



OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

OHRP Guidance on COVID-19

OHRP Live Webcast

April 28, 2020

Office for Human Research Protections



Key Message

- OHRP understands that institutions and investigators have needed to quickly implement actions necessary to protect public health, and appropriately protect human subjects.
- We will take into account the specific circumstances that institutions and investigators are experiencing, and will use available flexibility in our decision making.



OHRP's Guidance on COVID-19: Issued April 9, 2020

- OHRP's COVID-19 guidance: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html>
- Covered topics:
 - Public Health and Clinical Activities
 - Excluded Public Health Surveillance Activities
 - Legally Required Reporting
 - Research Changes to Eliminate Apparent Immediate Hazards
 - Proposing and Reviewing Study Changes
 - Whether Suspensions of Research Must be Reported



Public Health and Clinical Activities

Key point: Actions taken for public health or clinical purposes (and not for research) are not research activities. No institutional review board (IRB) approval required before implementation. For example:

- Mandatory clinical screening for COVID-19 for all who come to an institution, including research subjects.
- Sharing such clinical screening results with a public health authority or with the research subjects.

*Note that other permissions or notice may be necessary under applicable law or policy.



Excluded Public Health Surveillance Activities

Key point: Certain public health surveillance activities are excluded from the definition of “research,” even if they might otherwise meet the definition.

- These excluded activities are not required to comply with any provisions in the Common Rule

*Note that FDA regulations may apply if this involves use of an investigational in vitro diagnostic device. In addition, other regulations, policies, or standards may still apply to the conduct of these activities.



Public Health Surveillance Exclusion

45 CFR 46.102(l)(2) of the Revised Common Rule

“**Public health surveillance activities**, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a **public health authority**.

Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).

Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).”



Public Health Surveillance Exclusion: Definition of Public Health Authority

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 revised Common Rule)



Public Health Surveillance Exclusion: 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

Key Point: When required by law, information (including individually identifiable information) related to a research subject's COVID-19 tests results may be reported to a public health authority.

This is the case even when:

- Such reporting would be inconsistent with statements made in the study's consent form.
- The research is covered by a Certificate of Confidentiality.

*In such circumstances, investigators should inform the participant of the required reporting of results.



Research Changes to Eliminate Apparent Immediate Hazards

- **Key point:** 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 revised Common Rule and 45 CFR 46.103(b)(4)(iii) under the pre-2018 Requirements)

- 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

- **Key point:** 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

- **Key point:** 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.



Contact OHRP

Web Site: <http://www.hhs.gov/ohrp>

Email (policies/regulations): OHRP@hhs.gov

Email (education activities): OHRP-Edu@hhs.gov

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Join our ListServ: <http://www.hhs.gov/ohrp/news/sign-up-for-announcements/index.html>

OHRP's disaster guidance: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/effects-of-disasters-on-human-research-protections-programs-guidance/index.html>

Bookmark this page for quick reference to OHRP resources on the revised Common Rule:
www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html



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