**The University of Texas at El Paso**

**Office of Research and Sponsored Projects**

**Human Research Oversight & Compliance Office**

**Return to Human Subjects Face to Face (F2F) Research Guidelines**

**June 2020**

Face to Face (F2F) human subjects research (HSR) interactions can resume and proceed only to the extent that:

1) research activities can be performed safely; and

2) personal protective equipment (PPE) is used and provided to all research personnel and participants during F2F interactions.

Investigators must stay vigilant throughout the duration of their IRB protocol and continue to monitor current federal, state, and local guidelines as set forth by [City of El Paso Public Health](http://www.elpasotexas.gov/public-health), [El Paso County](http://www.epcounty.com/admin/covid19.htm), [Texas Department of State Health Services](https://www.dshs.texas.gov/), and [CDC](https://www.cdc.gov/coronavirus/2019-nCoV/index.html) .

**It is recommended that remote interactions be pursued and/or continued, if possible.**

Safety is based on following social distancing requirements within research spaces and on campus, utilizing personal protective equipment (PPE) and hygienic practices, such as hand washing/use of hand sanitizer gel, and routine sanitizing of work areas. Researchers should plan in advance for supply chain issues when conducting F2F research – under no circumstances should safety be sacrificed due to lack of supplies.

Investigators must submit for review a Work/Safety Plan and facility approval letter (if applicable) that addresses all requirements that are applicable to the research, including participant screening, social distancing, maintaining personal hygiene, use of appropriate PPE, cleaning/disinfecting of shared spaces/equipment, and infection control. If invasive procedures are to be conducted, such as venipuncture or oral/nasopharyngeal swab, detailed operating and safety procedures are required. These plans should be submitted through the unit head (department head, Director or Chair) and Dean to the Vice President for Research using the [Work/Safety Plan Submission Form.](https://forms.utep.edu/form.aspx?pid=303bd7c4-e334-4570-af66-867e2a2fad48&formid=04eb17a4-0b79-4801-b45b-2fd9b7fe7996)

**All research involving human subjects or contact with the public will be subject to additional review by the Institutional Review Board (IRB) of preventative measures to limit the exposure of UTEP researchers and members of the external community** **during the course of research activities.**

**UTEP Recovery Levels and Research Protocols**

**To facilitate planning for appropriate preventative measures, UTEP has identified three specific Recovery Levels. Determination of the current Recovery Level will be made by the President of The University of Texas at El Paso based on guidance provided by county and state health officials, as well as guidelines from the Center for Disease Control and will be posted on the Resuming Campus Operations website.**

Research projects that have successfully and safely transitioned protocols and operations to being fully remote, requiring infrequent or no access to university spaces, and no in-person interactions may continue remotely under all Recovery Levels, from Restricted through Open Campus.

HSR operations that require F2F activities must include preventative measures appropriate for the existing Response Level, as described below.

**Limited Campus Operations (CDC Phase 1)**

* All HSR operations involving F2F operations should remain paused at this level.
* On-campus preparatory activities by researchers, in anticipation of transition to the next level, may proceed, subject to an approved Work/Safety plan for these activities.

**Low Density Operations (CDC Phase 2)**

Upon protocol review and approval, F2F operations may resume, but with **heightened preventative measures**:

* Health screening tool (see below) to be utilized with participants 24 hours before scheduled session.
* Daily temperature checks with a non-contact thermometer are recommended for all researchers and research participants prior to entering the research area.
* Researchers must utilize and provide PPE to all research personnel and participants.
	+ If 6 feet distancing is maintained at all times, cloth face coverings are sufficient.
	+ If distancing cannot be maintained or if contact is required, appropriate, medical-grade PPE is required (masks, gloves, goggles/faceshield, gown).
* No more than 2-3 individuals congregated at one time (dependent upon lab size).

**HSR operations that involve prolonged or close contact work with participants and/or collection of or contact with human bodily fluids or tissue specimens should remain paused.**

**Off Campus Projects (Low and Medium density operations):** Projects utilizing non-UTEP facilities for human subject research activities must have a current letter from the facility allowing F2F activities to resume and/or begin. It is recommended that PIs provide their work safety plan to the facility for review and facility allowances/recommendations prior to obtaining the facility approval letter. These documents should be submitted through the approval process as indicated above.

**Medium Density Operations (CDC Phase 3)**

Basic requirements remain the same as for Low Density operations with the addition of:

* HSR operations that involve prolonged or close contact work with participants and/or collection of or contact with human bodily fluids or tissue specimens may resume, with **heightened preventative measures (see above)**.
* As long as distancing is maintained at all times, Rooms may be used up to 50% capacity.

**Additional Resources:**

* 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)
1. [OSHA Guidelines](https://www.osha.gov/SLTC/covid-19/) for COVID-19 Procedures and PPE
2. [CDC COVID-19 Vulnerable Populations](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html)
3. [Blood borne Pathogens Training](https://www.utep.edu/orsp/institutional-biosafety/training/)
4. [Correctional and detention facilities](https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-shelters/unsheltered-homelessness.html)

**UTEP Human Subjects Research Health Screening**

Have you had any of the following symptoms within the past 10 days?

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| **A new fever (100.4°F or higher) or feeling feverish** | [x]  | [x]  |
| **A cough and/or sore throat**  | [x]  | [x]  |
| **Shortness of breath or difficulty breathing** | [x]  | [x]  |
| **Muscle aches**  | [x]  | [x]  |
| **Chills and/or repeated shaking with chills** | [x]  | [x]  |
| **Gastrointestinal symptoms (i.e. diarrhea, vomiting, etc.)** | [x]  | [x]  |
| **Loss of smell or taste**  | [x]  | [x]  |
| **Headaches**  | [x]  | [x]  |
|  |
| **Have you travelled outside of El Paso in the last 14 days?** | [x]  | [x]  |
| **To your knowledge, have you been in close contact with anyone who has tested positive for COVID-19, is currently ill, or has been diagnosed with COVID-19?** | [x]  | [x]  |

If the participant answered “Yes” to any questions, please consider rescheduling the research session for a later date. Please continue to monitor and follow CDC guidelines for the purpose of re-scheduling, noting that researchers should not engage with any participants unless at least 10 days have passed since any exhibited symptoms.

Screener Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Contact Tracing Question

Upon participant arrival on campus:

Due to the current COVID-19 pandemic outbreak, potential exposure has become a part of our daily lives. As a participant in this research project, measures are being taken to minimize potential exposure. Unfortunately this risk cannot be completely controlled or eliminated. Should the researcher you interact with become exposed or tested COVID positive within the next 20 days, would you like to be contacted for Contact Tracing purposes?

Yes: \_\_\_\_\_\_\_\_\_\_\_ No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If Yes, your name and contact information will be taken and kept separate from the research data collected, to be forwarded to the appropriate officials for Public Health Contact Tracing.

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone # and/or e-mail address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_