

**Updated COVID-19 Guidance for Conducting Human Subjects Research**  
**Virginia Tech Institutional Review Board**  
**June 2021**

The Virginia Tech Institutional Review Board (IRB) has been monitoring the status of the COVID-19 pandemic and COVID-19 vaccination levels in our area. As we begin to return to campus over the summer and in anticipation of a full return by fall, we are updating guidance for conducting human subjects research. Please see below for details of requirements as of June 15, 2021. These requirements replace existing/past IRB guidance on conducting in-person research during COVID-19.

- It is the **principal investigator's (PI) responsibility to monitor local conditions** and to pause in-person research or to institute protective measures when warranted. The Virginia Tech Human Research Protection Program (HRPP) or the Institutional Review Board (IRB) does not need to be notified if the study is paused. If protective measures are such that an amendment is warranted, then an amendment must be submitted. Please keep the vulnerability of the participant population in mind when making decisions about pausing research or instituting protective measures. For example, medically vulnerable populations or protected classes of participants (e.g., children, prisoners, pregnant women) could require special protections. The study team may include protective measures that exceed current state, local, and university requirements.
- The PI should carefully **consider which research activities can be conducted remotely/virtually** and plan accordingly (following the principle of keeping activities remote when feasible). The PI should communicate the justification for conducting in person activities to all research team members.
- **Pre-approved COVID-19 prevention plans for in-person research are no longer needed for new research** (including lab and participant standard operating procedures, contact tracing logs, and consent addenda) as long as the team conducts the study according to current IRB, Centers for Disease Control and Prevention (CDC), and university guidance (<https://www.research.vt.edu/covid-19-updates-impacts/downloads.html>).
- **Amendments to approved resumption plans are not needed** for studies where such plans are already in place, as long as the team conducts the study according to current IRB, CDC, and university guidance.
- **Protocol amendments might be needed** to bring protocols into alignment with plans to resume in-person activities. Please carefully review the current, IRB-approved study materials and submit an amendment if one is needed. Amendments are necessary for protocols that included COVID-19 mitigation strategies that the researcher plans to lift.
- **Studies that were approved but paused** (i.e., studies without resumption plans) may resume with their previously approved research, as long as the team conducts the study according to current IRB, CDC, and university guidance. Due to the long break in research activities, PIs should carefully review the current, IRB-approved study materials and submit an amendment if necessary.

- **Vaccination status can be used as an inclusion/exclusion criterion** at the PI's discretion. If used, it must be documented in the eligibility criteria section so that it can be evaluated in the same way as other eligibility criteria (e.g., Does it make sense for this study and this population? Is it discriminatory in this context?). Researchers who plan to use vaccination status as a criterion must weigh whether they will require proof of vaccination (e.g., vaccination card). If so, appropriate care must be taken with such documentation as it can be viewed as sensitive information by some members of the public. Self-disclosed health information is not covered under the Health Insurance Portability and Privacy Act (HIPAA) regulations, so asking for vaccination status is not a HIPAA violation (see <https://www.hipaajournal.com/is-it-a-hipaa-violation-to-ask-for-proof-of-vaccine-status/>).
- Researchers and study staff **who will be interacting with participants should be vaccinated**, and be willing to disclose their vaccination status to participants.
- The PI should **consult current CDC and university guidance** regarding mask-wearing and social distancing requirements, taking into account factors such as research location (e.g., inside or outside), building and room ventilation, and duration of in-person interaction.
- **Cleaning and sanitation procedures** developed for COVID-19 laboratory SOPs should be retained to the degree possible, based on CDC and university recommendations. This applies to shared equipment, commonly touched surfaces, more frequent changing of HVAC filters, and shared clothing.