**Important Update (March 16, 2020):** Effective at 5:00 pm on Monday, March 16, 2020, all face-to-face human subjects research activities are to cease until further notice. This includes activities involving Purdue University researchers (faculty, student, staff) at any site. Principal Investigators are expected to pass this notification on to all human subjects research personnel immediately.

Purdue HRPP is communicating this additional precautionary measure in line with CDC recommendations to practice social distancing and Purdue’s requirement to pause face-to-face instruction. This notice modifies some of the previously issued guidance from HRPP dated March 12, 2020. A decision chart is included at the end of this message to assist researchers.

**Guidance Regarding New Studies**

- Purdue HRPP will continue to review new study submissions through the Cayuse system and communicate with researchers in the same manner. At this time the Purdue IRB plans to continue to hold virtual full board meetings on the scheduled dates.
- Any new study that proposes to use face-to-face means of data collection will not be issued an approval letter until further notice.

**Guidance Regarding Currently Approved Studies** *

- Researchers must contact affected study participants to cancel any upcoming face-to-face visits.
- If a study cannot be conducted virtually, cease research activities. Examples of virtual means are included below.
- As stated in our March 12 communication, a switch to virtual means does not require an amendment to IRB at this time.
- Modifications to add face-to-face (in-person) interactions will not be approved or exempted until further notice.
- As necessary, researchers should continue to utilize proper Personal Protective Equipment (PPE) as designated by campus Radiological and Environmental Management (REM) or the Institutional Biosafety Committee (IBC) protocol for a given lab. Be certain that all researchers are trained on safety practices and any measures to maintain hygienic lab and equipment conditions.

*If a principal investigator believes that ceasing face-to-face interaction will increase the risk to a participant or decrease a direct benefit of health to currently enrolled participants (such as a treatment study or emergency-use study), they must submit a written request to irb@purdue.edu prior to continuing research. The request must contain detailed information about the exact risk or benefit change, how many active participants are affected, and measures that will be taken to limit face-to-face contact time and potential COVID-19 exposure.*
The following exceptions continue to be temporary changes not requiring review under HRPP Standard Operating Procedure (SOP) 305. The HRPP/IRB will allow the following changes without an amendment to the IRB protocol.

1. Substitution of telephone, web conferencing, and secure electronic communication (examples like Purdue’s instances of Box, WebEx, Qualtrics, and Docusign) to conduct data collection procedures normally done in-person. These methods may be added when possible and practical for mitigating research risks related to COVID-19 to subjects or others. If there are questions about any changes to participant risk, please contact the HRPP/IRB Office at irb@purdue.edu or 765-494-5942.

2. **Between March 12, 2020 and 5:00 pm on March 16, 2020 only**: For the purposes of screening, recruitment, data collection, and follow-up visits with in-person contact or collection of biospecimens, the IRB waives the modification requirement to add the questions below to screening/eligibility questionnaires.
   - Have you traveled within the last 14 days to a location designated by the CDC to be an at-risk area for COVID-19?
   - Have you or members of your household been diagnosed with COVID-19 or asked to self-quarantine due to potential exposure to the novel Coronavirus, COVID-19?

   If the above questions are implemented by the Principal Investigator, they should be a documented part of a screening or eligibility script and asked in the same manner to every potential participant. Researchers must also consider and document the follow-up process that will occur (according to best-available public health resources) should a participant give an affirmative answer. Such actions could include a participant not being eligible for the study, recontact/rescheduling for contact at a later date.

   If researchers choose to implement use of these practices, the revised documents must become part of the study file in the Principal Investigator’s records. To allow the IRB to have a record of the implementation of either procedure above, please send an e-mail message noting the study record title(s), PI name, and reference number(s) to the IRB (irb@purdue.edu) within 10 business days of the implementation. The office will include this information in your study file in the Cayuse system.

Please direct questions to the IRB office irb@purdue.edu. We thank the research community in advance for their cooperation.

Is the human subjects research already approved/exempted by the Purdue HRPP/IRB?

No, it is a new study

Submit for review in Cayuse IRB. No face-to-face human subjects research will be approved.

Yes, it is an existing study

Does the existing study currently involve any face-to-face activity with research participants?

Yes

Can the face-to-face activity be switched to virtual means (e.g., WebEx, Qualtrics) or telephone?

Yes

Switch to secure virtual means. An amendment to the IRB protocol is not required at this time.

No

No, all activities are virtual or telephone

Continue human subjects research activities that do not involve face-to-face interactions.

STOP! Cease all face-to-face human subjects research activity!

Contact Purdue HRPP/IRB
irb@purdue.edu
or 765-494-5942