Human Subjects Research Guidance

ASU Knowledge Enterprise has updated guidelines for resuming human subjects research activities. All research activities, including human subjects research activities must be conducted in a manner consistent with all University guidance to minimize risk, ensure health and safety of faculty, staff, and research participants. For more information, review the guidelines and policies in the Research Intensification Plan.

Starting Monday, October 5, all in-person visit(s) for human subjects’ research activities can resume, regardless of location.

All human subjects’ research activities that involve in-person interaction/contact require submission of a Human Subjects Safety Plan, and approval by the unit/department/school director and college dean. Once the Human Subjects Safety Plan is approved, the PI/Researcher will receive confirmation their research activities can resume. The Human Subjects Safety Plan should always identify a direct or indirect benefit to the participants and ensure health and safety for all involved. For research activities to be conducted at an off-campus location, the plan should also include any location safety requirements in which the research will be conducted.

*The determination of risks for when in-person research visit are reasonable in relationship to anticipated/potential benefits includes such factors as 1) direct (e.g. health improvements) 2) indirect (e.g. opportunity to help others) 3) benefit to others (e.g. benefits to generalized population), if any, to/of a participant is determined by the principal investigator of the research study, the participant in consultation with a healthcare provider, as appropriate, and should be informed by current public health guidance regarding the COVID-19 outbreak. This will continue as the guiding principle of planning and implementation for in-person human subject research activities.*

As a reminder, off-campus research activities involving in-person visit(s) (e.g., face-to-face interaction) should always consider first and foremost if the research activities can continue to be conducted virtually (e.g., by phone, email or Zoom).

Approved human subjects research with in-person visits must follow the additional guidance below:

**Pre-screening**

Principal Investigators/Researchers should -

- Review participant’s individual risk profile to weigh the risks of missing the visit vs. risks of attending the visit in-person.
- Contact all research participants prior to an in-person research visit to conduct pre-screening questions and provide participant with information to comply with ASU social distancing (e.g. physical distancing)/safety/health screening guidelines as well as CDC and State while at location where research activities will be conducted.
• Screen for possible exposure to COVID-19, international and domestic travel history, symptoms such as fever, cough and flu-like symptoms before scheduling of in-person visit. If participant answers “Yes” to any questions, then the in-person visit must be postponed.
  o Questions may include but not limited to the following:
    ▪ Have you had any contact or been exposed to a person who may have possible COVID-19?
    ▪ Have you tested positive for COVID-19 and recovered?
    ▪ Have you traveled outside and/or within the US state in the past two weeks?
    ▪ Have you experienced any of the following symptoms in the past two weeks?
      • Fever, cough, difficulty breathing, sore throat, headache, flu-like symptoms. For updates on symptoms, visit CDC Coronavirus Symptoms Information Page
• Provide participants with information regarding the current COVID-19 pandemic and how best to reduce their risk of infection. This information should be shared before the research visit. Link for reference and materials: CDC COVID-19
• Ensure that all research personnel are active/current on their CITI human subjects research training.
• All research personnel have been provided guidance on what Personal Protective Equipment (PPE) to use and how to use it.

Preparing for Participants Arrival to research location/facility

Principal Investigators/Researchers should -

• Ensure a repeat screening for participants (similar to pre-screening) is completed prior to in-person research visit.
• Advise participants to take their temperature at home before leaving for their research study visit (if they have a thermometer).
• Ensure that participants and research personnel use a cloth facecovering, regardless of symptoms, upon arrival to location.
• Have a plan for participants and research team to practice Federal and State guidelines for social distancing, and mask requirements in addition to other PPE to minimize risk of exposure to COVID-19 during in-person visits at the research location including waiting room(s).
• Stagger participant arrivals for in-person data collection. It is recommended having the participants text or call the research personnel when they have arrived at in-person location.
• Have a safety plan for in-person site which includes cleaning protocol (prior to participant’s visit) and making sure that cleaning, hand-washing supplies are available at the location.
During Participants’ in-person visit to research location/facility

Principal Investigators/Researchers should consider -

- Advising participants that show symptoms of COVID-19 at the time of their visit despite passing initial pre-screening to contact a healthcare provider and reschedule their visit for a later date.

Following Participants In-person visit to research location/facility

Principal Investigators/Researchers should consider –

- Have a sanitization plan in place for in-person site location including waiting room to make sure that research areas are cleaned following every visit (door handles, chairs, tables, light switches, etc.); hand-washing supplies are refilled, when needed at location; social distancing is re-verified.
- Remind participants about best practices to reduce their risk of infection. Link for reference and materials: CDC COVID-19
- Inform participants that if they become ill within 3 days of in-person visit, they are to contact the principal investigator and primary care provider.

IRB Compliance

Note: IRB approval for human subjects research is separate from the Dean/Chair/Director approvals in this Guidance.

1. When are modifications to already approved IRB protocols required/not required? Modifications are required
   - if there are intentions to include COVID screening questions for publication purposes rather than just screening.
   - If changes to IRB-approved data collection procedures include instructions/plans for continuing any procedures at home or other sites not previously approved by the IRB.

Modifications are not required –

- if COVID screening questions are added to merely screen participants.
- If PIs are temporarily stopping subject recruitment or placing a temporary hold on all or certain study procedures that cannot be performed in-person without maintaining social distancing. However, we request that the PI send an email to research.integrity@asu.edu to inform the IRB.

2. What are some other considerations?
   - Consent forms do not need to be revised if the procedures do not create new or increased risks.
   - External IRB Review: Studies under review by an external IRB or studies that are already approved by an external IRB as the IRB of record must follow the guidelines of that IRB, but the ASU researcher must still get approvals
from Dean/Chair/Director before in-person data collection.

- We encourage PI/researcher(s) to submit the Continuing Review for their studies in order to prevent them from lapsing. Please note that resuming in-person data collection under an approved CR still requires the approvals from Dean/Chair/ Director if the plan is to collect data in-person as stated in this Guidance. The PI/researcher is responsible for obtaining these approvals.

3. What are considered Reportable events?
   - If a participant reports infection by COVID-19, unrelated to study participation, then no RNI submission is needed.
   - If it is in the best interest of the PI/researcher to eliminate an immediate apparent hazard to one or more participants and there is no time to obtain prior IRB approval, a researcher may do so. The PI must then submit this modification as reportable new information (RNI) within 5 business days to the IRB for review. If it is a serious event, it must be reported within 24 hours to the IRB for review.
   - The PI should also contact the IRB with any questions that are study specific to determine if reporting is required. Please refer to the Reportable EventLink for more information.

4. Important notes:
   - Approval for in-person data collection applies to ASU PIs/ researchers no matter where they conduct in-person data collection (on-campus or off-campus and even outside the U.S.). Note: Off-campus and work outside U.S. may be subject to other ASU restrictions and/or requirements such as travel.
   - The IRB doesn’t decide when in-person data collection can begin or resume. This is the ASU PI/researchers decision after all approvals (including IRB) have been received.

The ORIA IRB staff continues to be available to support your human subjects research needs during these very challenging times. Please don’t hesitate to contact us directly at research.integrity@asu.edu.