**University of Virginia**

**Guidelines for Return to Social and Behavioral Sciences Research**

**With Human Participants**

**September 30, 2020**

**Overarching Goal**:

* Research with human participants, both on and off grounds can proceed only to the extent that it can be performed safely.
* UVA faculty, research team members and staff must continue to comply with executive orders and health authority guidance from national, state, local, and University authorities to protect the safety of research participants, staff, visitors, students and faculty.
* Consistent with the [Governor’s Phase 1 Reopening Plan](https://www.governor.virginia.gov/newsroom/all-releases/2020/may/headline-856681-en.html) and the [Phase 2](https://www.vdh.virginia.gov/coronavirus/frequently-asked-questions/phase-1-safer-at-home/) guidelines, the approach outlined in these guidelines is based on established physical distancing requirements for our various research spaces, requiring the use of personal protective equipment (PPE) which remains a limited resource, and sound hygienic practices, such as recommended hand washing/use of hand gel, and routine sanitizing of work areas.
* **Under no circumstances should safety be sacrificed due to the lack of adequate supplies, such as the type and quantity of PPE.** Plan in advance for PPE supply chain issues when reopening research.
* **Required personnel and core services (if required) must be available.**
* **Failure to follow these guidelines will result in revocation of research approval.**

**Timeline for re-opening non-clinical research:**

**Phase 1**: Research off-grounds with human subjects which was not previously paused, may continue provided that face-to-face contact is not required.

**Phase 2**: July 31, 2020 Off-grounds research with human subjects requiring face-to-face contact.

**Phase 3**: October 1, 2020 Research with human subjects requiring face-to-face contact on grounds or under lease by UVA in support of UVA faculty and staff activities.

*Researchers must maintain plans and be prepared to halt all activities on short notice should this becomes necessary.*

In order for researcher/staff to initiate or resume off-grounds research which requires face-to-face contact in **Phase 2**, the University will require: 1) approval under the [research ramp-up guidance procedures](https://research.virginia.edu/research-ramp-guidance) for Field-Based Research; 2) approval for the required travel to the off-grounds location, including adequate personnel procedures and PPE; and 3) project specific approval that may be required at the research site.

If a project requires international travel, this will require approval from the **International Studies Office**. Domestic travel must also adhere to relevant guidelines. Also see [UVA travel restrictions](https://www.virginia.edu/coronavirus/faq#travel) If traveling out of state, written permission must be obtained from the Department Chair/Center Director and the Associate Dean for Research. In either case, domestic or international travel, care must be taken to protect the human subjects in keeping with local requirements as well as observation of any and all cultural restrictions.

**Phase 3**, research with human subjects requiring face-to-face contact on grounds or under lease by UVA in support of UVA faculty and staff activities. This research which must be done on-grounds and which requires face to face contact on grounds is likely to be complex and might require multiple visits or specific instrumentation or interactions. In some cases there may be multiple participants and/or children escorted by parents. This will require special attention to guidelines for social distancing and density of personnel. Though this work may not resemble the work in a laboratory, the same issues hold for density, spacing and flow patterns. Shorter duration encounters may not require more than 6’ distances, however longer interactions will require greater spacing.

