

Date: July 31, 2018

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: Permissible Changes to the Common Rule for Human Subjects Research

As you may know, significant changes to the U.S. federal rules that prescribe protections for human participants in research (collectively known as the Common Rule) are now slated to come into effect on *January 21, 2019*. We are prepared to embrace these burden-reducing changes on that day here at Purdue. In the meantime, I write with good news regarding three burden-reducing provisions that research institutions are permitted to make in their operations immediately. Below I detail these changes, which became effective here at Purdue on the earliest allowable date of *July 19, 2018*. **Please distribute this memo to your college's dean, department heads, faculty, post docs, graduate students, and research staff.**

- 1. Eliminating Annual Continuing Review of Approved IRB Protocols Deemed “No Greater Than Minimal Risk”:** Perhaps the most impactful regulatory change for campus researchers who conduct human subjects research is the elimination of annual continuing review requirements for studies determined by the IRB to be “no greater than minimal risk.” Although the IRB retains the authority to require review for specific studies as it sees fit, the vast majority of approved studies will no longer require investigators to complete continuing review forms or revise study materials on an annual basis. Studies deemed “greater than minimal risk” by the IRB must still be reviewed annually. Purdue’s Human Research Protection Program (HRPP) will contact researchers if a given approved protocol requires additional review. The HRPP will also assist Principal Investigators (PIs) with modifying previously approved consent forms so as to allow ongoing studies to be prepared for anticipated consent form changes effective January 21, 2019. As always, the primary responsibility for reporting study status, including unanticipated adverse events, rest with a study’s PI.
- 2. Eliminating the Need for IRB Review of Grant Applications.** The IRB is no longer required to review all grant applications that include human subjects research. Be aware, however, that the HRPP must have accurate information regarding the review requirements of each funding source, as sponsors often have distinct requirements with respect to an IRB’s review and documentation processes. Thus, a degree of regulatory confirmation remains necessary. The requirement to review grant applications still applies for other forms of regulated research (e.g., for research involving vertebrate animals).

3. **Constraining the Definition of What Constitutes “Human Subjects Research”**: The regulations now clarify the definition of “Research” to remove a number of activities from IRB review. These activities include:

- certain scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship);
- public health surveillance activities ordered, required, or authorized by a public health authority necessary for assessing or monitoring public health outbreaks;
- collections/analyses by law or court order solely for criminal justice or criminal investigative purposes for criminal justice or criminal investigative purposes;
- federal agency-authorized activities in support of specified missions of intelligence, homeland security, defense, or other national security missions.

Researchers planning to undertake such activities are encouraged to discuss potential projects with the HRPP to be certain the project’s scope falls within permissible parameters.

It is important to note that these burden-reducing provisions do not decrease a PI’s responsibility to manage, document, and communicate reportable events to the IRB during the conduct of research. Reports by PIs to the IRB include adverse events, changes in personnel or procedures, and protocol closures. Moreover, all IRB exemptions and approvals remain subject to random or for-cause monitoring as outlined in our newly-revised Standard Operating Procedures (SOPs), which can be found here: <https://www.irb.purdue.edu/sops>

In preparation for additional anticipated Common Rule changes on January 21, 2019, the HRPP is increasing guidance material on our website and continuing to conduct monthly training sessions for researchers. If you have questions on writing a protocol or on accompanying documents (e.g., consent forms), the HRPP remains accessible during both walk-in hours and by appointment to provide you with assistance. Our SOPs have been carefully revised and we are prepared to implement further revisions as they become permissible under federal law, with the goal of further streamlining the research review and approval process here at Purdue.

Speaking on behalf of the entire HRPP team, we very much appreciate the positive and constructive feedback we have received from members of the Purdue research community in the past months. We continue to look for ways to improve the review process and look forward to working with you in the days ahead.