

GUIDELINES AND REQUIREMENTS FOR RESUMING OR STARTING HUMAN SUBJECTS RESEARCH DURING THE PANDEMIC

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This document outlines principles, guidelines, and requirements for restarting Human Subjects Research (HSR) across Texas A&M University-Texarkana (TAMUT) in the context of the SARS-CoV-2 (COVID-19) pandemic. Our goal is to provide a broad and consistent structure for departments and colleges to conduct safe HSR activities. This set of guidelines pertains to research activities under the purview of the Institutional Review Board (IRB), including, but not limited to, those involving experimental and non-experimental research with human subjects, and interinstitutional collaborations involving HSR.

These guidelines apply immediately, and until the IRB determines pandemic risks are minimized.

For any questions, suggestions, or corrections to this information, please contact the IRB Chair, Dr. Yusun Jung at 903-223-3009 or IRB@tamut.edu

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VERSION HISTORY

September 14, 2020: Initial Release

September 27, 2020: Revision per changes to campus visitor policy as stated in September 25 email to campus authored by John Bunch, Communications Manager.

April 14, 2021: Revisions consistent with current CDC data and guidelines: Revised exposure definition; updated age-related risk data; updated groups needing special protection; updated campus visitor guidance; updated guidance for fully vaccinated individuals; updated surface cleaning requirements consistent with new CDC guidance; updated research meeting guidance for fully vaccinated individuals.

July 23, 2021: Revisions per changing risk levels of COVID-19 infection: Specified different levels of COVID risks; Updated mask requirements; updated social distancing requirements; updated campus visitor guidance; revised the requirement for the university COVID Protocol and Certification Form; updated sanitization requirements; updated research meeting guidance for fully vaccinated individuals; added a quick summary.

DEFINITIONS

EXPOSURE: This is defined consistent with the TAMUT Return To Campus Guide (available at https://tamut.edu/About/Administration/COVID_19/index.html). Currently, it is defined as close contact (within 6 feet for at least 15 minutes total in 24 hours) with, physical contact (hugging, touching, kissing) with, providing at-home care for, sharing eating/drinking utensils with, or having been coughed or sneezed on by, a sick individual.

HUMAN SUBJECT: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. [45 CFR 46102(f)] The FDA defines a human subject as “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may either be a healthy human or patient.” [21 CFR 50.3(g)].

RESEARCHER: Any employee, student, or other agent of Texas A&M University–Texarkana that is engaged in HSR as part of an IRB-approved protocol or interinstitutional agreement.

FULLY VACCINATED INDIVIDUALS: People are considered fully vaccinated for COVID-19 ≥ 2 weeks after they have received the second dose in a 2-dose series (Pfizer-BioNTech or Moderna), or ≥ 2 weeks after they have received a single-dose vaccine (Johnson & Johnson [J&J]/Janssen)±; there is currently no post-vaccination time limit on fully vaccinated status. Unvaccinated people refer to individuals of all ages, including children, that have not completed a vaccination series or received a single-dose vaccine. (See <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html> for guidance for the vaccinated.)

