**Coronavirus Disease 2019 (COVID-19) Research Protocol Risk Reduction Checklist**

**(Updated 7/6/20)**

The goal of the Texas State University Institutional Review Board (IRB) is to guide investigators in reducing the risk of Coronavirus Disease 2019 (COVID-19) among investigators, participants, and study teams, thereby preventing the spread of the disease within the populations of Texas State University, communities, and state. All IRB protocols will continue to be reviewed on an individual basis. IRB members will use the *COVID-19 Research Protocol Risk Reduction Checklist* to guide their review and decisions for recommendations and approval. The *COVID-19 Research Protocol Risk Reduction Checklist* (from here on out will be referred to as the “Checklist”) will be updated as knowledge and national recommendations change over time. Therefore, it will be all investigators’ responsibility to stay vigilant to the IRB postings throughout the duration of their protocol/study. It is also the expectation that all researchers follow current federal and state guidelines. ([CDC guidelines](https://www.cdc.gov/coronavirus/2019-nCoV/index.html), [Texas Department of State Health Services](https://www.dshs.texas.gov/), [Texas State Student Health Center](https://www.healthcenter.txstate.edu/))

The following checklist describes the needed COVID-19 risk reductions according to four levels from 0 – 3 with Level 0 meaning “No Risk” up to Level 3 or “High Risk.” Any needed changes to an existing approved protocol to reduce immediate or hazardous risks to participants can be implemented without IRB approval; however, the IRB still needs to be notified within 5 business days.

**A. Texas State IRB Level 0 Risk Reduction** – (No Risk) designated for protocols with no face-to-face contact with participants. For example, survey research, secondary data analysis, on-line teaching protocols, observation studies using videoconferencing methodologies, etc.

**B. Texas State IRB Level 1 Risk Reduction** – (Low Risk) designated for protocols that implement data collection or recruitment process that requires face-to-face interaction but does not include physical contact. Protocols must include proper participant screening, hand hygiene and social distancing (each researcher and each participant are at least 6 feet apart). The protocol may include an assessment that requires the participant to perform an activity (e.g. stack blocks; draw a shape as part of mental status assessment; wear virtual reality equipment; perform exercise; in-person surveys; in-person observation; educational research in a school or program setting; etc.) which require in-person interactions with the investigator.

**Conditions to be met:**

1. Schedule participants so that there is no congregating in research settings.
2. Perform temperature checks as part of investigator and participant screenings. Using a noncontact thermometer (or disposable equipment) for adults and one accompanying family member (if a minor) or translator (if indicated).
3. Follow [CDC guidelines](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fprepare%2Fprevention.html) for social distancing and handwashing, cough/sneeze etiquette, surface cleansing and disinfecting after each participant encounter and use ofappropriate personnel protective equipment (PPE).
4. Disinfect all equipment that will be in contact with the subject and all contact surfaces after each subject exits.
5. Address new University SOP (Lab, field work, etc.) questions in the IRB application (new or amendment).

**Researcher Education (Recommended):**

1. General education about proper use of PPE and general hygiene:
	1. CDC General hand hygiene guidelines
		1. [When and How to Wash Your Hands](https://www.cdc.gov/handwashing/when-how-handwashing.html)
		2. [What you need to know about handwashing](https://www.bing.com/videos/search?q=what+you+need+to+know+about+hand+hygience+cdc&&view=detail&mid=5CE9AB72CAAF423D66595CE9AB72CAAF423D6659&&FORM=VRDGAR&ru=%2Fvideos%2Fsearch%3Fq%3Dwhat%2Byou%2Bneed%2Bto%2Bknow%2Babout%2Bhand%2Bhygience%2Bcdc%26FORM%3DHDRSC3) (video)
	2. [Texas State Environmental, Health Safety and Risk Management](https://www.fss.txstate.edu/ehsrm/)
2. Educational requirements for special risk populations:
	1. [Correctional and detention facilities](https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-shelters/unsheltered-homelessness.html)
	2. [Homeless populations](https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-shelters/unsheltered-homelessness.html)

**C. Texas State IRB Level 2 Risk Reduction** – (Moderate Risk) designated for protocols that have face-to-face contact with participants with unknown COVID-19 exposure that does not allow for social distancing. Examples may include physical activity where there is active investigator (faculty, graduate assistants, students) hands-on interventions (e.g., physical assessments) such as those that may be performed by a physical therapist, nurse, exercise physiologist, educator, or community-based researchers.

These recommendations follow the clinical guidelines issued by the CDC entitled:

[*Healthcare Infection Prevention and Control FAQs for COVID-19*](https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html):

**Conditions to be met:**

1. Enact Level 1 risk reduction strategies with the addition of the following:
2. Use face masks (procedural) for both investigator and participant as recommended by [CDC guidelines](https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf).
3. Clean nonporous gowns or change gowns between participants when appropriate.
4. Address new University approved SOP (Lab, field work, etc.) questions in the IRB application (new or amendment).

**Researcher Education (Recommended):**

1. Investigator and research team members proof of completion of:
	1. CITI Training “Infectious Disease and Risk Reduction” (hyperlink TBA) collaboration of RIC and EHSRM
	2. Consultation with [Texas State Environmental, Health Safety and Risk Management](https://www.fss.txstate.edu/ehsrm/) (EHSRM)

**D. Texas State IRB Level 3 Risk Reduction** – (High Risk) designated for protocols involving prolonged or close contact work with participants and/or collection of or contact with human bodily fluids or tissue specimens.

**Conditions to be met:**

1. Enact Level 1 and Level 2 risk reduction strategies with the addition of the following:
2. Refer to [Institutional Biosafety Committee](https://www.txstate.edu/research/orc/biosafety.html) review and upload documentation or statement of pending/approved review.
3. Address new University approved SOP (Lab, field work, etc.) questions in the IRB application (new or amendment).

**Researcher Education (Recommended):**

1. Bloodborne Pathogens Training sponsored by Texas State ([SAP training](https://www.txstate.edu/sap/))
2. Biosafety Level 2 Training sponsored by [EHSRM](https://www.fss.txstate.edu/ehsrm/)
3. [OSHA](https://www.osha.gov/) recommendations for proper PPE