PURDUE UNIVERSITY

OFFICE OF THE EXECUTIVE VICE PRESIDENT FOR RESEARCH AND PARTNERSHIPS

ASSOCIATE VICE PRESIDENT FOR RESEARCH, REGULATORY AFFAIRS

Date: April 5, 2018

To: Associate Deans of Research

cc: Suresh V. Garimella, Executive Vice President for Research and Partnerships
Jay T. Akridge, Interim Provost and Executive Vice President for Academic Affairs and Diversity

From: Christopher R. Agnew, Associate Vice President for Research, Regulatory Affairs

Re: Update on Improvements to IRB Processes at Purdue

I write to update you regarding recent improvements to Institutional Review Board (IRB) processes at Purdue, implemented as part of a general revamping of Purdue's Human Research Protection Program (HRPP). **Please distribute this memo to your college's dean, department heads, faculty, post docs, graduate students, and research staff.**

As you may recall, based on feedback received during Spring 2017 from faculty, graduate students, and staff regarding their experiences with IRB processes at Purdue, we implemented changes at the start of the Fall 2017 semester to improve processing and review of research protocols involving human participants, while ensuring no reduction in protections for research participants. Included among those changes:

1. Principal Investigators (PIs) can submit new protocols, amendments to approved protocols, requests for protocol renewals, and requests for exemption determinations via our new IRB web portal (https://www.irb.purdue.edu/submit-protocol/). The vast majority of submissions to IRB are now accomplished via the portal. Coeus is still used for internal processing by IRB and PIs continue to have access to it should they wish to review any current or past protocol materials they submitted to IRB.
2. We began "Fast Lane" processing of exemption determinations, procedural amendments to approved protocols and renewals of protocols, moving closer to our goal of 72-hour turnaround on these types of protocol submissions when submitted via the IRB web portal. Those PIs seeking more immediate turnaround for exemption determinations can call to schedule an appointment (765-494-5942) to meet with an IRB analyst and have an exemption request application reviewed and, if the application meets exemption criteria, approved as exempt at the meeting.
3. IRB analysts have been designated as being specialized in one of the broad types of research that distinguish our two IRBs (biomedical vs. social sciences), thus providing greater continuity of feedback across protocols of a given type.
4. On the IRB website, we have posted pre-approved wording for commonly-used procedures (e.g., for blood draws; use of Amazon's MTurk) for use by researchers in crafting their protocols.
5. A faculty advisory committee, composed of faculty from across colleges of the university conducting research with human subjects, now meets with me each semester to review changes that have been made at IRB and to provide ongoing process improvement input.

Federal regulations governing human subject research are known collectively as "The Common Rule" and have been in place since 1991. After years of effort by the research community to streamline these regulations, to both focus on improving review of riskier protocols and reduce administrative burden

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regarding the review of less risky protocols, significant changes to the Common Rule were approved by the Federal Government and were to become effective on January 19, 2018. We worked feverishly to be prepared to embrace these very welcome changes at Purdue, but, unfortunately, the Federal Government delayed the implementation date to July 19, 2018. Information from a variety of sources suggests that this July implementation date may also be delayed, perhaps to January 2019. We continue to monitor the situation and to advocate for moving ahead with these needed reforms as soon as possible. We intend to embrace and implement all of these reforms on the very first day we are allowed to do so.

For now, however, we are pleased to announce some upcoming changes and continuing efforts to further our goal of improving researchers' experiences with IRB and shortening response time, while maximizing protections to human research participants. These changes include:

1. ***The introduction of PROPEL***: A large percentage of submissions to IRB involve requests to determine if IRB needs to review a given research project, as projects that meet particular criteria are exempt from IRB review. For decades, Purdue's IRB has reviewed exemption requests, meaning that the IRB has been tasked with reviewing what is exempt from its review. Beyond maddening in its logic, this approach both increases the total number of protocols that IRB has to process and increases total processing time for all other IRB submissions. We have now designed, tested, and will be launching PROPEL (Purdue Research Online Portal Exemption Logic) this month, a new approach to determining if a research project requires IRB review. PROPEL allows Purdue-affiliated researchers to determine for themselves, online and within minutes, whether or not research that is being planned requires IRB review. If review is not required, researchers will be provided with a letter to that effect immediately via email and a record will be created for post-exemption monitoring by HRPP.
2. ***Obtaining accreditation***: We are working closely with the Association for the Accreditation of Human Research Protection Programs (AAHRPP) to meet their accreditation standards, with the goal of becoming an accredited IRB in 2018. Our peer and aspirational-peer institutions are all accredited by AAHRPP and we welcome their input to help ensure that Purdue maintains the requisite infrastructure to support our ongoing efforts to protect human research participants.
3. ***Monitoring ongoing studies***: To ensure adequate protection of research participants, AAHRPP requires that institutions have in place a system for ensuring that the research an investigator planned to do matches what is done. Whether a study has been determined to be exempt from review or has been approved following review by IRB, it is critical that we have a system in place to regularly monitor research in progress. We have now engaged the Research Quality Assurance (RQA) unit from Sponsored Program Services to conduct post-exemption determination and post-IRB approval monitoring. A small, randomly-selected subset of protocols will be monitored by RQA each month, following an easy, standardized process detailed on the IRB website (https://www.irb.purdue.edu/after-approval/).
4. ***Improving connectivity to researcher training***: Purdue uses the web-based CITI Program to train researchers on responsible conduct of research. CITI login can now be done using one's Purdue Career Account login information. No more having to remember a separate CITI Program password. Current CITI accounts of Purdue folks will be seamlessly merged with your Purdue Career Account.
5. ***Improving and making public IRB's Standard Operating Procedures (SOPs)***: Now posted on the IRB website, for the reading pleasure of our human researcher community, the procedures followed by IRB (https://www.irb.purdue.edu/docs/new/Signed%20IRB%20SOPs%2012.5.17.pdf).
6. ***Holding monthly IRB information sessions****:* Conducted by IRB staff, these live on-campus trainings demonstrate how to submit a new IRB protocol, followed by a question-and-answer session and one-to-one assistance on submissions.

Other improvements are planned and will be announced as implemented. On behalf of Purdue's HRPP and IRB team members, my thanks for helping to make these changes possible and for your continued support of our ongoing efforts to improve Purdue's research infrastructure.