

**Research Ethics & Compliance Committee - Human Subjects FAQs
May 4, 2020 (Version 1.0)**

1. What criteria are institutions using to determine what clinical trials will be allowed to continue while COVID restrictions are in place?

Answer: State and local COVID-related restrictions on work, travel and social interactions may greatly impact the ability to conduct clinical trials that require in-person interaction with study participants. NIH has recognized that sites may need to prioritize which research continues and issued guidance regarding items that may be considered by institutions, Institutional Review Boards (IRBs) and Human Research Protection Plans (HRPPs) in this regard. [See, *Considerations for New and Ongoing Human Subjects Research During the COVID-19 Public Health Emergency* (“NIH COVID-19 Considerations”) at <https://grants.nih.gov/policy/natural-disasters/corona-virus.htm>, *Human Subjects & Clinical Trials* tab].

Many sites are limiting the continued conduct of ongoing research to clinical trials that (a) constitute research regarding COVID-19; or (b) have the potential for direct benefit to subjects through therapeutic intervention, or more restrictively, (c) if discontinued, would negatively impact the patient’s care. [See, e.g., *Partners Healthcare Policy on Conduct of Human Research Activities during COVID-19 Operations* (“Partners COVID-19 Human Research Policy”), Section A at <https://www.cogr.edu/sites/default/files/Partners%20Health%20Human%20Subjects%20Policy.pdf>] Michigan State University COVID-19 FAQs (“MI State COVID-19 FAQs”) at hrpp.msu.edu/COVID-19/covid-faq.html; & Harvard University Committee on the Use of Human Subjects *Questions About COVID-19 and Your Research?* (“Harvard COVID-19 FAQs”) at cuhs.harvard.edu/questions-about-covid-19-and-your-research]. Even when this initial threshold criterion is met, the site must then determine if on-going conduct of the study is feasible by evaluating the following factors:

- Availability of the principal investigator (PI) to provide oversight;
- Availability of sufficient study personnel to perform study-required interventions;
- Adequacy of supplies necessary to conduct the trial, including the investigational agent and personal protective equipment (PPE);
- Availability of the study site, or an alternate site/method (e.g., home visits, telehealth visits, use of local labs/imaging centers) to perform study-required interventions;
- Ability to provide, administer and account for the investigational agent if visits to the study site are no longer possible (e.g., home delivery of self-administered medication, use of home nursing visits to administer medications); and

- Continuing ability to monitor the study.

In all cases, the safety of the study subject is paramount, and the study sponsor and investigator (in consultation with the reviewing IRB as appropriate and required), must determine for each particular study that the participant’s “safety, welfare and rights is best served by continuing a study participant in the trial as per the protocol or by discontinuing the administration or use of the investigational product or even participation in the trial.” [FDA *Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic* (“FDA COVID-19 Guidance”), updated April 16, 2020, p. 6 at <https://www.fda.gov/media/136238/download>].

If studies that include direct person interactions are permitted to continue because of the study’s therapeutic benefit, sites should be prepared to follow Centers for Disease Control (CDC), state/local, and site recommendations regarding the use of PPE, handwashing, and limiting the size of groups. In this respect, sites should ensure that appropriate handwashing/hand sanitizing supplies and PPE such as masks are available for study use. [See CDC Guidance *How to Protect Yourself and Others* at <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>].

Finally, research institutions and personnel that are affiliated with and/or conduct clinical trials at health care facilities/entities (e.g., hospital, clinics, practice plans), must ensure that all their plans and criteria for the conduct of clinical trials are closely coordinated with these entities. For example, if a hospital must re-assign space that is typically used for clinical study visits to COVID-19 patient care, then it may not be possible to continue the research. Further the research and health care institutions must ensure that the research in no way detracts from the ability to provide COVID-19 patient care, and, therefore, the IRB may give deference to local site/hospital guidelines controlling the conduct of research, even when IRB criteria are satisfied. NIH recognizes this need to prioritize clinical care when it states in the [NIH COVID-19 Considerations](#) that institutions may “need to slow or pause certain human subjects research studies” because “recipient institutions will need to minimize exposure to patients, research participants, and staff and must prioritize care of patients affected by COVID-19,” as well as consider potential supply chain interruptions.

