Baylor University

INSTITUTIONAL REVIEW BOARD

COVID-19 and Human Subject Research

Baylor University thanks the University of Minnesota, the University of Washington, Harvard University, and Penn State University for their public sharing of materials about COVID-19 preparation plans related to human research.

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Are Research Compliance and the Baylor IRB operating as usual?

Research Compliance and the IRB are fully functional and operating at our standard capacity. We expect this to continue even if Baylor suspends operations for contagion control purposes. All IRB staff are able to work from home and IRB meetings can be held remotely, should it become necessary. All email addresses will continue to be monitored with the same or greater frequency as typically provided. We encourage email over phone calls and for researchers to email IRB@baylor.edu which is a mailbox shared with all IRB staff.

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Can I still interact with my research participants?

General Policy. The IRB does not have a blanket recommendation or requirement about postponing or cancelling study visits, but you should minimize in-person interactions following the recommendations of the CDC, Texas Department of Health & Human Services, the McLennan County Health District, and Baylor University.

Participant Screening. In addition, the IRB is asking study teams to conduct a short phone or email screening for exposure to COVID-192 or symptoms of illness before any study-related

visits and in-person interactions. Research participants with possible exposure or symptoms of illness should not participate in in-person interactions until after the time recommended by current public health recommendations. **This screening procedure does not require IRB approval.**

Appropriate screening questions might include the following, which could be modified to fit your participant population and the location of in-person interactions. Any YES answer should be considered sufficient reason to postpone in-person visits. Decisions about in-person visits should be especially conservative for people at higher risk per public health recommendations:

- Over 60 years of age
- Underlying health conditions including heart disease, lung disease, or diabetes
- Weakened immune systems
- Pregnant

1. Have you had any of the following symptoms in the past two weeks, even if they were mild?
    a. Fever
    b. Cough
    c. Shortness of breath
2. Have you had close contact* with a person who is under investigation for possible COVID-19?
3. In the past three weeks, have you visited a country with sustained (ongoing) occurrence of COVID-19, such as:
    a. China
    b. Iran
    c. Japan
    d. South Korea
    e. Any country in Continental Europe (Italy, Spain, France, Germany, etc.)

In addition, researchers should:

- Follow the recommendations from public health authorities.
- Follow any guidelines or instructions from the specific facility where participant interaction would occur.
- Consider the participant population (e.g., are they considered "high risk" for COVID-19?) and the setting in which the interaction would occur.
- Develop possible alternatives to in-person study visits that are important for subject safety and monitoring.
- Ensure that hand sanitizer, hand washing facilities and/or cleaning wipes are readily available for screened participants, when in-person interactions will occur.

**Close contact is defined by the CDC as (a) being within approx. 6 feet (2 meters) of a COVID-19 case for a prolonged period of time. Close contact can occur while caring for, living with, visiting, or sharing a health care waiting area or room with a COVID-19 case OR (b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on).*

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I want to modify my study procedures to occur remotely. How do I do that?

Studies may modify their procedures to replace in-person study visits with "remote" options for questionnaires, surveys, check-ins, screening, and consenting. Remember that these changes must be approved in advance by the IRB as a Change to the study, unless they are necessary to eliminate immediate apparent hazards to participants. **The submission requirement for a change only applies to expedited and full board studies, not to exempt research.** If you have any questions about whether a remote option is possible or approvable (especially for consent), contact research compliance staff at IRB@baylor.edu. Staff and the IRB are prioritizing these change requests.

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Is study visit cancellation recommended?

The IRB does not have specific recommendations or requirements about postponing or cancelling study visits, but we believe it would be prudent for investigators to follow recommendations of public health authorities to minimize risks to participants.

You may choose to hold study visits remotely if feasible for the study and in person visits are not required. You may also consider changing the schedule of study visits or postponing your research.

You will need to change your protocol before implementing any changes (unless they are necessary to eliminate apparent hazards to the participant and there is not time to obtain IRB approval) if the study is not exempt and the protocol specifies in-person visits.

You do not need to change your protocol in order to hold visits remotely or change the schedule if the study is exempt or if the protocol does not describe whether the visit would be in person or remote or give specifics about visit schedule.

You might also consider whether you will need other flexibility in order to continue conducting the research. For example, many low risk procedures qualify for a waiver of written documentation (signed) consent. If the protocol describes written consent, you may wish to change and request a waiver to remove that requirement to allow for easier remote implementation.

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If I continue in-person visits, do I need to update my consent form with COVID-19 risks?

You do not need to modify the risks section of consent materials. Potential exposure to COVID-19 should not be considered a risk of study procedures.

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I want to place a temporary halt on study enrollment. What do I do?

Researchers may voluntarily halt or delay participant enrollment because of COVID-related public health recommendations, facility requirements, study team availability, and/or participants considered to be at high risk for susceptibility to COVID-19. This does not need to

be reported to the IRB unless the study hold is initiated at the request of an external funding agency.

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Are there any changes to handling human specimens?

Researchers are reminded to follow proper safety procedures for handling human specimens that may contain COVID-19. Human specimens are handled at Biosafety Level 2 (BSL-2). Researchers are reminded that appropriate PPE (lab coats, gloves, eye protection, and face shields) should be worn in BSL-2 laboratories and procedures should be performed within a biological safety cabinet if there is a risk of infection. The CDC offers additional guidance: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

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Do I need to register modifications with ClinicalTrials.gov?

If your study is registered at ClinicalTrials.gov and you are modifying research procedures to include assessment of COVID-19 symptoms, you will need to update the ClinicalTrials.gov information for the study to include this new procedure, *if the assessment is being done for research purposes*. If it is being added as screening to help determine if an in-person visit should occur, the registration information does not need to be modified. The federal requirement about modifications is that any research-related changes that are communicated to the participants (past, ongoing, future) must be added to the study's ClinicalTrials.gov registration within 30 days after IRB approval of the modification.

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If a student or researcher needs to access and/or analyze a data set from home in order to keep working on a project, how do we address privacy requirements, if the data set contains sensitive or private information?

As Baylor prepares to support remote operations, we anticipate that research teams may need to rethink how they access and analyze research data sets. Successful remote research operations require maintaining compliance with required controls. If your research data use is covered by a data use agreement (DUA) or other contractual obligations or if it involves identifiable private sensitive information, please submit a protocol change through IRBNet.org if your storage and use location will no longer match your protocol due to remote operations. Ensure the change is approved before moving data sets to a new technology platform. Visit ITS's website for Resources for Working Remotely. We encourage the use of BOX and Microsoft Office 365 through your Baylor accounts. Our staff will expedite change reviews to the extent possible to support continuity. **This change requirement only applies to expedited and full board studies, not to exempt research.**

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