) under the pre-2018 Requirements).
- **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.

It is OHRP's view that the guidance FDA issued on March 18, 2020 and as updated on April 2, 2020 (see FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic at <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 if the research is not also regulated by FDA.

In addition, OHRP's May 14, 2018 guidance, "Effects of Disasters on Human Research Protections Programs," may also be applicable to the current circumstances. This 2018 guidance indicates that OHRP will take into account the situations institutions are experiencing in emergency circumstances such as the COVID-19 outbreak, and will use available flexibility in its decision making (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 asked to contact OHRP if they have questions about how the requirements of 45 CFR part 46 apply to actions being taken or planned in response to the current circumstances. OHRP is available by telephone at 240-453-6900 or 866-447-4777, or by email at ohrp@hhs.gov.

[1] In this document, the term "pre-2018 Requirements" refers to subpart A of 45 CFR part 46 (i.e., the Common Rule) as published in the 2016 edition of the Code of Federal Regulations. The pre-2018 Requirements were originally promulgated in 1991, and subsequently amended in 2005. The pre-2018 Requirements may also be referred to as the "pre-2018 Common Rule." The term "2018 Requirements" refers to the Common Rule as published in the July 19, 2018 edition of the e-Code of Federal Regulations. The 2018 Requirements were originally published on January 19, 2017 and further amended on January 22, 2018 and June 19, 2018. The 2018 Requirements may also be referred to as the "revised Common Rule."

[2] *Public health authority* means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. (45 CFR 46.102(k) of the 2018 Requirements)

[3] Refers to Certificates of Confidentiality under 301(d) of the Public Health Service Act (42 U.S.C. §241 (d)).

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