2. How are institutions addressing the issue of continued recruitment to studies that are already underway?

Answer: Institutions’ ability to continue recruitment into clinical trials depends in large extent on the local conditions under which they are operating in terms of number of COVID-19 cases in the area, state and local restrictions, and need for facilities, personnel and supplies to be re-assigned to clinical care. Some institutions have stopped recruitment into on-going trials that require in-person contact, except for COVID-19-related clinical trials. [See, e.g., Columbia University, Columbia Research *COVID-19 Impact on Human Subjects Research FAQs* (“Columbia COVID-19 FAQs”) at [research.columbia.edu/COVID-19_Research/human-subjects-research and https://research.columbia.edu/COVID-19_Research/Researchers/FAQs](https://research.columbia.edu/COVID-19_Research/human-subjects-research-and)]. Others may permit recruitment for therapeutic research that is potentially “life-saving” or “disease altering” and

for which there is no other alternative clinical treatment. Finally, many institutions permit the continued conduct of and recruitment into research studies for which both recruitment and the study itself can be safely and effectively conducted remotely without the need for in-person interaction. [See, e.g., [Harvard COVID-19 FAQs](#); Partners COVID-19 Human Research Policy].

3. How are institutions addressing the issue of patients who can no longer come to the institution for in-person protocol-required visits because of state and local COVID-19 related restrictions?

Answer: Study sponsors and investigators, in consultation with IRBs, are reviewing protocols to determine what alternative processes can be used to replace in-person interactions while still ensuring participant safety. [[FDA COVID-19 Guidance](#) at p. 6]. Investigators should review their particular IRB requirements to determine local requirements. For cases in which protocol modifications are required to eliminate in-person interactions (e.g., substituting phone visits for in-person visits), such changes may be made without prior IRB approval if they are necessary to eliminate “apparent immediate hazards to the subjects”; however, these changes should be reported to the governing IRB as soon as possible. [Office for Human Research Protections (OHRP) *Guidance on COVID-19* (“OHRP COVID-19 Guidance”), April 8, 2020 at [hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html); [FDA COVID-19 Guidance](#) p. 7; 21 CFR 56.108; 45 CFR 46.108(a)(3) & (4)]. Changes that are not related to removing harm or offering therapeutic benefit (e.g., omission of a safety lab that cannot be conducted remotely) should be submitted to the IRB in advance for review and approval. When protocol changes involve an investigational item under an Investigational New Drug Application (IND) or Investigational New Device Application (IDE), amendments also will be required to the IND or IDE. [[FDA COVID-19 Guidance](#) at p. 7].

In some cases, changes may not be required to the protocol as a whole, but rather some minor deviations may be necessary to accommodate a subject who cannot travel to the study site because of COVID-19 restrictions. In these cases, sponsor permission should be sought for such deviations, and sites may want to develop forms for this purpose. Additionally, the PI should carefully review protocol, clinical trial contract and governing IRB policies to determine requirements for reporting such deviations to the IRB. Deviations that do not adversely affect data integrity or a subject’s safety, welfare, or willingness to participate in the study may require reporting only at continuing review, unless the sponsor requires otherwise. [21 CFR 56.108; 45 CFR 46.108].

4. Who must receive notice if a PI temporarily pauses a clinical trial?

Answer: Only suspensions or terminations of approved research that are put in place by an IRB must be reported to OHRP [[OHRP COVID-19 Guidance](#)]. For FDA-regulated studies, however, sponsors must be notified, and sponsors (or sponsor-investigators), in turn, must notify the FDA. [[FDA COVID-19 Guidance](#) at p. 8-9]. Funding agencies also should be made aware of research pauses. [See, e.g., NIH FAQs COVID-19 Flexibilities, Section VII, Question 2 at <https://grants.nih.gov/faqs#/covid-19.htm?anchor=question55854>]. In general, the IRB with

jurisdiction over the study should be made aware of a pause in the research. Additionally, for protocols subject to reporting in clinicaltrials.gov, any changes to the protocol that must be communicated to participants must be “submitted not later than 30 calendar days after the protocol amendment is approved by a human subjects protection review board.” [*Id.* at Question 1].

5. Must COVID-related precautions (e.g., screenings) and risks (e.g., study team member test positive for COVID) be reviewed by IRBs and/or addressed in informed consent documentation for clinical trials?

