# **Guidelines for Conducting Human Subjects**

# **Research During the COVID-19 Pandemic**

The COVID-19 pandemic has presented an unprecedented challenge to the university community. The University of Arkansas has implemented a plan to resume research and teaching activities while also making the health and safety of everyone a top priority. Institutional guidance for returning to campus may be found here: <https://health.uark.edu/coronavirus/returning-to-campus/index.php>.

The university Research Continuity plan, which describes the phased return of research activities, may be found here: <https://health.uark.edu/coronavirus/media/Research-continuity-recommendations-final.pdf>. Researchers should ensure that they have approval from their college leadership to resume research activities.

The safety of everyone conducting or participating in Human Subjects Research (HSR) is imperative. The following checklist is a tool researchers should use before beginning any new protocol or restarting one that was temporarily halted due to the pandemic. This checklist is not intended to replace the usual IRB process; IRB approval is still required before any project involving human research may be initiated.

Note that modifications to existing protocols that are intended to enhance the safety of researchers and/or participants and minimize the spread of SARS-CoV-2 (the etiologic agent of COVID-19) do not require review and approval by the IRB prior to implementation. Such changes should, however, be communicated to the IRB coordinator at irb@uark.edu as soon as possible.

* **In-person interactions**. Investigators should identify the minimum number of in-person interactions with research participants that are necessary for the research and that cannot be conducted remotely (*e.g.* via teleconference or web conference).
* **Location-specific restrictions and requirements.** Researchers should be aware of any restrictions or requirements that exist for a given research location, whether this is on-campus or at an off-campus location. Researchers should be prepared to meet those requirements.
* **Participant population.** It is important to obtain relevant, current information about the population participating in the study and to understand the risks of COVID-19 symptoms or related complications, compared to the general population. Consider modifying the inclusion/exclusion criteria for a protocol to reduce the number of high-risk individuals participating in the study.
* **Identify COVID-19-specific risks.** Issues to consider include:
1. **Interactions with Participants**: How many? How long? Do the interactions involve close contact including touching?
2. **Research Equipment**: Does the project involve the use of equipment and/or devices that may be handled by multiple participants? How will they be disinfected between uses?
3. **Research Space**: Does the space allow for appropriate social distancing given the number of people involved? How will surfaces be disinfected between participants?
4. **Hygiene**: Are handwashing facilities available for researchers and participants?
5. **PPE**: Are you providing personal protective equipment (PPE) for participants, including face coverings? Face coverings should be worn during all in-person interactions unless the study procedures preclude it.
6. **Transportation**: How will researchers and participants travel to the research location?
7. **Consent form information**: While it is important to identify participants who may be at higher risk for COVID-19, it is not advisable to include that information in the consent form unless directly related to the study.
* **Participant Infection**. Participants who have a confirmed case of COVID-19 or are presumed be positive should be excluded from the study unless essential to the focus of the study (*e.g.* studies involving COVID-19 disease).
* **Risk Mitigation**. Investigators should develop and implement a feasible plan to reduce or eliminate the risk of infection and/or spread of SARS-CoV-2. This should include actions to be taken if an exposure is identified in either a researcher or a study participant.
* **Testing for antibodies**. If study participants will be tested for antibodies to SARS-CoV-2 for either screening or research purposes, investigators must understand their responsibilities and any applicable regulations or guidelines regarding with whom that information may or must be shared, including public health officials.

# **Additional Resources**

Additional guidance has been issued by several federal agencies. Note that this guidance may be updated periodically.

- The Office of Human Research Protections (OHRP): [Guidance on COVID-19](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html)

- FDA: [Guidance on Conduct of Clinical Trials of Medical Products during COVID-19](https://www.fda.gov/media/136238/download)

- NIH: [NIH Extramural Response to Natural Disasters and Other Emergencies](https://grants.nih.gov/policy/natural-disasters.htm)

- NSF: [Guidance on the Effects of COVID-19 on Human Subjects Research](https://www.nsf.gov/bfa/dias/policy/covid19/covid19_humansubjects.pdf)

Guidelines from the Arkansas Department of Health may be found here: [Arkansas Department of Health](https://www.healthy.arkansas.gov/programs-services/topics/novel-coronavirus)

# **Questions and Answers**

1. **Are protocols being reviewed and approved during the pandemic?**

The IRB is reviewing protocols during this time. Investigators should confirm that they have approval from their respective college leadership to conduct research prior to submitting a protocol for review.