NINE PRINCIPLES OF SAFE HSR IN THE MIDST OF THE COVID-19 PANDEMIC

1. **HSR is valuable.** Research is an important function of the faculty, staff, and students of TAMUT, and the results of research are of great value to society.
2. **HSR is our job.** The careers and livelihoods of many faculty, staff, students, and others at the university depend on the ability to continue ongoing research and initiate new research activities.
3. **Safety first.** The safety of members of the University campus community, the greater Texarkana community, and of our research participants is of paramount importance, and will not be superseded by principles 1 & 2 above.
4. **Safety for everyone.** HSR involves both researchers and human subjects, so safety, ethics, and building access/density considerations are needed for both groups.
5. **Science-based.** Planning should be grounded in science and CDC guidance regarding both good laboratory practice with infectious agents and specific information about SARS-CoV-2 (COVID-19) and its observed manifestations in our local area. Planning should **not** be done on the grounds of expediency, economics, or political considerations.
6. **Make unbiased decisions.** HSR should avoid potential conflict of interest, where the research needs of the principal investigator (PI) or research staff unduly influence decision-making about safety.
7. **In-person HSR has risks.** Some HSR necessarily involves close physical interactions between dyads and/or groups of individuals interacting with each other, and/or the recruitment of individuals especially vulnerable to COVID-19. In addition, HSR poses liability risks, due to possible transmission of COVID-19 from a researcher to a participant and vice versa.
8. **Reduce risks outside the research space.** Researchers do not risk exposure to COVID-19 unnecessarily so that they and their human subjects can be safe. Researchers can be vectors of transmission of the virus. In order to maintain the highest level of safety for your research, we recommend that researchers practice optimal hygiene: avoid gathering in groups (> 10 people), always wear masks when around others not in your immediate household, wash your hands for at least 20 seconds after every activity as is practical, always maintain physical distance (at least 6 feet) from others at all practicable times, stay home as much as possible, self-monitor for symptoms, isolate if you are sick, quarantine until 14 days after last exposure, and avoid contact with people who are symptomatic or are not practicing safe hygiene.
9. **Reduce risks inside the research space.** Researchers respect their human subjects and their research. Use situationally appropriate personal protective equipment (PPE) such as masks, eye protection, face shields, gloves, gowns, barriers between individuals, etc.

GUIDELINES AND REQUIREMENTS OF SAFE HSR

The IRB is presenting these guidelines and requirements to help researchers conduct research in the safest ways possible, given the current state of the COVID-19 pandemic. As new data becomes available, these guidelines and requirements may change, and the university community will be apprised.

The IRB will review protocols in light of these guidelines and requirements, and deviations from them may require additional explanation or justification before approval of the protocol is granted.

OVERARCHING GUIDELINE: To put it quite simply, **all work that can be performed remotely/online should be performed remotely/online.** Does my research require individuals to be in an enclosed space together, and if not, can it be done effectively otherwise? If it does, can I delay in-person research activities until after the pandemic? Consider that another research agenda may be safer to pursue during the pandemic.

SPECIFIC GUIDELINES:

1. Certain individuals are more vulnerable to severe illness from COVID-19. Individuals in the below groups should consult with a physician to assess their level of risk if they want to engage in in-person research activities. See <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>. **Researchers should especially help protect human subjects in these groups by informing them about their additional risk as part of recruitment and informed consent procedures.**
 - a. As people get older, their chance of needing hospitalization increases (<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html>). For example, as of March 2021, data indicate that individuals 40–49 years old have a hospitalization rate 2.5 times greater than 18–29 years old. Those over 65 have hospitalization rates 2.67 to 6.33 times those 40–49 years old.
 - b. Researchers and human subjects of all ages with underlying medical conditions (as described by the CDC at <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.htm>) are encouraged to **only engage in research activities remotely**. These underlying conditions include such common conditions as obesity (BMI ≥ 30), Type 2 diabetes, etc.
 - c. Some groups of individuals need extra precautions. If researchers or human subjects are in the following groups, additional measures to protect them may be necessary: racial & ethnic minority groups, rural communities, homeless, individuals with disability, and developmental and behavioral disorders (for details, see <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/other-at-risk-populations.html>).
2. Research personnel (including staff, undergraduate, graduate, and postdoctoral students) should work within all university guidelines and requirements specified by TAMUT and in consultation with their faculty supervisor/PI, department chair, dean, or appropriate designee. Human subjects research may require additional protections beyond any university requirements. Those additional protections are described herein.
3. Principal Investigators should be prepared with contingency plans for the event of a widespread outbreak that necessitates the IRB to suspend in-person human subject research activities. The IRB will give researchers as much advance notice as possible in the event of a suspension.
4. Any individuals returning from travel should take extra care to practice safe interactions with human subjects and other research personnel.
 - a. In general, individuals should quarantine after travel as recommended by the CDC (see <https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html> for guidance).

