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Comparison of OHRP COVID-19 Guidance to FDA's

HRP is providing the following information to assist clients and the research community at large during the COVID-19 pandemic. OHRP issued guidance on COVID-19 on April 8th in response to questions from the research community. In its introduction to the guidance, OHRP emphasized that the research community should prioritize public health and safety, while still appropriately protecting research subjects. OHRP's guidance is focuses on 4 primary areas: (1) Public Health (including when public health activities are not research), (2) Research Changes to Eliminate Apparent Immediate Hazards, (3) Proposing and Reviewing Study Changes, and (4) Whether Suspensions of Research Must be Reported.

The below table provides a quick comparison of the key points in OHRP's guidance to FDA's Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic (both are quoted or paraphrased as appropriate), important differences are highlighted for ease of reference. This table does not include guidance provided by FDA that isn't also addressed in the OHRP guidance. This table compares the April 8th version of the OHRP guidance with the April 2nd version of the FDA guidance. Organizations should consult the federal websites regularly to ensure that they have the most current information:

- https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html
- https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs
- https://www.fda.gov/medical-devices/emergency-situations-medical-devices/medical-devices-and-covid-19-coronavirus-pandemic

Key Points	
OHRP	**FDA**
Public Health	
Actions taken for public health or clinical purposes, and not for research purposes, are not research procedures and therefore do not require IRB approval before being implemented. *Example: When a hospital implements clinical screening procedures for all people who come to that institution, the screening procedures do not need to be reviewed by the IRB nor is IRB review necessary for the sharing of these results with a public health authority or the research subjects.*	COVID-19 screening procedures that may be mandated by the health care system in which a clinical trial is being conducted do not need to be reported as an amendment even if done during clinical study visits unless the sponsor is incorporating the data collected as part of a new research objective.
Excluded public health surveillance activities – Some types of public health surveillance activities, including collection and testing or information or biospecimens, by or for a public health agency are explicitly excluded from the revised Common Rule definition of research. However,	The FDA guidance is silent on this topic, the public health exclusion from the definition of research in the revised Common Rule is not in FDA regulations.

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FDA regulations may apply if this involves the use of on investigational diagnostic device. *Example: If a public health authority authorizes COVID-19 screening for public health surveillance purposes, and requests that test results are shared with the public health authority so that they may monitor the outbreak, an investigator may incorporate these activities into an existing research study visit without IRB review and approval.* **Legally required reporting** - When provision of information related to an individual's COVID-19 test results to a public health authority is required by law, neither the Common Rule nor the existence of a Certificate of Confidentiality prevents an investigator or institution from fulfilling their obligation to report, even when doing so would be inconsistent with statements in the consent form. In such circumstances, the participant should be informed of the required reporting.	The FDA guidance is silent on this topic.
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. 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.	Changes in a protocol are typically not implemented before review and approval by the IRB, and in some cases, by FDA. Sponsors and clinical investigators are encouraged to engage with IRBs as early as possible when urgent or emergent changes to the protocol or informed consent are anticipated as a result of COVID-19. Such changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants (e.g., to limit exposure to COVID-19) may be implemented without IRB approval or before filing an amendment to the IND or IDE, but are **required to be reported afterwards** [emphasis added] . FDA encourages sponsors and investigators to work with their IRBs to prospectively define procedures to prioritize reporting of deviations that may impact the safety of trial participants. **In FAQs**: Protocol amendments that are **not required to prevent imminent safety risks** [emphasis added] can be implemented once they are submitted to FDA and IRB approved. FDA recognizes that during the rapidly evolving circumstances of a pandemic, a sequence of changes may

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	be needed. Consolidating several protocol modifications in a single protocol amendment would be acceptable but should be done expeditiously. Clinical investigators must document as protocol deviations any modifications to protocol-specified procedures that occur prior to IRB approval and FDA submission of the protocol amendment implementing the modification
Proposing and Reviewing Study Changes Investigators may submit proposed changes to previously approved research to the IRB at any time. The IRB may use expedited review procedures to review and approve those changes if the changes are minor.	FDA's guidance is oriented towards sponsors and investigators and is silent on the use of expedited review for IRB review of changes. We expect that FDA's position would be the same as OHRPs because the regulations align.
Reporting of Suspensions of Research 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.	FDA's guidance is oriented towards sponsors and investigators and is silent on the reporting of IRB suspensions or terminations of research. We expect that FDA's position would be the same as OHRPs because the regulations align.