1. **Am I still expected to come to the IRB meeting to discuss my protocol?**

 IRB meetings are currently being conducted via webinar in order to comply with social distancing guidelines. Investigators are asked to participate in these meetings when they have a protocol being reviewed. The IRB Coordinator will send you a link to the meeting and invite you into the virtual meeting room when your protocol is up.

1. **Should research studies that require face-to-face interaction be suspended during the pandemic?**

 The decision whether or not to continue or suspend a research protocol must be made by the researcher. The IRB will review protocols for measures that will protect both research personnel and study participants. Protocols that do not sufficiently describe safety measures to be implemented will be returned to the researcher for further details.

 Study participants should be screened prior to conducting any face-to-face interactions. Participants exhibiting symptoms consistent with COVID-19 should be rescheduled for a later date to minimize the risks to everyone involved with the study.

 Possible Screening Questions may include:

 *Have you had any of the following symptoms in the past two weeks, even if they were relatively mild? Note that the incubation period*

 - cough

 - shortness of breath

 - two or more of the following symptoms:

 - fever

 - chills

 - headache

 - muscle aches not attributable to another medical condition or specific activity

 - throat pain

 - loss of taste or smell

 *Have you had close contact\* with a person who has tested positive or is currently being evaluated for possible COVID-19?*

 *\* Close contact is defined as a) being within approximately six feet (two meters) of a COVID-19 case for 15 minutes or more, or b) having direct contact with infectious secretions of a COVID-19 case (e.g.* *being coughed on).*

 Researchers should also consider that the following groups may be at increased risk:

 - Those who are over 60 years of age

 - People with underlying health conditions including heart disease, lung disease, or diabetes

 - People with weakened immune systems

 - Women who are pregnant

1. **Do I need IRB approval to make changes to my protocol during the pandemic?**

 Changes to an approved protocol that are intended to enhance the safety of research personnel and/or study participants (*e.g.* replacing face-to-face interviews with phone calls or web conferences) do not require prior approval before implementation. Researchers are asked to notify the IRB Coordinator of such changes at their earliest convenience. Changes not involving enhanced safety measures still require prior IRB approval.

1. **If I put a study on hold due to the pandemic, will the expiration date automatically change?**

 Researchers who wish to put their studies on hold due to the pandemic may do so at any time, and are asked notify the IRB Coordinator of such decisions. The study will not automatically be extended, but will need to be renewed by the IRB prior to the expiration date.

1. **What should I do if a member of my research team gets diagnosed with COVID-19?**

 Any individual who has symptoms that suggest infection with SARS-CoV-2 or has been diagnosed with COVID-19 should not report to work but should self-quarantine as per CDC and Arkansas Department of Health guidance. If you suspect that any research participants may have been exposed, you should notify them promptly. In order to ensure privacy of all individuals involved, names and roles of research staff should not be shared.

 Notice should also be communicated to the IRB Coordinator.

1. **What should I do if a research participant informs me that s/he has been diagnosed with COVID-19?**

 Inform all research personnel who may have been in close contact with the research subject so they may take necessary precautions including being tested for COVID-19. Notification may also need to be communicated to certain study participants. The Office of Research Compliance and the IRB Coordinator should be notified so that a determination may be made as to whether this constitutes a reportable, unexpected event.

1. **My approved protocol states that informed consent will be obtained in person. In light of the pandemic, may I obtain informed consent via electronic means (email, e-signature, etc.) instead?**

In accordance with guidance from the Office of Human Research Protections, you may make needed changes to your protocol to ensure the safety of all involved. This includes obtaining informed consent from study participants electronically rather than in person. While you do not need prior IRB approval to implement this change, the IRB Coordinator should still be notified of such changes.

For additional questions, please contact:

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