Coppersmith Briefs

OHRP and FDA Guidance on Clinical Trials during the COVID-19 Pandemic

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As the COVID-19 pandemic progresses, clinical trial sponsors, sites, investigators, participants, and regulatory authorities all recognize that many clinical trials either cannot proceed as planned or must be modified to continue in the near-term. This Brief covers useful guidance issued by the Department of Health & Human Services Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). Both agencies have signaled flexibility in enforcement as long as sites and investigators prioritize protecting research participants.

OHRP Guidance

On April 8, 2020, OHRP published non-binding recommendations appropriately titled "OHRP Guidance on COVID-19" to clarify how the HHS human research subjects regulations (the "Revised Common Rule" at 45 C.F.R. Part 46) apply during the pandemic. *See* https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html. OHRP suggested it would be flexible, but stressed that "the research community is encouraged to prioritize public health and safety" while still protecting individual research participants.

While OHRP did not issue any unexpected guidance or suspend the Revised Common Rule, the guidance provides useful highlights for how the regulatory requirements apply during the pandemic:

- Sites and investigators may conduct clinical or public health activities without IRB approval, because they are not research activities. This would include integrating COVID-19 screening procedures as part of a research visit.

- Sites and investigators may conduct public health surveillance activities (such as collection and testing of biospecimens at the request of a public health authority) without IRB approval, because public health surveillance activities are expressly excluded from the Revised Common Rule.

- Sites and investigators may report COVID-19 results to a public health authority if required by law, without IRB review. This is the case even if the disclosure to a public health authority includes individually identifiable health information and even if the consent form signed by the participant does not discuss public health reporting.

- Sites and investigators may disclose COVID-19 results to research participants without IRB review.

- Investigators may implement protocol changes without prior IRB approval "if the changes are necessary to eliminate apparent immediate hazards" to research participants. Protocol changes must be reported to the IRB consistent with the IRB's reporting requirements. As an example, many in-person visits are being replaced with video or phone visits to reduce disease transmission. That can be done without IRB approval, as long as the investigator reports the changes to the IRB.
- Institutional Review Boards (IRBs) may review proposed minor changes to a research project using an expedited review procedure.

OHRP also noted that while IRB terminations or suspensions of a research project must be reported to OHRP, site or investigator termination or suspension of research do not need to be reported. So, sites that suspend clinical trials due to COVID-19 do not need to report that to OHRP (but they should report it to the reviewing IRB and sponsor).

Finally, OHRP cited its earlier 2018 guidance titled "Effects of Disasters on Human Research Protections Programs," which signals flexibility in OHRP enforcement during emergency circumstances. *See* https://www.hhs.gov/ohrp/regulations-and-policy/guidance/effects-of-disasters-on-human-research-protections-programs-guidance/index.html. While the 2018 guidance addressed physical devastation from hurricanes, tornados and earthquakes, some of the points may apply to a pandemic. For example, if a study investigator is unable to perform research activities, OHRP noted that an institution may extend its FWA to cover "collaborating individual investigators" and may designate agents to perform research activities.

FDA Guidance

On April 16, 2020, the FDA published a second update to its nonbinding guidance for clinical trials of medical products, titled "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency: Guidance for Industry, Investigators, and Institutional Review Boards." See https://www.fda.gov/media/136238/download. This recent update includes the FDA's responses to 17 FAQs and was published as a response to the numerous questions the FDA received regarding the conduct of clinical trials during the pandemic.

Like the OHRP, the FDA prioritizes the safety of research participants. The FDA does not require COVID-19 screening procedures by the site to be reported as an amendment to the protocol, even if they are done during clinical study visits (unless the sponsor is incorporating the data collected as part of a new research objective). The FDA also permits modifications to protocols to address immediate safety risks to participants, as long as the deviations are documented and reported to the reviewing IRB.

The FAQs provide helpful information for sponsors, clinical trial sites, investigators, study monitors, and IRBs on the following topics:

- Analyzing whether to continue a current trial, or initiate a new trial;
- Analyzing whether to continue administering an investigational product to a trial participant;
- Managing protocol deviations and protocol amendments;
- Submitting protocol changes in an IND amendment or IDE supplement;
- Conducting virtual clinical trial visits to monitoring participants: "changes in protocol conduct necessary to immediately assure patient safety, such as conducting telephone or video contact visits for safety monitoring rather than on-site visits, can be immediately implemented with subsequent review by the IRB and notification to the FDA";
- Documenting protocol deviations;
- Delivering investigational products to participants at home, and administering infusions of investigational product at home or by a local health care provider (and whether such provider would be considered a sub-investigator);
- Determining whether participants may procure investigational drugs commercially or through their health care provider;
- Conducting remote on-site visits and remotely or virtually monitoring trial sites;
- Obtaining electronic or alternative informed consent for participants in isolation or for those unable to travel (including suggestions for specific processes to use);
- Using remote performance outcomes or clinician-reported outcomes;
- Reviewing source documents and site study records remotely;
- Requesting a waiver of the electronic common technical document requirements; and
- Communicating with the applicable FDA review divisions.

Although the updated guidance document remains virtually unchanged from the original version published on March 18, 2020, the FDA clarified that the guidance is only temporary, and will remain in effect only for the duration of the COVID-19 public health emergency and future renewals of that declaration.

About the Authors

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