

Guidance for the Continuation of Human Subjects Studies with Regard to COVID-19

The IRB has been actively discussing the coronavirus situation and how investigators can continue their research in a safe manner. According to federal regulations, investigators are permitted to perform any task that is in the best interest for direct safety of subjects without the need for IRB approval, with a subsequent report to the IRB within five days.

Therefore, the IRB is allowing investigators to take the following measures in the interest of safety regarding covid-19, without the need to submit a report or modification.

1. First, if investigators are able to substitute online or telephone communications instead of in person meetings that do not include clinical procedures, they can do so.
2. They can also include screening questions for potential subjects, such as asking if they have any symptoms, have been exposed to persons with covid-19, or have travelled to areas that have a CSC Level 3 warning, and if so, potentially exclude those persons in the interest of safety.
3. The use of thermal scanners, to measure a person's temperature may also be allowed to monitor for potential illness.

Investigators who conduct research in areas that share spaces with subjects should also take additional cleaning measures such as using a disinfectant cleaner between use.

To prepare for potential disruptions of study procedures and study procedures to safeguard subjects, investigators should consider the following:

1. Assess circumstances and develop a specific plan for each active study based on the criteria below. Continue to submit all associated application materials to the reviewing IRB for research unless otherwise instructed by the IRB (including external IRBs):
 - a. Evaluate the need to continue research in evolving circumstances, including national and regional conditions and restrictions.
 - b. Consider study team availability, including the ability to recruit participants or conduct study procedures.
 - c. Plan for alternative study locations or facilities and modes of data collection (e.g. phone or electronic interactions rather than in-person, if possible).



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- d. Establish or revise data and biospecimen safety and management plans (if necessary).
 - e. Communicate directly with sponsors about study-specific needs.
 - f. Students conducting research should consult with faculty advisers about project or deadline changes.
2. For Clinical studies, investigators should consider:
- a. Consider the need for continuity of the research intervention (behavioral, drug or device) during the study period.
 - b. Assess clinical staff availability as required per the study protocol.
 - c. Plan for alternative medical or treatment locations, if needed.
 - d. Check the availability of pharmacy operations.
 - e. Plan for the orderly withdrawal of subjects, if necessary.
 - f. Prepare for delays in the ability of the team or participants to complete study procedures.
 - g. Consider other treatment options for patients not able to access clinical trials.
 - h. Create a plan for continued assessment and reporting of adverse events if participants are unable to return to the study site
3. Consider preparations for absence of study team members:
- a. Prioritize study activities.
 - b. Create or update a communications plan for the study team and subjects.
 - c. Identify emergency contacts within the study team.
 - d. Develop procedures for team members to work remotely, whenever possible.
 - e. Consider travel restrictions.
4. Communicate directly with study sponsors:
- a. Contact study sponsors/industry for study-specific information on how to continue the study or pause the research.
 - b. Obtain sponsor guidance for study conduct, including:
 - i. Changes in reporting requirements.
 - ii. Sample storage and shipping.
 - iii. Drug shortages or delays in shipping.
 - iv. Alternative safety assessments due to delays.
 - v. Delayed or missed participant contacts/visits.
 - vi. Changing the study procedures with appropriate IRB approval

Since the covid-19 pandemic is a fluid situation, additional changes and guidance may be provided as events progress.

If you have questions, please contact the IRB (888-4888).