Answer: OHRP has issued guidance stating that actions taken for clinical or public health purposes, such as clinical screening procedures for all persons who come to a health care facility, are not considered research activities and do not require IRB approval prior to implementation. [[OHRP COVID-19 Guidance](#); [FDA COVID-19 Guidance](#) at p. 7]. Research sites should contact participants before study site (or home) visits and implement screening procedures to determine if participants have COVID-19 symptoms, have recently traveled to areas in which COVID-19 is prevalent, or have been in contact with a person who has a confirmed or suspected case of COVID-19. Participants who answer positively to such screening questions should have their study visits rescheduled. Persons who pass initial screening but show symptoms of COVID-19 at the time of their visit should similarly be rescheduled and advised to contact their healthcare provider. [See, [Harvard COVID-19 FAQs](#) and [Columbia COVID-19 FAQs](#) for sample screening protocols]. The risk of contracting COVID-19 from a study team member is not a research-related risk, and therefore does not need to be included in the research informed consent. [21 CFR 50.25; 45 CFR 46.116]. Nevertheless, the question will arise as to whether participants should be notified if they have been in contact with a study team member who has tested positive for COVID-19. The CDC has stated that although “contact tracing and risk assessment” is ideal for reducing the risk of COVID-19 transmission, “it is not practical or achievable in all situations” because community transmission of the virus in the U.S. is widely reported. The Centers for Disease Control (CDC) has further stated that if healthcare facilities devote resources to contact tracing, they may divert resources from more “important infection prevention and control activities.” [CDC, *Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease 2019 (COVID-19)*, April 15, 2020 at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>]. Further, HIPAA regulations generally permit communication of reportable diseases to public health authorities, but further contact notification and tracing is done through those public health authorities. [45 CFR 164.512(b)]. Accordingly, any disease reporting and notification should be handled in accordance with state and local public health reporting requirements.

Sites that conduct research at healthcare facilities (e.g., hospitals, clinics, practice plans) must be sure to coordinate with those facilities to ensure that any health and safety measures that they take with respect to research participants are consistent with the facilities’ health and safety measures for clinical populations.

6. How should privacy requirements be addressed when researchers need to access sensitive data in a telework setting?

Answer: The use of sensitive data in an at home telework setting requires continued conformance to institutional guidance and requirements for the security of sensitive data. Further, if the data is subject to HIPAA (or other data privacy and security) regulations, a data use agreement, or contractual obligations, any use of the data must be in conformance with those requirements. If possible, the use of virtual desktops or other technology solutions that permit duplication of security parameters that are in place at your institution are best, but if these tools are not available, then IT guidance should be sought with respect to alternate security arrangements. Sensitive data should not be downloaded to or used on a computer that does not meet institutional security standards (e.g., non-encrypted computer, personal computer to which multiple family members have access via use of a single password, etc.).

7. How should privacy requirements be addressed when researchers are conducting study visits via telehealth mechanisms?

Answer: The Department of Health & Human Services Office of Civil Rights (HHS OCR) issued a notice of enforcement discretion per which it stated that it:

[W]ill not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency. [*HHS OCR Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency* at <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>].

Under this notice of enforcement discretion, healthcare providers can use non-public facing audio or video technology to provide “telehealth” services to patients during the COVID-19 public health emergency, whether or not the telehealth services pertain to the diagnosis or treatment of COVID-19. [*Id.*]. The notice provides examples of non-public facing apps that providers can use for such communication, including Apple FaceTime, Facebook Messenger video chat, Zoom, Skype and Google Hangouts video.

HHS OCR also issued accompanying FAQs that define “telehealth” to include:

“[U]se of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, and public health and health administration.” [*HHS OCR FAQs on Telehealth and HIPAA During the COVID-19 Nationwide Public Health Emergency* at <https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf>].

These FAQs also clarify that the enforcement discretion will be extended to all healthcare providers that are subject to HIPAA and provide telehealth services in “good faith” during the COVID-19 public health emergency; covered entities that only pay for healthcare services (e.g., health insurance companies) are not within the scope of the enforcement discretion. [*Id.*] Though the enforcement discretion notice does not explicitly address research, research activities that include the provision of telehealth by HIPAA-covered healthcare providers appear to fall under the notice. Following this guidance, some institutions have issued advice regarding appropriate applications for contacting and communicating with research participants (*see., e.g.,* Columbia Research, *Communicating with Research Subjects Remotely* at [https://research.columbia.edu/COVID-19 Research/Communicating-With-Research-Subjects](https://research.columbia.edu/COVID-19%20Research/Communicating-With-Research-Subjects)].

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