IRB: In-Person Human Subjects Research Process DRAFT

1. **Select Research Personnel**. PIs can select up to 4 research personnel that will be designated for in-person contact with human subjects (HSR Personnel). PIs must email research@utdallas.edu with the Name and NetID's of their research personnel selection and request the number of existing campus time slots to be re-designated as active human subject research slots.

2. **Consent.** COVID-19 testing is performed by UTSW and individual consent to share the results is required. Therefore, after the selection process, designated HSR Personnel will be contacted via email with a link to a questionnaire and the consent form. HSR Personnel must complete the questionnaire and sign a consent form in order to conduct in-person human subjects procedures. The consent form will only need to be signed one time while the HSR Personnel is designated to run in-person human subjects experiments, regardless of the number of times the HRS Personnel is tested.

3. **Designating Expected Contact with Human Participants.** Each lab is limited to 3 COVID-19 tests a week for HSR Personnel (Lab PI + 2 additional research personnel). HSR Personnel must be tested for COVID-19 once every week that they intend to come in contact with human subjects.* After a research participant is scheduled for an in-person study session with a PI's lab, this session must be added to the Lab Resources Scheduler (LRS) using the human subjects research slots added in item #1 above. **Note: these research slots are meant to indicate HSR Personnel's expected contact with human subjects and do not actually schedule an appointment with a human participant.**

4. **HRS Personnel Testing Appointments.** HRS Personnel will schedule their respective COVID-19 testing appointments in LRS using (name of resource) slot. The testing slots are scheduled on an individual basis and are timed so only one HRS Personnel will be tested at any one time.

5. **Testing Results.** Results will typically be available within 12 – 24 hours of testing. If the COVID-19 test results are negative, then the HRS Personnel may proceed to their previously scheduled appointments with human subjects. If the test results are positive, the research personnel will be contacted by the COVID-19 coordinator and should NOT proceed to their human subjects' appointments. Participant appointments will be rescheduled or an alternate lab HSR Personnel assigned to run the participant.

6. **Repeat.** Steps 3 – 5 shall be repeated each week that a PI plans to run in-person human subjects experiments at UTD.

   * There are two locations available for testing (Brain Health & Campus). More info on testing.

   ** Example of human subjects time slot vs COVID-19 test appoint time slot

Suggested

It is recommended that a PI divides their 4 research personnel into "A" "B" teams to take turns coming in-person contact with human subjects. For example, in the case of an unexpected event such as a positive COVID-19 test from team A, team B would still be operationally available.
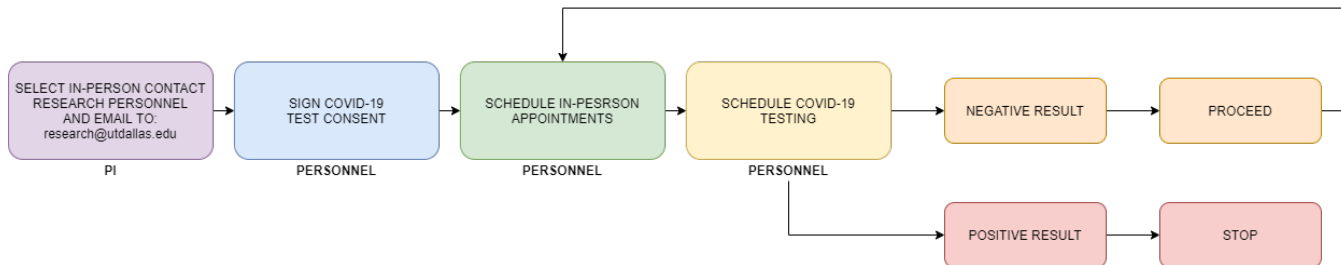
Testing Process

1. COVID-19 tests will be administered at (insert locations) and will be submitted to the University of Texas South Western (UTSW) for analysis. Results will typically be available within 12 – 24 hours of testing.
2. From UTSW, test results are relayed to the COVID-19 Coordinator (Karlynda Poage). If there is a positive result, the HSR Personnel who tested positive will be contacted by the COVID-19 Coordinator via phone and the Coordinator will develop a timeline of the 2 days prior to the time of testing.
3. COVID-19 Coordinator will follow up on the phone call with an email for documentation.

4. COVID-19 Coordinator will contact the Lab PI listed on the Veoci consent form, the Office of Research, and facilities to ensure the lab is cleaned appropriately.

If HSR Personnel had <u>no contact</u> with participants:

1. HSR Personnel who tested positive will quarantine for ten (10) days after receiving the test results. They will not be able to return to campus until they have been fever-free for at least 24 hours and have seen an improvement of any (if HRS Personnel is symptomatic).
2. Lab members who maintain negative results will continue their research projects.

If HSR Personnel <u>had contact</u> with participants:

1. Lab PI will notify participant(s) who had contact with the COVID-19 positive HSR Personnel via phone for verbal notification followed by an email / letter for written documentation.
2. The Lab PI will reach out to the COVID-19 Coordinator for assistance on the appropriate language to use in the notification to participant(s).
3. HSR Personnel who tested positive will quarantine for ten (10) days after receiving the test results. They will not be able to return to campus until they have been fever-free for at least 24 hours and have seen an improvement of any symptoms (if HRS Personnel is symptomatic).
4. Lab members who maintain negative results will continue their research projects.