5. Fully vaccinated individuals resume research activities without wearing masks or physically distancing, except where required by federal, state, local, or university authorities.
 - a. Principal Investigators should verify participant's COVID-19 vaccination through legitimate proof such as a valid copy of COVID-19 vaccination card.
6. Principal Investigators should be mindful of changing situations of COVID-19 and guidelines and be ready to adapt their research protocols to the changes. The IRB presents four risk levels of COVID-19 infection and differentiated guidelines and requirements for each level: high, high-to-moderate risk, moderate risk, and low risk. The definition of each risk level and overarching guidelines are appraised below. As the current situation may worsen or improved, it would be best to prepare research protocols considering all risk levels. When changes are needed, the IRB will notify principal investigators. At the time you prepare your application, please use the guidance for the current risk of COVID-19 infection (shown on the IRB's main web page <http://tamut.edu/IRB>) to prepare your application and Infection Control Plan.
 - a. **High risk of COVID-19 infection:** CDC, state, federal, local, or university authorities may require the university to operate its primary functions (e.g., lecture and meeting) online. All in-person HSR is prohibited on- or off-campus, unless specifically authorized by the IRB.
 - b. **High-to-moderate risk of COVID-19 infection:** CDC, state, federal, local, or university authorities may allow the university to operate with limited capacity. Masks and social distancing are **STRONGLY** recommended for **ALL** unvaccinated and vaccinated individuals per current CDC guidelines.
 - c. **Moderate risk of COVID-19 infection:** CDC, state, federal, local, or university authorities may advise the university to operate with caution. Masks and social distancing are **STRONGLY** recommended for unvaccinated individuals and recommended for vaccinated individuals per current CDC guidelines. When unvaccinated individuals are involved, masks and social distancing are **STRONGLY** recommended for vaccinated individuals.
 - d. **Low risk of COVID-19 infection:** CDC, state, federal, local, or university authorities allow the university to operate HSR on new normal. Masks and social distancing are optional for all participants, except where required by federal, state, local, or university authorities.
 - e. The vulnerable population described in Specific Guideline 1 is strongly recommended to wear masks and do social distancing at all risk levels even when fully vaccinated to avoid contracting new COVID-19 variants.

REQUIREMENTS BEFORE ENGAGING IN HSR (ON- OR OFF-CAMPUS)

OVERARCHING REQUIREMENT: Follow guidance from CDC, state, local, and university authorities regarding working on-campus or off-campus safely. When guidance from the institutions collides, CDC should be prioritized, followed by university authorities, local, state, and federal, respectively.

Principal Investigators who are resuming or initiating in-person research must complete a Human Subjects Research Infection Control Plan to document the COVID-specific provisions that are in place to protect human subjects. The form is available on the IRB website: <http://tamut.edu/IRB>

Some specific requirements from the TAMUT IRB are listed below that ensure safety for human subjects and researchers.

- The informed consent process for in-person research must include a statement to help human subjects be completely informed about COVID-19 risks. The IRB requires, at the minimum, consent documents include the following statement at all risk levels:

“This research is being conducted during the SARS-CoV-2 (COVID-19) pandemic. COVID-19 is a new virus, and experts currently have incomplete information about it. Although the researchers and university are carefully reducing risks at all stages of this research, Texas A&M University-Texarkana cannot completely guarantee you will not become infected with COVID-19 during this research. If you have any questions or concerns about COVID-19 risks in this research, and how those risks are being reduced, ask the researchers for details.”

- According to current university regulations, all human subjects who enter TAMUT property are treated as **visitors** to the campus.
 - At the high-risk level of COVID-19 infection, all HSR must be done online/remotely. No visitors are allowed to enter the campus.
 - At the high-to-moderate risk level, the IRB must approve all human subjects who will enter university property. This approval is granted by the approval of the research protocol as specified in the IRB Application form and the IRB’s Infection Control Plan form. TAMUT requirements for visitors on campus at high-to-moderate risk are the following:
 - Researchers must record the arrival and departure times of each human subject. These records are to be retained securely with the study materials.
 - Researchers are responsible for ensuring human subjects are aware of and follow TAMUT requirements (e.g., masking, etc.) while on campus property.
 - Each human subject who will be on campus property for more than four hours **must** complete the university’s **COVID Protocol and Certification Form** prior to arrival on campus. This form is available from the TAMUT COVID-19 Resources page: https://tamut.edu/About/Administration/COVID_19/COVID_19_Resources.html. The completed and signed form must be retained securely with the study materials.
 - At the moderate-risk and low-risk levels, principal investigators are responsible for monitoring all human subjects who will enter university property. This monitoring should follow the approved research protocol as specified in the IRB Application form and the IRB’s Infection Control Plan form. TAMUT requirements for visitors on campus at these levels are the following:
 - Researchers must record the arrival and departure times of each human subject. These records are to be retained securely with the study materials.
 - Researchers are responsible for ensuring human subjects are aware of and follow TAMUT requirements (e.g., masking, etc.) while on campus property.
- Unvaccinated researchers immediately **must not engage in in-person research, and you must follow university reporting requirements** (via

