June 1, 2020 Update from Purdue Human Research Protection Program (HRPP):

Purdue HRPP is updating its guidance to reflect the University’s phased return to research operations process as outlined by the Executive Vice President for Research and Partnerships (EVPRP). The phased ramp-up includes the gradual reopening of both on- and off-campus buildings and research spaces. In addition to consulting the information provided below, Purdue researchers are advised to review the latest information about research operations posted on the Purdue COVID-19 research website.

For researchers seeking to resume face-to-face data collection on a previously approved IRB protocol:

- PIs must submit and obtain EVPRP approval of a COVID-19 Research Space SOP using the SOP template provided by EVPRP. Note that approvals will be issued only after public spaces in the building in which research activity is located have received COVID-19 safety enhancements.
- Submit a modification in Cayuse IRB for each previously approved protocol. Your modification needs to include:
  - EVPRP-approved COVID-19 Research Space SOP;
  - Any study changes, including those that will be enacted to protect participants and researchers from the spread of COVID-19 and other changes included in the approved COVID-19 Research Space SOP;
  - A description of mitigation procedures to be enacted for research involving at-risk / vulnerable populations. Please consult updated CDC information regarding at-risk / vulnerable populations.

Purdue HRPP will allow the following changes to a previously approved IRB protocol without the submission of an amendment, consistent with Purdue HRPP Standard Operating Procedure 305:

- Substitution of telephone, web conferencing, and secure electronic communication (examples include use of Box, WebEx, Qualtrics, DocuSign) to conduct data collection typically done in-person. These methods may be added when possible and practical for mitigating research risks to subjects or others related to COVID-19. If there are questions about any changes to participant risk, please contact the HRPP/IRB Office (765-494-5942 or irb@purdue.edu).
- Researchers with EVPRP-approved COVID-19 Research Space SOPs are permitted to implement the use of screening questions without modification to an IRB protocol to pre-screen for risk of exposure or spread of COVID-19. This may include:
  - Questions in verbal or written/electronic form used to confirm that a participant is not at increased risk for complications from COVID-19 by participation in the study;
  - Questions in verbal or written/electronic form to determine if a participant is experiencing COVID-19 symptoms (e.g., temperature, cough) prior to an in-person research visit or information about their possible exposures and travel;
- Outreach to a participant to notify them of the timing, scheduling, and any requirements of their visit or to answer questions about a study prior to the visit.

Purdue HRPP will continue to review new study submissions through the Cayuse system. The Purdue IRB continues to hold virtual full board meetings on these scheduled dates. Approval letters issued to researchers will contain language to indicate that face-to-face procedures must have an EVPRP-approved COVID-19 Research Space SOP to begin or resume in-person research.

The IRB has initial procedures to assist researchers in obtaining biospecimens related to COVID-19 from participants for broad use. Interested researchers should contact IRB for more information on these procedures (765-494-5942 or irb@purdue.edu).

Below is a decision-tree illustrating the Purdue HRPP process related to the University’s phased return to research operations process: