

Management of Ongoing Human Subjects Research During COVID-19

IRBs and Ethics Committees worldwide are facing operational challenges during the COVID-19 pandemic. HRP Consulting provides this guidance to help organizations and IRBs develop an appropriate approach for the management of ongoing studies. There is no one best practice in circumstances such as this, instead organizations and IRBs must consider the nature of the research they conduct, the challenges that the research community (including the IRB and IRB office) are facing as a result of the pandemic, and develop and communicate a plan that makes the best sense for their circumstances. The following summarizes some of the key considerations that organizations, researchers, and IRBs may want to consider as they plan and respond to the evolving situation.

Key Considerations for Ongoing Research:

1. Whether the research involves in-person contact with participants
2. The locations and facilities where research activities take place
3. The prevalence of COVID-19 and the risk of exposure both due to geographical location and the facility types (e.g., hospitals, clinics, schools, etc.)
4. Any requirements or restrictions that have been or may be put into place at a national, regional, organizational or facility level and how these impact the research (e.g., travel restrictions, school closings, remote work mandates, etc.)
5. The study population and their risk profile
6. The risk profiles of investigators and staff, and their likely availability
7. Whether there are opportunities to conduct certain research activities remotely (e.g., telemedicine, videoconference, phone, electronic surveys) or in alternative settings (e.g., at an outpatient phlebotomy center vs. a hospital-based center)
8. Whether investigational product and any subject materials may be delivered directly to participants rather than having them come on-site
9. Whether and how any interruptions in standard care will impact the research
10. Whether all or a subset of research activities may be safely suspended
11. The necessity or importance of continuing the research during the pandemic
12. The risks of exposure (for all) compared to the potential for benefit

Key U.S. Regulatory Considerations:

1. Modifications to research may not be implemented until the proposed changes have been reviewed and approved by the IRB, unless the change is necessary to eliminate apparent immediate hazards to the subject(s)
2. Whether and how the pandemic itself and any proposed modifications to research impact the criteria for approval, for example:
 - a. Whether risks to subjects remain minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk; and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes

- b. Whether risks to subjects remain reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result
 - c. Whether the research plan continues to make adequate provisions for monitoring data to ensure the safety of subjects
 - d. Whether the research plan continues to provide adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
3. Informing subjects of information that may impact their willingness to continue participation (such as any changes to their risk and any changes to research procedures)
 4. Prompt reporting and management of COVID-related unanticipated problems involving risks to subjects or others

IRB Operational Considerations:

1. Are there existent procedures for IRB operations during emergencies such as natural disasters that apply to or could be modified for the pandemic?
2. Are modifications needed to SOPs to ensure timely and appropriate oversight of research during the pandemic? If so, consider how to best memorialize these modifications (e.g., in a note-to-file or SOP addendum) and communicate them to researchers, IRB members, and leadership.

Consider:

- Procedures for prompt reporting of changes made to research to eliminate apparent immediate hazards to subjects related to COVID-19
- Procedures for the submission and timely review of:
 - Proposed modifications to research related to COVID-19
 - Potential unanticipated problems involving risks to subjects or others related to COVID-19
 - Investigator-initiated holds or suspensions of research activities related to COVID-19
- Forms specifically for the above purposes or guidance for the research community on how to label submissions and use existing forms (so that the IRB office can quickly identify COVID-related submissions and so that the IRB has the information it needs to perform the review in a timely manner)
- Procedures for the IRB meetings (e.g., frequency of meetings, videoconferencing, ensuring quorum)
- Procedures for expedited and other reviews that do not require convened IRB review
- The definition of minor changes and the eligibility of such for expedited review
- The management of exempt studies and whether modifications to the research may impact the eligibility of the research to remain exempt or trigger the requirement for limited IRB review
- The management of expedited studies and whether the pandemic or modifications to the research alter the eligibility for expedited review (e.g., risk determination, categories)
- The availability of reviewers and staff and back-up plans in the event of illness

- The ability to conduct reviews remotely (e.g., if you do not have an electronic system what procedures can be put into place to accept and review submissions electronically and ensuring the security of such?)
- Communication plans – research community, leadership, IRB members, staff

Other considerations:

1. For collaborative or multi-site research, consulting with sponsors, lead investigators, and coordinating centers to avoid potential negative study impacts due to variabilities in site approach
2. For grant-funded research, consulting with the grantor regarding modifications to the research plan, grant timelines, and reporting requirements
3. For student research conducted to fulfill an academic requirement, organizations may want to consider alternatives or exceptions to these requirements. Advisors and IRBs may want to consider provisions for “plan b” protocols that can be quickly developed, reviewed, and implemented.