https://tamut.edu/About/Administration/COVID_19/index.html under **any** of the following conditions:

- a. You have **tested positive or have symptoms** for COVID-19;
 - b. You have had **close contact** with someone who has had COVID-19, which includes any of the following:
 - i. have **been within 6 feet or in contact with** someone known to have COVID-19 for a total of 15 minutes or more total in 24 hours;
 - ii. **provided at-home care** to someone who has COVID-19;
 - iii. **shared eating or drinking utensils** with someone who has COVID-19;
 - iv. was **sneezed or coughed on**, or otherwise got respiratory droplets from someone with COVID-19
 - c. You have been told by a public health official or employer that you **may have been exposed** to COVID-19 in the past two weeks;
 - d. You have **been in contact with anyone showing COVID-19 symptoms** (as specified by the CDC at <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>).
 - e. Unvaccinated researchers in the above conditions may return to in-person research consistent with CDC guidelines (see <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/end-home-isolation.html>), currently:
 - **Think or know you had COVID-19, and had symptoms** (condition a above) – return no fewer than 10 days since symptoms first appeared **and** at least 24 hours with no fever without fever-reducing medication **and** symptoms have improved.
 - **Tested positive for COVID-19 and had no symptoms** – return no fewer than 10 days since positive viral test. If you experience symptoms, see above.
 - **Close contact, contact with a symptomatic individual, or been told you may have been exposed** (conditions b, c, & d above) – return no fewer than 14 days after your last contact with someone who has COVID-19. NOTE: **Fully vaccinated individuals** who may have been exposed do NOT need to wait 14 days.
- Fully vaccinated researchers may refrain from testing or self-quarantine after known contact with or exposure to someone who has had COVID-19, if asymptomatic. If symptomatic, they must pause in-person research and obtain a negative PCR result to return to in-person research. If contracted, they may return to in-person research consistent with CDC guidelines described above.

REQUIREMENTS BEFORE ENGAGING IN HSR SPECIFIC TO OFF-CAMPUS LOCATIONS

In addition to the above requirements, off-campus research poses specific risks that require specific safety protocols.

- At the high-risk level of COVID-19 infection, all HSR must be done online/remotely. No in-person research is allowed.
- At the high-to-moderate risk level, principal investigators should conduct the fieldwork with limited capacity enough to ensure adequate social distancing, especially where unvaccinated individuals are involved.
 1. Principal Investigators (PIs) are expected to conduct the fieldwork with the fewest persons needed to complete the activity while assuring the safety of all members of the research team. It is the responsibility of the PI to remain in frequent communication with team members conducting essential research. At a minimum, PIs must require team members to check in daily to verify no exposure, symptoms, or infections have occurred.
 2. For research conducted on privately owned property (excluding a private residence), you may be expected to obtain written (e.g. email) approval of the property owner or delegate before visiting the site. The site may have specific requirements for COVID-19 safety, but researchers and human subjects must be allowed to follow, at a minimum, the protocols as laid out in these requirements. Consult with the IRB if the site's requirements conflict with the IRB's requirements.
- At the moderate-risk and low-risk levels, principal investigators should conduct the fieldwork with precaution, especially where unvaccinated individuals are involved.
 - Principal Investigators (PIs) are expected to conduct the fieldwork with the limited number of persons specified by federal, state, local, or university authorities while assuring safety of all members of the research team. It is the responsibility of the PI to remain in frequent communication with team members conducting essential research. At a minimum, PIs must require team members to check in daily to verify no exposure, symptoms, or infections have occurred.
 - For research conducted on privately owned property (excluding a private residence), you may be expected to obtain written (e.g., email) approval of the property owner or delegate before visiting the site. The site may have specific requirements for COVID-19 safety, but researchers and human subjects must be allowed to follow, at a minimum, the protocols as laid out in these requirements. Consult with the IRB if the site's requirements conflict with the IRB's requirements.

