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OFFICE OF THE EXECUTIVE VICE PRESIDENT FOR RESEARCH AND PARTNERSHIPS

ASSOCIATE VICE PRESIDENT FOR RESEARCH, REGULATORY AFFAIRS

Date: January 22, 2019

To: Associate Deans for Research

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

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

Re: Important Updates from the Purdue Human Research Protection Program (HRPP)

This memo is being sent to all Associate Deans for Research, with the request that each of you distribute this information to your college's dean, department heads, faculty, post docs, graduate students, and research staff.

I write to update the Purdue research community on the latest changes to regulations and associated processes governing human subjects research. Purdue's HRPP, which includes our Institutional Review Boards, stands ready to assist researchers as they navigate these latest welcome changes.

1. Long Awaited Final Implementation of Changes to the Common Rule

Final changes to the federal rules that prescribe protections for human participants in research (collectively known as the Common Rule) became effective yesterday, January 21, 2019. We are now fully embracing all of these burden-reducing changes. Here are some highlights:

a) **Moving from Annual to Triennial Review.** Qualifying protocols deemed by IRB to be "No Greater Than Minimal Risk" are being (or have been) converted from an annual to a triennial (i.e., every 3 years) review cycle. The conversion process involves PIs providing a short update on the status of their data collection and minor new required changes to approved consent forms. Principal Investigators (PI) are being contacted by HRPP on a rolling basis for this purpose. Once complete, a new approval letter will be issued that reflects the extended approval period.

b) **Implementing Broad Consent for Future Data Use.** Storage and use of samples for future studies may now be eligible for exemption from IRB review. However, the process involves a separate participant "broad consent" process in parallel with tracking and monitoring provisions typically associated with established bio- or data-banking facilities. HRPP will evaluate pending guidance as it becomes available from the federal government. For now, HRPP will determine applicability on a case-by-case basis.

c) **Adding Benign Behavioral Intervention Exemption Category.** Additional categories of research that are exempt from IRB review have now come into effect. Of particular

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importance for social and behavioral researchers is the inclusion of new Exemption Category 3, which involves studies classified as "benign behavioral interventions." To qualify, the research must involve only adults participating in brief research interventions involving the study of psychological states and processes, cognition, ideas and attitudes, or behavior. Note that studies involving physical (bodily) tasks, such as exercise or blood collection, do not qualify for this new exemption category. Common examples of benign behavioral interventions include adults solving puzzles, playing computer games, or answering survey questions. Like all human subject research (exempt or not), researchers are still required to provide information about their study to HRPP prior to beginning their study. This is most easily done via our online PROPEL tool (Purdue Research Online Portal Exemption Logic: www.irb.purdue.edu/getting-started/). Researchers who conduct benign behavioral interventions will notice a significant decrease in review time and in the number of documents required for protocol submission. The HRPP is already accepting and reviewing applications accordingly.

2. Storing Research Data Using Box

Recently, Purdue's Office of Research and Partnerships collaborated with Information Technology at Purdue (ITaP) to provide a new data storage resource for the Purdue research community. Purdue researchers now have access to Box, a cloud-based storage service that allows investigators to store and share data. HRPP/IRB will accept protocol applications that make use of Box as an acceptable means to store research data. However, please be aware that any storage of Protected Health Information (PHI) covered under HIPAA, or storage of other data with specific access parameters, will require special account set-up through ITaP *prior* to data storage. Note that ITaP and other campus units are currently exploring the possibility of storage options for data covered under additional regulations (e.g., export controlled data). To access Box, use your Purdue Career Account login here: https://purdue.account.box.com/login

3. Additional Investigator Resources

HRPP efforts in recent months follow the dual themes of (1) removing the mystery from what is necessary for an IRB protocol submission, and (2) working collegially with researchers to meet, as efficiently as possible, their regulatory obligations. In addition to offering monthly training sessions and an online Researcher Guide, updated infographics give an at-a-glance overview of the process involved in putting together an IRB application. One of the more recent tools added to our website outlines what to consider when making a study recruitment flyer. New resources will be added continuously. As you review the current resources, please feel free to submit your ideas regarding topics we should add (email irb@purdue.edu).

PIs continue to be responsible for reporting any changes to procedures, personnel, funding, or problems that occur during the course of an approved study. Please do not hesitate to reach out to the IRB should changes occur. Also, please note that all approved and currently open studies are subject to post approval monitoring by HRPP (for more on this process, go here: https://www.irb.purdue.edu/after-approval/). As we transition to these long-awaited regulatory changes, we will continue to look for efficiencies that can be added to our processes, without compromise to research protections. We welcome your comments and feedback as we work together to ensure the welfare of human research participants.

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