Purdue Human Research Protection Program (HRPP) and Institutional Review Board (IRB) COVID-19 Response

**UPDATED 4/2/2020.** 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 (PIs) are expected to pass this notification on to all human subjects research personnel immediately.

Purdue HRPP is updating its guidance to reflect the most recently defined critical research and support functions (see https://www.purdue.edu/research/covid-19 ). 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.
- We encourage researchers to submit new protocols for review. If a new study is ready for approval, but proposes face-to-face human subjects research, HRPP staff will postpone the issuance of an approval letter. HRPP/IRB maintains the goal of continuity to ensure that new studies can begin as quickly as possible when the restriction is lifted. If a proposed study requires an approval letter to fulfill an external sponsor request, be sure to alert the HRPP/IRB in your application or via e-mail. Please include the sponsor name, PI, and project title. We recommend attaching the sponsor’s written request to your IRB application. You may also consider the “Just-in-Time” application type in the Cayuse IRB system. Researchers should feel free to contact the HRPP/IRB Office for review status questions or check status in Cayuse IRB. Please see the review status table at the end of this communication to help define Cayuse review status.

**Guidance Regarding Currently Approved Studies**

- Human subjects research activities requiring face-to-face (in-person) contact must be put on hold unless considered Critical Research. Specifically, the consideration relates to clinical trials or human subject research that if discontinued would result in significant negative impact on patient care or human health. 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 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. Human subjects research activities that can be conducted without in-person contact may continue.

- Researchers must contact study participants to cancel any upcoming face-to-face visits.
- Modifications to add face-to-face (in-person) interactions are still accepted through the Cayuse system. HRPP staff will actively review, but postpone approval. HRPP/IRB maintains the goal of continuity to ensure that existing research can resume as quickly as possible once the restriction is lifted. Researchers should feel free to contact the HRPP/IRB Office for review status questions or check status in Cayuse IRB. Please see the review status table at the end of this communication to help define Cayuse review status.
- As stated in previous communications, a switch to virtual means does not require an amendment from IRB at this time. Examples of virtual means are included below.

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 to subjects or others related to COVID-19. 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 waived 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 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 for their cooperation.
Purdue HRPP/IRB Decision Chart for Human Subjects Research During COVID-19 Restrictions (updated for clarity 4.2.2020)

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

- 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
          - STOP! Cease all face-to-face human subjects research activity!
    - No, all activities are virtual, mail, or telephone
      - Continue human subjects research activities that do not involve face-to-face interactions.

- No, it is a new study
  - Continue to submit applications for review in Cayuse IRB. HRPP/IRB will review and provide feedback, but withhold final approval letters involving face-to-face research interactions until the restriction is lifted.

Questions or unique situations? Contact Purdue HRPP/IRB irb@purdue.edu or 765-494-5942
## Defining the Common Stages of IRB Review in the Cayuse IRB System

Login at [https://purdue.cayuse424.com/rs/irb](https://purdue.cayuse424.com/rs/irb) Click on each reference number to view the status of review.

<table>
<thead>
<tr>
<th>Status at top of page</th>
<th>Stage in Review Process</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 In-Draft</strong></td>
<td>An HRPP/IRB protocol submission is being prepared. The HRPP/IRB is not reviewing the study.</td>
</tr>
<tr>
<td><strong>2 Awaiting Authorization</strong></td>
<td>The Principal Investigator must certify the protocol submission. Please see the quick reference guide for instructions. The HRPP/IRB is not reviewing the study.</td>
</tr>
<tr>
<td><strong>3 Pre-Review</strong></td>
<td>HRPP staff members are verify training, checking application completeness, gauging risk level, highlighting questions or comments to a reviewer.</td>
</tr>
<tr>
<td><strong>4 Under-Review</strong></td>
<td>When the orange “Under Review” banner appears above the title of your protocol, it is with the assigned reviewer. Often, a reviewer has several items in their queue at one time, so please allow several business days.</td>
</tr>
<tr>
<td><strong>4 Under Review</strong></td>
<td>When the orange “Under Post Review” banner appears above the title of your protocol, it has been reviewed. The HRPP staff will generate the communication to you. HRPP/IRB will issue either a request for revisions or an approval memo.</td>
</tr>
</tbody>
</table>

*Submissions requesting a different IRB of record (reliance) will remain in this status until completion by the collaborating IRB.

*Submissions assigned to an IRB full board meeting will remain in this status until completion the IRB meeting date assigned to the protocol.

**IMPORTANT:** During the Human Subjects Research COVID-19 face-to-face restriction, effective March 16, 2020, protocols will appear in this status until the restriction is removed.