REQUIREMENTS WITHIN THE RESEARCH ENVIRONMENT (ON- OR OFF-CAMPUS)

Researchers and human subjects entering TAMUT property are subject to any TAMUT policies or screening procedures that are currently in place.

- Masks
 - Fully vaccinated individuals are exempt from mask requirements at all risk levels of COVID-19 infection, except where required by federal, state, local, or university authorities or where unvaccinated individuals are involved in the research. In principle, wearing masks is recommended as the most effective preventative measure at all risk levels.

- At the high-to-moderate risk level of COVID-19, unvaccinated individuals (both researchers and human subjects) must wear a mask that complies with CDC guidelines (see <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html>): fully covers the nose and mouth; fits snugly but comfortably against the side of the face and allow for breathing without restriction; including **multiple layers of material with no open valves** (note this may exceed TAMUT requirements).
 - i. Researchers must inform both fully vaccinated and unvaccinated human subjects of these requirements before traveling to campus.
 - ii. Masks must be worn by unvaccinated individuals (researchers and human subjects) from the time of entry into any building or facility until the time of exit from the building or facility, except while eating with greater than 6 ft distancing, or in an enclosed single-person office space. The IRB recognizes that certain individuals should not wear masks, or certain situations make them infeasible (see CDC <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html>). Principal Investigators should consult with the IRB for exemptions based on their human subject populations and protocols.
 - iii. Use of masks is **required** during the entire commute for unvaccinated individuals (researchers and human subjects) taking public transport or sharing transportation/carpooling. When in transit, maintain as close to minimum 6 feet distance from other passengers as is possible, and limit the number of individuals in the vehicle to reduce risk.
- Mask requirements for other risk levels are consistent with Specific Guideline 6.
- Screening researchers and participants for symptoms and exposure
 - Researchers must pre-screen human subjects, either vaccinated or unvaccinated, for any exposure or self-reported COVID symptoms prior to the human subject arriving on-campus. See Appendix A for a sample Pre-Screening Checklist. This screening may occur over email, telephone, etc.
 - Researchers must screen human subjects immediately upon contact with the human subject.
 - i. The human subject will be required to sign and date an acknowledgement form (see Appendix B for a sample of an acknowledgment form). These forms should be securely retained with the study materials. In the event the research protocol requires anonymity, contact the IRB for guidance.
 - ii. The researcher will then collect the screening information to determine the human subject is not currently experiencing symptoms (see Appendix C for a sample). If the human subject is experiencing symptoms, they must be excused immediately and not remain in the research space.
 - Upon arrival at the research location each day, researchers must also complete a screening for symptoms (see Appendix C for a sample log). This screening documentation should be securely retained with study materials.

- Physical distancing and safety
 - Fully vaccinated individuals are exempt from the social distancing limit at all risk levels of COVID-19 infection, except where required by federal, state, local, or university authorities. In principle, social distancing and limiting spatial capacity are recommended as crucial preventative measures.
 - At the high-to-moderate risk of COVID-19, when conducting research with unvaccinated human subjects, a minimum of 6 feet physical distancing **must** be maintained by unvaccinated individuals (researchers and human subjects) at all times.
 - i. Do not have physical contact between researchers and/or human subjects, e.g., shaking hands, hugging, etc. without adequate PPE.
 - ii. Human subjects and researchers in elevators should be limited as much as possible. Follow any posted occupancy limits, and spread individuals out within the elevator to maximize distance. For example, 2 people per elevator, in opposite corners, both wearing masks.
 - iii. Flow of foot traffic within the research location should be maintained in one direction where possible to avoid passing interaction.
 - iv. In special work areas or situations where 6 feet distancing is **not** possible, unvaccinated individuals (researchers and human subjects) must wear a minimum of standard surgical ASTM level 1 mask and eye protection; additional PPE such as face shields, gowns, and/or gloves may be required by the IRB for specific research protocols/projects. In these areas or situations, researchers should be prepared to provide participants with the necessary PPE.
 - v. To maintain physical distancing, adjustments to the research space or schedule may be required. For example, it may be necessary to decrease personnel density and/or furniture/equipment to maintain physical distancing. Schedules should be synchronized with other researchers on the same floor to minimize interaction in hallways and communal areas. Faculty/PIs, in consultation with department chairs, deans, or appropriate designee should come to amicable agreements to specific shift assignments, including weekend activity, (including any remote work).
 - Social distancing guidelines for other risk levels are consistent with Specific Guideline 6.
- General hygiene and sanitation
 - Above low-risk levels, the following requirements are applied;
 - i. Where feasible, the use of transparent or opaque physical barriers to separate human subjects and researchers is recommended. Examples may include protocols in which the participant and/or researcher remains stationary at a desk or workstation, or where the participant is observed at a distance. Researchers should describe the use and location of physical barriers in their submitted plans.

