Considerations for New and Ongoing Human Subjects Research During the COVID-19 Public Health Emergency

NIH recognizes the challenges faced by applicants and/or recipients of NIH grant/cooperative agreement awards during the current declared public health emergency caused by COVID-19. NIH remains dedicated to the safety and welfare of human research participants and the research staff involved in these studies. On March 16, 2020, NIH published NOT-OD-20-087 for NIH-funded clinical trials and human subjects studies. The guidance encourages recipients to consult with their IRB and their institution regarding flexibilities in the research that will help protect participants and staff.

NIH understands that applicant and/or recipient institutions may need to exercise flexibility as they navigate the current public health emergency, and that some research may need to slow or pause altogether as hospitals and clinics prioritize patients affected by COVID-19, work to prevent exposure to patients and staff, and navigate supply chain interruptions. NIH encourages recipient institutions to consider how to prioritize which research may continue and offers points that could be considered by institution Human Research Protection Programs (HRPP), IRBs and monitoring entities as these decisions are made and implemented.

1. Institutional considerations when clinical needs compete for research resources

NIH realizes that recipient institutions will need to minimize exposure to patients, research participants, and staff and must prioritize care of patients affected by COVID-19. In addition, institutions may experience significant interruptions in the supply chain. Any of these circumstances may create a need to slow or pause certain human subjects research studies. In order to better protect the participants of these studies, NIH encourages recipients to thoughtfully consider plans to identify ongoing research that could be impacted by the public health emergency, and to develop appropriate strategies to minimize the risk to the individual participants, while maximizing potential benefit to them. Institutions should involve their Human Research Protections Program and the responsible IRB(s) as these plans are devised and implemented.

2. IRB and HRPP flexibilities

NIH encourages institutions and IRBs to exercise flexibility as they work with investigators to protect human participants and minimize the impact on the scientific integrity of the studies they review. Potential areas of flexibility to consider include, but are not limited to:

a. Institutions and IRBs could consider flexibility with processes and timelines for reporting missed study visits and interventions.

b. HHS regulations at 45 CFR 46.108(3)(iii) allow investigators to implement changes before obtaining prospective IRB approval in situations when necessary "to eliminate apparent immediate hazards to the subject." Institutions and IRBs could consider flexibilities in policies and practices regarding institutional reporting timelines if investigators need to exercise this provision. See OHRP Guidance on COVID-19 for more information.
c. Institutions and IRBs are encouraged to work with their investigators to develop a process to quickly and safely handle situations where study products and interventions are no longer feasible because of quarantines, lack of supply, or other COVID-19 scenarios. Changes in monitoring or additional safety visits may be required, and IRBs and institutions are urged to exercise necessary flexibility to allow enactment of these safety measures.
d. Institutions and IRBs could consider allowing flexibility in the collection of safety labs and how study visits are conducted in order to minimize the impact of missed study visits. Examples might include allowing virtual study visits when appropriate or allowing safety labs to be drawn at a local clinic.
e. If health systems require COVID-19 screening procedures, institutions and IRBs could consider circumstances in which these screenings could be done without amendment to protocols.
f. Institutions that choose to utilize provisions outlined in OHRP engagement guidance are reminded that **they need to very carefully comply with the guidance and remember that as in all cases, all FDA regulations around drug accountability still apply. Questions about the OHRP engagement guidance should be directed to OHRP (OHRP@HHS.gov)**
g. If the funded study involves FDA regulated research, please consult with FDA guidance on conduct of clinical trials of medical products during COVID-19 pandemic
h. NIH funded research within the scope of the NIH CoC policy is automatically covered by a Certificate of Confidentiality. Disclosure of information from a study protected by a certificate is permitted, among other reasons, when required by Federal, state or local laws, such as for mandatory reporting of communicable diseases. For additional information, see 42 U.S.C. § 241(d), NOT-OD-17-109 and the NIH Grants Policy Statement, Section 4.1.4.1, Certificates of Confidentiality.

3. Flexibility in planned monitoring activities

NIH encourages flexibility in monitoring activities when it can be exercised without increased risks to the participants. The recipient institution and the investigator could consider identifying alternate methods to support continuing, planned monitoring activities.

a. Institutions could consider allowing Data and Safety Monitoring Boards or Committees alternate methods of conducting the required safety review, such as allowing virtual meetings.
b. Onsite monitoring activities could be affected by the public health emergency. The recipient institution and the principal investigator could consider working with the sponsor to identify alternate methods of conducting monitoring activities, such as remote monitoring visits.

Note that alteration of the DSMP or monitoring activities needs to be communicated to the NIH Program Officer and the reviewing IRB(s).

4. Other relevant information:

a. Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding

b. Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19 (NOT-OD-20-087)

c. Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19 (NOT-OD-20-086)

d. FDA guidance on conduct of clinical trials of medical products during COVID-19 pandemic

e. HHS Office of Civil Rights (OCR) has announced notification of enforcement discretion for telehealth remote communications during the COVID-19 nationwide public health emergency.

f. Waiver of HIPPAA Sanctions and Penalties During a Nationwide Public Health Emergency

5. Additional Resources:

NIH does not endorse any specific COVID-19 plan, but provides the following examples of various approaches:

a. Johns Hopkins (JH) Research: Human Subject Research Contingency Plan
b. Washington University in St. Louis Guidance for Researchers on COVID- 19: Continuity of Research and Human Subjects Research
c. University of Miami COVID-19 Information for Researchers
d. Washington State University Mitigating Impacts to Research Activities due to COVID-19