



Peoria Institutional Review Board  
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## **COVID-19 (Coronavirus)**

### **Frequently Asked Questions Relating to Research**

(Issued March 16, 2020, 9:30 am)

The University of Illinois College of Medicine Peoria Office of Human Research Oversight is monitoring the release of information related to COVID-19 from the University of Illinois College of Medicine (Chicago) as well as local clinical partners and affiliates. This information may be updated frequently.

#### **1. Is my COVID-19 related project considered research that needs IRB oversight?**

If you are planning to do COVID-19 research, please contact the IRB Office immediately at 309-680-8630.

#### **2. Will the Peoria IRB office continue to operate as usual?**

Yes. The Peoria IRB, as a department of the University of Illinois College of Medicine Peoria (UICOMP), is open for business as usual and maintaining normal business hours throughout the campus (as of March 14, 2020).

#### **3. Do I need IRB approval in order to contact subjects to determine COVID-19 exposure or symptoms?**

No. If you implement procedures in order to identify subjects whose visits should be postponed, modified, or delayed, you do not need to modify the IRB protocol because this activity is not a research procedure. You should follow the recommendations for the institution that you work in. This includes administration of questionnaires or other procedures to determine COVID-19 exposure or symptoms.

If a subject endorses answers that may indicate exposure or symptoms, they should contact their PCP.

#### **4. Can I still conduct research procedures and interact with subjects?**

Procedures that do not require in-person contact with subjects can continue as approved in the IRB protocol. Procedures that are approved as in-person may need to be modified or postponed (See # 7 "Do I need to modify my study to make changes for alternatives to in-person study visits?")

The Peoria IRB recommends contacting subjects prior to their arrival for a study visit to determine possible exposure or symptoms.

Researchers should be considering ways to limit in-person interaction with subjects and considering alternative ways to continue study procedures in the event that in-person visits are not possible. For

example, interviews may be conducted by phone or the schedule of visits may be safely modified or delayed.

The protocol will need to be modified through a “Change in Research” via IRBNet. If you submit a modification related to COVID-19, please contact the Peoria IRB at 309-680-8630 or email a Peoria IRB staff member to prioritize these modifications through expedited review, if appropriate.

## **5. Contingency Plan Development**

Study teams should proactively prepare contingency plans for their active research protocols. Assess if the disruption of a research protocol might impact the safety of your research participants.

**Investigational Drugs:** If research participants are on investigational drugs, work with the Investigational Drug Service (IDS) to determine what the plan would be if the investigational drug could not be dispensed to your research participants. If the investigational drugs cannot be dispensed to research participants, you should make plans to transition research participants back onto their most appropriate clinically available medications. This transition should include consultations with the IDS and the clinical team caring for the research participants.

**Research Procedures:** PIs need to assess whether possible reduction in staff makes it unsafe to complete the planned research procedures.

**Timely review of research data:** If research team members are not available, integration of research care such as reviewing lab results in a timely manner might not be possible and will require special attention under the direction of the study PI. Study teams should consider the availability of appropriate back-ups to the PI to make safety assessments.

## **6. I need to monitor subjects for safety. Can I continue to do so?**

Some clinical studies require in-person study visits in order to conduct safety monitoring of the subjects. For example, subjects in a drug treatment study may need to have regular examinations, interviews, or laboratory tests for monitoring of specific possible side effects.

Researchers should plan for alternatives to in-person monitoring visits, when possible. For example, interviews could be conducted by phone or email. Visits to participants’ homes might be an alternative location for examinations or specimen collection. A modified or delayed schedule of monitoring may also be possible.

These modifications to safety monitoring procedures should be approved in advance by the IRB through a “Change in Research” via IRBNet, except when necessary to eliminate apparent hazards to a participant and there is not sufficient time to obtain IRB approval.

If you DO need to change an approved study visit in order to eliminate apparent immediate hazards to research participants, please report it to the Peoria IRB within two weeks using the UICOMP “Unanticipated Problems Form” as a deviation.

Visits that are postponed or subjects seen out of window should also be reported as protocol deviations.

## **7. Do I need to modify my study to make changes for alternatives to in-person study visits?**

Any changes to a study must be approved in advance by the IRB as a “Change in Research” to the study, unless they are necessary to eliminate immediate apparent hazards to participants. Modifications should be submitted through the regular process in IRBNet.

You will need to modify your study if the protocol specifies in-person visits.

You do not need to modify your study if the protocol does not describe whether the visit would be in-person or remote or give specifics about visit schedule.

If you submit a modification related to COVID-19, please contact the Peoria IRB at 309-680-8630 or email a Peoria IRB staff member to prioritize these modifications through expedited review, if appropriate.

**8. What if a subject reports possible COVID-19 exposure or symptoms during a study visit?**

Please follow your institutional policy.