- ii. Researchers must wash hands thoroughly (see <https://www.cdc.gov/handwashing/when-how-handwashing.html>) **prior to and after** any interaction with human subjects or equipment. Deviations from this protocol should be discussed with the IRB Chair. Routine use of hand sanitizer (minimum 60% ethyl alcohol or 70% isopropyl alcohol content) within the research space is recommended for both researchers and participants.
 - iii. Researchers using PPE must follow usage guidelines from the CDC (e.g., donning and doffing; see <https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html>).
 - iv. Clean research spaces at least once per day. See CDC guidelines: <https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html>).
 1. At the beginning of any shift period or workday, researchers must first clean **all** actively used surfaces and equipment¹ with appropriate cleaning or disinfectant materials.
 2. If anyone in the space is suspected or confirmed to have COVID-19, then cleaning must be done immediately.
 3. Clean after each research participant has been in the room, if either researchers or participants are part of groups at increased risk for severe illness from COVID-19 (see <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>).
 - v. Do **not** have food and beverages in the research space. Plan to have a separate area for eating and drinking.
- At the low-risk level, the above requirements are optional.
 - Contact tracing
 - Principal Investigators are required to maintain a written log of interactions between researchers and human subjects. This log will be used primarily in case contact tracing is necessary. The log should include the date and time of the beginning and end of interaction, names of researcher(s) and human subjects, and confirmation of lack of exposure. This log should be stored securely with the study materials.
 - To facilitate contact tracing, researchers must collect contact information for human subjects (e.g., telephone, email, address. Such information should be retained securely with study materials. In the event confidentiality must be maintained, participant identifiers may be used, so long as those identifiers can be used to link participants to contact information in the event of contact tracing.

¹ NOTE: Sensitive electronic equipment may need specific procedures; see the manufacturer's instructions.

- In-person researcher meetings
 - If **all** attendees at the meeting have been fully vaccinated, they may meet indoors without physical distancing or wearing masks.
 - Mask and social distancing requirements for research meetings are consistent with Specific Guideline 6.
- Reporting of contraction, exposure, or close contact
 - Researchers must report potential or actual exposure using the TAMUT online reporting system at <http://www.tamut.edu/covid-19>. Principal Investigators who become aware of human subjects that died, are hospitalized, or suffered serious complications that occurred as a result of COVID-19 exposure caused by research procedures must be reported to the IRB as a Serious Adverse Event. Contact the IRB Chair for details.
 - If the PI or any other researcher is notified of a positive test result by researchers or human subjects, areas where the positive-test individual has visited in the 48 hours before emergence of symptoms, or before notification of a positive test (whichever is the more recent), must be prepared to close for up to 24 hours and appropriate cleaning and disinfection procedures must be undertaken according to university protocols. Any researchers that meet criteria for exposure to the positive-test individual must report. Unvaccinated researchers must undergo a quarantine period consistent with university guidelines, before returning to work with human subjects. If vaccinated researchers with COVID-like symptoms must obtain a negative PCR result before returning to in-person research. Human subjects who may have been exposed to the individual should report their exposure to their local health authorities.
- Per the IRB Standard Operating Procedures (SOP 12.5), the IRB Chair may temporarily suspend any research protocol because of an adverse event, noncompliance, or other danger to human subjects. Violation of safety protocols designed to protect human subjects from COVID-19 exposure will be considered as cause for suspension.

