Date: August 19, 2019

To: Associate Deans for Research

cc: Theresa Mayer, Executive Vice President for Research and Partnerships
         Jay T. Akridge, Provost and Executive Vice President for Academic Affairs and Diversity
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         Tomas Diaz de la Rubia, Purdue Chief Scientific Officer
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         Jennifer Linvill, IRB Administrator
         Steve Elliott, Chair, Purdue IRB
         Jeff Haddad, Associate Chair of HRPP Education, Purdue IRB
         Jeannie DiClementi, Associate Chair of Protocol Monitoring, Purdue IRB
         Ken Sandel, Senior Director, Sponsored Program Services

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

Re: New Cloud-Based IRB Submission and Processing Software -- Cayuse IRB

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.

The Purdue University Human Research Protection Program (HRPP) has worked over the summer to implement a new approach to Purdue Institutional Review Board (IRB) protocol submission and processing. Effective today, investigators who conduct research with human subjects will use a cloud-based software system called **Cayuse IRB** to submit new protocols to IRB for review (accessed via www.irb.purdue.edu). Cayuse streamlines protocol submission communications between investigators and HRPP, provides researchers with immediate access to all of their protocol materials in real time, and offers significant advantages over previous submission approaches:

- Cayuse provides users with a dashboard to track an application through the entire review process. HRPP anticipates that this will eliminate nearly all questions about review status, timelines, and document receipt.

- All submissions will be made online via Cayuse, with the ability to save submitted information at any time for future editing or retrieval. Within Cayuse, IRB application questions are presented in short-answer and multiple-choice formats. Consistent with our widely used online exemption determination system (PROPEL), we have designed the user interfaces within Cayuse to follow the review logic that fits various study types. This should eliminate some inefficiencies that result from use of the previous essay-style application approach.

- When working with HRPP staff and IRB members, researchers can make any needed changes within the body of their protocol application using in-line commenting and corrections within Cayuse. Revisions will appear in relevant sections of the protocol application rather than in separate documents, memos or e-mails. Use of this approach will create a more conversational dialogue between investigators and the HRPP/IRB. All will be working on the "same page" (literally), within Cayuse IRB.

- CITI training certification status will be imported directly from CITI to Cayuse for all Purdue University investigators. This will help eliminate the need for continuous manual cross-checking and uploading of separate training verifications documents. However, this automated step will only detect those in the CITI system who have connected their CITI accounts to their Purdue University Career Account (i.e., Purdue e-mail address). *This is an opportune time to ensure that your CITI account is linked to your Purdue University Career Account.* Please see www.irb.purdue.edu/training or contact the HRPP Office for assistance with this, as needed.

We ask for your help and patience as we now work with you to develop best practices in using Cayuse. We will work with investigators to address any questions that they have and will post frequently asked questions (and answers!) to the IRB website as they arise. We will also increase training outreach by holding additional in-person training sessions. Moreover, we will use the first few months following implementation to fine tune both the interface and our training materials. If your research team submits one of the first new 200 applications, it is likely that we will ask for your feedback on how to improve the new system.

Note that only new protocol applications will be accepted via Cayuse IRB at this time. Applications that were submitted or reviewed by IRB prior to today will be considered "legacy protocols" and will only be converted for use within Cayuse on an as-needed basis (e.g., if study modifications are requested or protocol renewals are required). We anticipate having a process in place to amend legacy protocols via Cayuse by the end of October 2019.

We have made great strides in improving HRPP over the past months. Please know that HRPP staff remain ready to assist you. For one-on-one assistance, please feel free to schedule an appointment or attend walk-in hours, as you prefer: www.irb.purdue.edu/contact