PURDUE UNIVERSITY

HUMAN RESEARCH PROTECTION PROGRAM & INSTITUTIONAL REVIEW BOARD

June 19, 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 research spaces. Recently, guidelines were issued for off-campus research and personal protective equipment (PPE) used in research. 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:

- Principal Investigators must submit a modification in Cayuse IRB for each previously approved protocol. Your modification must include:
    - **For research conducted on-campus-** Include the EVPRP-approved COVID-19 Research Space SOP if Purdue University research space is included. Do not submit a modification until the Research Space SOP is approved;
    - **For research conducted off-campus-** Human subjects research that cannot be conducted virtually or on-campus under a COVID-19 Research Space SOP (such as field research) must ensure that the practices outlined in the EVPRP Guidance for Off-Campus Research Activities in the Continental U.S. are followed (available here). The Principal Investigator (PI) of the study is responsible for implementing procedures for all personnel. Researchers are asked to certify their understanding through a modification to the protocol in the Cayuse IRB system. Updated permission letters or e-mails from participating off-campus research sites (e.g., businesses, schools) may be necessary.
    - **For all human subjects research-** Any study changes, including those that will be enacted to protect participants and researchers from the spread of COVID-19;
    - **For all human subjects research-** 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 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. This includes measures and forms necessary to comply with the Guidance for Research-Related Visitors to On-Campus Buildings or Facilities or Guidance for Enhanced PPE for Close-up, Person-to-Person Interactions in Research (both available here);
- 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.

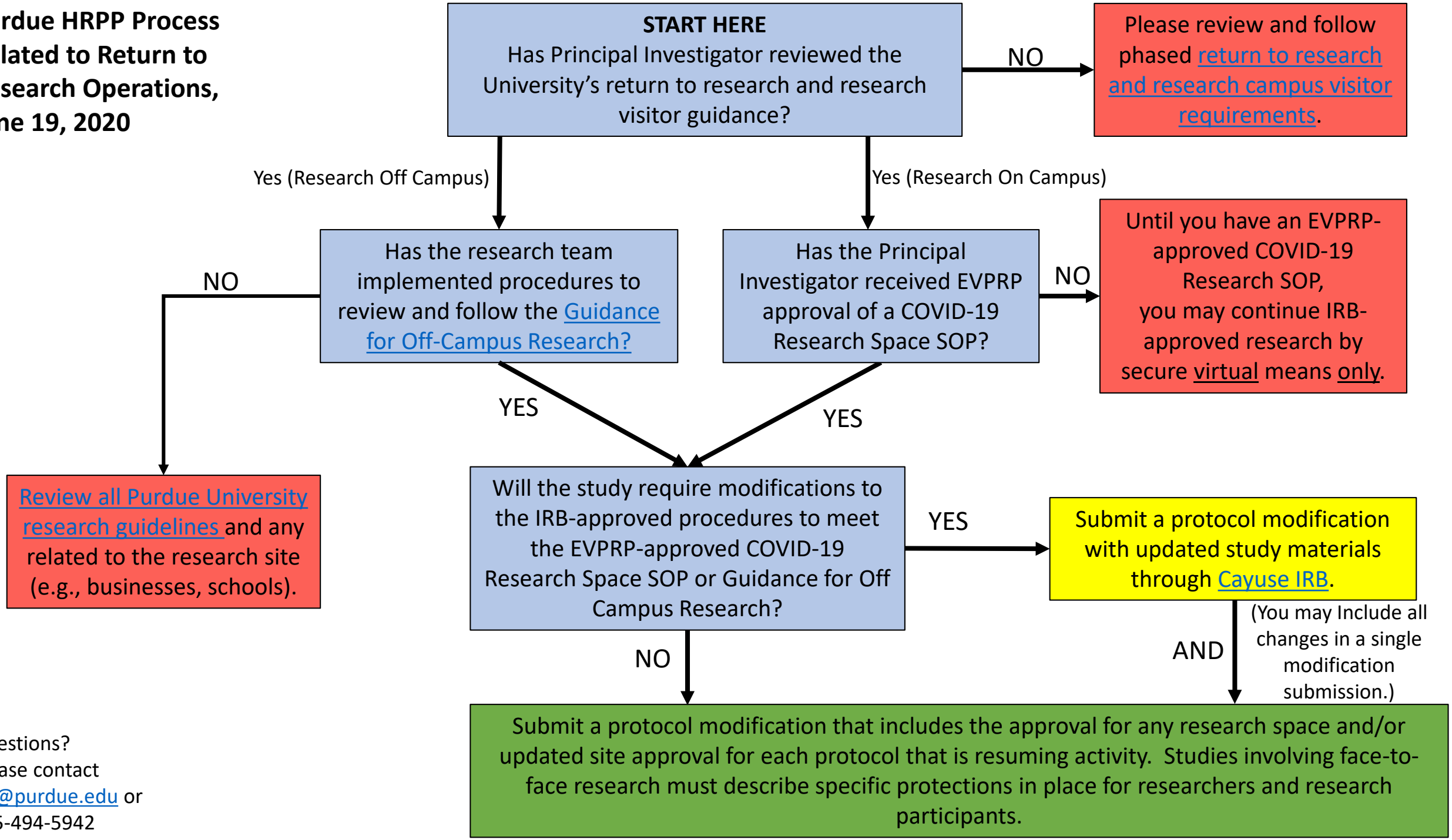
Purdue HRPP will continue to review new study submissions through the Cayuse system. The Purdue IRB continues to hold virtual full board meetings on these scheduled dates. Approval letters issued to researchers will contain language to indicate that face-to-face procedures must have an EVPRP-approved COVID-19 Research Space SOP and/or confirm that the research team has reviewed and understands the university's Guidance for Off-Campus Research Activities 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).

If the scope of a research activity changes because Purdue travel to a research site is no longer possible, the HRPP/IRB must know and approve of the details of the changes, including the methods used for human subjects research protections (examples are proper training, voluntary participation, informed consent, and oversight of the work). We remind investigators that HRPP/IRB approval or exemption are only one component of the changes that may need to occur to the overall project. Considerations related to personnel payment, effort reporting, financial responsibilities, and funding are mostly outside of the scope of the HRPP/IRB, but may also need to change when restructuring a research project. Please continue to monitor the guidance presented on the Protect Purdue Website.

Below is a decision-tree illustrating the Purdue HRPP process related to the University's phased return to research operations process as of June 19, 2020:

Purdue HRPP Process Related to Return to Research Operations, June 19, 2020



Questions?
Please contact
irb@purdue.edu or
765-494-5942