REQUIREMENTS WITHIN THE RESEARCH ENVIRONMENT SPECIFIC TO OFF-CAMPUS RESEARCH

In addition to the requirements for on-campus research above, and excepting the requirements referring specifically to TAMUT research locations (i.e., #1 above), off-campus research will be conducted with the following requirements.

1. Personnel entering a non-Texas A&M University-Texarkana research facility or building may be subject to private screening procedures/requirements that are currently in place for that facility or building. Those procedures/requirements do not supersede any other requirements specified by the TAMUT IRB in this document.
2. Research in international locations may be subject to country-specific or local governmental requirements or restrictions. If those requirements or restrictions conflict with the TAMUT IRB requirements in this document, or if local customs or taboos preclude following these requirements, consultation with the IRB will be required before approval of the protocols.

3. To the extent that this is not taboo per local cultural practices, do not shake hands or share food with research participants. If local customs or taboos require interpersonal contact or shared food, consultation with the IRB will be required when designing the protocol.
4. At least once at the beginning of research session, researchers must first clean any hard surfaces normally subject to touch, including any building doorknobs, fixtures, countertops, vehicle steering wheels, handles, gear sticks, dashboards, etc. All tools and equipment are to be cleaned before use.
 - a. This policy applies to property or surfaces in the off-campus location, and items owned by individual researchers or Texas A&M University-Texarkana.
 - b. If anyone in the space is suspected or confirmed to have COVID-19, then cleaning must be done immediately.
 - c. Clean after each research participant if either researchers or participants are part of groups at increased risk for severe illness from COVID-19 (see <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>).
 - d. Minimize direct contact with tools and equipment. Quite simply, if it's likely to be touched, clean it.
5. Researchers are expected to carry hand sanitizer (minimum 60% ethyl alcohol or 70% isopropyl alcohol content) and useable disinfectant at all times, which may include disinfectant wipes, sprays, or gels. Frequent hand sanitizing or hand washing is expected by all research team members involved in the fieldwork activity, including handwashing prior to, and after, interaction with human subjects.
6. If a researcher is informed that they, or any human subject they worked with, tested positive for COVID-19, they must immediately notify any buildings or facilities that the researcher and human subject were in during the 48 hours prior to emergence of symptoms or the positive test, whichever is sooner.

A QUICK SUMMARY OF REQUIREMENTS AND GUIDELINES

| Requirement | High risk | High-to- Moderate risk | Moderate risk | Low risk |
|---|--|---|---|---|
| Notifications for COVID-19 risk and highly vulnerable populations in an informed consent form | Required | Required | Required | Required |
| Infection Control Plan form | All HSR must be done online or remotely. | Required | Required | Required |
| Symptom log | | Required | Required | Required |
| COVID Protocol and Certification Form | | Required | Recommended | Optional |
| Mask | | <ul style="list-style-type: none"> • Unvaccinated: Required • Fully Vaccinated: Recommended | <ul style="list-style-type: none"> • Unvaccinated: Recommended • Fully Vaccinated: Optional | Optional |
| Indoor social distancing | | <ul style="list-style-type: none"> • Unvaccinated: Required • Fully Vaccinated: Recommended but can be exempted | <ul style="list-style-type: none"> • Unvaccinated: Recommended • Fully Vaccinated: Exempted | Optional |
| Spatial capacity limit | | Required | Required | Recommended |
| Self-isolation after known exposure following CDC guidance | | <ul style="list-style-type: none"> • Unvaccinated: Required • Fully vaccinated: if asymptomatic, optional; if symptomatic, a negative PCR result is required. | <ul style="list-style-type: none"> • Unvaccinated: Required • Fully vaccinated: if asymptomatic, optional; if symptomatic, a negative PCR result is required. | <ul style="list-style-type: none"> • Unvaccinated: Required • Fully vaccinated: if asymptomatic, optional; if symptomatic, a negative PCR result is required. |
| Reporting of contraction, exposure, or close contact to the university | | <ul style="list-style-type: none"> • Unvaccinated: Required • Fully vaccinated: if asymptomatic, optional; if symptomatic, required. | <ul style="list-style-type: none"> • Unvaccinated: Required • Fully vaccinated: if asymptomatic, optional; if symptomatic, required. | <ul style="list-style-type: none"> • Unvaccinated: Required • Fully vaccinated: if asymptomatic, optional; if symptomatic, required. |
| Cleaning | | Required | Required | Required |
| Contact tracing | | Required | Required | Required |
| In-person research meeting | | <ul style="list-style-type: none"> • Unvaccinated: Masks and social distancing required • Fully Vaccinated: Masks and social distancing recommended | <ul style="list-style-type: none"> • Unvaccinated: Masks and social distancing recommended • Fully Vaccinated: Masks and social distancing optional | No restriction |