**General policies**

* Only research activities requiring on-Grounds presence can be conducted on-Grounds.
* In addition to the IRB approval needed in order to conduct research proceedings, during this time of research ramp-up, principal investigators (PIs) must submit a ramp-up plan via the UVA VPR Office Portal through NetBadge and receive an approval. Please see the below link for the Research Ramp-up Toolkit, which has templates and information that will assist in applications for research approval: <https://research.virginia.edu/research-ramp-toolkit>.
* Only those who actually need to be in the research space for conducting research activities are allowed.
* All faculty, researchers and research staff must take the required UVA training for return to Grounds before assisting with in-person research proceedings.
* Schedules of research space access for faculty, researchers and research staff will be determined by lab managers and approved by the Department/Program Chair and Dean’s Office in advance.
* Social distancing will be maintained by designing space between people to be at least 9 ft. during prolonged work. When moving around, a minimum of 6 ft. social distancing is required.
* All faculty, researchers, research staff and participants must wear appropriate face coverings at all times. See [UVA Policy on Face Coverings](https://uvapolicy.virginia.edu/policy/SEC-045).
* Staff must wash hands at regular intervals. When hand washing is not possible, use ethanol (>60%) hand sanitizer.
* Research space must be regularly cleaned. High contact surfaces must be regularly disinfected. Disinfect high touch areas between shifts, or more frequently as desired. Use disinfectant wipes on sensitive equipment.
* Under no circumstances should safety be sacrificed due to the lack of adequate supplies, such as the type and quantity of PPE.
* Researchers must maintain lists of all participants who attended research sessions and the dates they were on Grounds, in the event this information is needed for contact tracing by the Virginia Department of Public Health (VDH).

**Research session protocols**

* All faculty, researchers, and research staff must wear face coverings throughout research session procedures, including when in contact with research participants. See [UVA Policy on Face Coverings](https://uvapolicy.virginia.edu/policy/SEC-045).
* Throughout the study visit, including during the screening process, research staff should follow physical distancing guidelines (i.e., 6 ft. - 9 ft. of physical distancing), except as necessary to complete required procedures.
* The number of people in the research space should be limited to a density of ~250 sq. ft. /person in research areas.
* The duration of the research interaction should be limited to not more than 60 minutes. In special circumstances where this is impractical, contact your school’s Assoc. Dean for Research for possible alternatives (e.g., increased distancing in a larger space).
* Research staff will utilize non-traditional alternatives during research check-in and check-out processes (e.g., check-in performed outside when weather permits, participants led directly to research rooms after brief check-in process, etc.).
* Research participants will be required to adhere to physical distancing guidelines and flow patterns in the research space as directed by research staff.
* Research participants should not bring guests to the visit. Children and adults who require assistance may have one caregiver (unless the research protocol requires the presence of both parents). If a caregiver is present, the caregiver must also be screened prior to the visit as outlined below.
* Research participants and caregivers must wear face covering throughout the visit, except when removal of the covering is necessary for research procedures.
* Research participants will not be allowed to bring food or drink to the research space.
* Research participants will be required to sanitize hands prior to entry and exit of the research space.
* Research staff will contact participants via phone within 24 hours prior to the visit. Research staff will administer a UVA health screening during this call: <https://redcapsurvey.healthsystem.virginia.edu/surveys/?s=H9AEYA3DCC>. [Use the SBS tracing number where required.]
	+ If the participant indicates positive results for potential COVID-19 exposure during the phone screening, research staff will suggest that the participant contact their primary care physician (PCP) by phone or email or if there is no PCP, call the VDH hotline at 1-877-ASK-VDH3 (877.275.8343) and cancel this participant’s research session.
	+ If the participant does not indicate positive results for potential COVID-19 exposure, research staff will verbally confirm and document that the participant is well. Research staff will explain the procedures for on-site screening, including that wearing a face covering is required throughout the visit. Research staff will instruct the participant to cancel her/his session if health status should change in the time prior to the scheduled research session.
* Research staff will administer and submit UVA health screening again upon participant arrival: <https://redcapsurvey.healthsystem.virginia.edu/surveys/?s=H9AEYA3DCC>.
	+ If the participant indicates positive results for potential COVID-19 exposure, research staff will provide participant with a recommendation to contact their primary care physician (PCP) by phone or email or if there is no PCP, call the VDH hotline at 1-877-ASK-VDH3 (877.275.8343) and direct participant to exit premises.
	+ If the participant does not indicate positive results for potential COVID-19 exposure, research session protocol will proceed.
* In the event that research participant is confirmed for COVID-19 and has entered the space for research proceedings, research staff will follow the guidelines on proper closure and sanitization of research space and materials.

**NOTE: If the facility in which this research occurs has stricter restrictions than outlined above, the facility guidance must be followed. Failure to follow these guidelines will result in revocation of onsite privileges.**