RESOURCES FOR PRINCIPAL INVESTIGATORS, RESEARCHERS AND LABORATORIES

- [CDC Guidance for General Laboratory Safety Practices during the COVID-19 Pandemic](#)
- [CDC Guidance for Cleaning and Disinfecting](#)
- [U.S. Department of Health and Human Services, Office for Human Research Protections \(OHRP\) Guidance on Coronavirus](#)
- [CDC Fully Vaccinated Guidance](#)
- [COVID Risk Levels of Concordia College](#)

APPENDIX A – SAMPLE PARTICIPANT PRE-SCREENING CHECKLIST

Human Participant PRE-SCREEN Health Checklist

Have you been fully vaccinated for COVID-19? YES NO

If YES, when was your second dose or a single shot?

Have you received a diagnosis of COVID-19 in the past 14 days YES NO

In the last 14 days, have you had:

Fever >100.0 F YES NO

Cough YES NO

Shortness of breath or difficulty breathing YES NO

Chills YES NO

Muscle aches YES NO

Sore throat YES NO

Loss of taste or smell YES NO

Diarrhea YES NO

Have you had contact with a known or presumed COVID patient in the last 14 days? YES NO

If the answer to any of the above questions is YES, the participant should not be admitted to the research space.

This information does not need to be maintained as part of the research record unless the data will be analyzed as part of the research (requires protocol modification)

(source: <https://vpr.tamu.edu/forms/human-participant-health-checklist>)

APPENDIX B – SAMPLE SCREENING ACKNOWLEDGEMENT

COVID-19 SCREENING ACKNOWLEDGEMENT

Texas A&M University-Texarkana is implementing measures to help reduce the spread of COVID-19 in Texas. These measures are part of standard health protocols and guidance issued by the Texas Department of State Health Services.

You will be asked screening questions to see if you have signs or symptoms of COVID-19, if you have had close contact to a person who is suspected or confirmed to have COVID-19, or if you have recently traveled to a restricted area.

If any of your answers are positive, or if you decline the screening, your visit will be rescheduled after a period of at least two weeks. You will also be asked to follow-up with your normal health care provider.

Your participation in the COVID-19 screening is voluntary. Any information you provide to us will be kept completely confidential and used or disclosed for public health purposes, only.

If you have any questions or concerns, please contact:

(Insert PI or Study Coordinator name and contact information)

OR

The Texas A&M University–Texarkana Institutional Review Board a IRB@tamut.edu

Signature

Date

APPENDIX C – SAMPLE SYMPTOM LOG

Researcher Symptom Log

Please record daily temporal temperature

| Date | Time | Name | Temp | | Have you had contact with anyone diagnosed with COVID-19 in the past 2 weeks? | Do you have shortness of breath? | Have you had a fever in the past 2 weeks? | <i>If temperature > 100.3 or any response YES, <u>do NOT continue in the research space.</u></i> |
|------|------|------|------|--|---|----------------------------------|---|---|
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Participant Symptom Log

Please record daily temporal temperature

| Date | Time | Name or Identifier | Temp | | Have you had contact with anyone diagnosed with COVID-19 in the past 2 weeks? | Do you have shortness of breath? | Have you had a fever in the past 2 weeks? | <i>If temperature > 100.3 or any response YES, <u>dismiss participant from the research space.</u></i> Staff Initials |
|------|------|--------------------|------|--|---|----------------------------------|---|---|
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