

SPRING 2016

Improving Buck-IRB

Enhancements to the [Buck-IRB](#) submission system include features requested by investigators.

- Investigators and research staff can notify co-investigators with outstanding signatures within the system
- Study options re-ordered in the study workspace to prevent inadvertent submission withdrawals
- Help text to personnel change submissions to state why specific study team members may not be eligible for editing/removal
- Investigators receive a list of all submitted documents with every submission notification
- Study team members can track all study notifications, including PI notifications, and department chair and co-investigator signature reminders
- Alerts to the study workspace to indicate if an event report is pending submission
- Study number added to the subject line of all notifications to PIs to better track pending submissions
- Amendments allowed beyond personnel changes on external studies (i.e., WIRB, NCI CIRB, NCH), including HIPAA authorization waiver requests, location changes, and requests for Human Subjects Radiation Committee (HSRC) review

Contact Susan Ebert at ebert.55@osu.edu with questions.

Reducing Regulatory Burden

Under certain conditions, the requirements for continuing IRB review can be satisfied by completing a brief annual status report. The abbreviated, annual status report is available for minimal risk, expedited studies that are not FDA-regulated or federally funded.

The annual status report is limited to questions regarding study changes over the previous year and current study status. Unless the IRB requires that the study undergo continuing review, researchers can submit the annual status report for studies meeting all of the following conditions:

- Studies considered minimal risk and qualifying for expedited review even if the study initially received convened review
- Studies not supported by a federal agency or not having received federal funding at any time during the research, including through a sub-award from another institution
- Studies not FDA-regulated including studies involving drugs, devices, and data submission
- The investigators do not intend to make personnel changes at the time of the annual review. Personnel changes are not permitted with the annual status report but continue to be available with the full, continuing review application

Note: Investigators must continue to submit proposed changes (i.e., amendment submissions) and event reports for studies meeting the conditions for an annual status report.

Helpful Guidance and Template for dbGaP

New guidance is posted on the Office of Responsible Research Practices (ORRP) website to assist investigators required to share genomic data and materials through repositories such as dbGaP. This guidance explains the requirements and processes for obtaining the necessary institutional certification required in order to submit data to these repositories. For more information, see [Submission of Data to dbGaP and Other Requests for Genomic Data Sharing](#). In addition, template consent form language has been created for use in studies required to share data through dbGaP, NIH, and other external, publicly-accessible scientific databases. For more information, refer to this topic on the [Consent Template Language by Topic](#) page of the ORRP website.

Contact Cheri Pettey at pettey.6@osu.edu for more information.

New Submission Forms for WIRB Protocols

Western IRB (WIRB) has released new [SMART submission forms](#) for initial industry-sponsored submissions. The forms are dynamic, responsive PDFs that auto-populate based on information entered and help make the submission process more efficient. The forms require the use of Adobe Acrobat version 9.1 or newer. Investigators should begin using the forms with all new submissions.

Contact Susan Ebert at ebert.55@osu.edu with questions.

IRB FAQs

ORRP has added a 'Frequently Asked Questions' page to its Human Subjects website. This new page offers questions and answers on topics such as engagement, review determinations, and exempt research. Over time the FAQs will grow with new topics being regularly added. The Human Subjects FAQ page can be found at: <http://orrp.osu.edu/irb/irb-faqs/>.

Submission Help for Behavioral and Social Sciences

Do you have questions regarding IRB review or exemption procedures, or need assistance navigating IRB policies and procedures? Please make plans to visit our staff during weekly office hours, held Tuesdays and Thursdays from 9-11am or Wednesdays from 1-3pm in Research Commons, 3rd Floor, 18th Ave. Library.

Contact Joni Barnard at (614) 688-3405 or barnard.15@osu.edu with questions or for additional information.

Upcoming Workshops

[Data and Specimen Repositories \(SBS Research\)](#)

Research Commons, 3rd Floor 18th Avenue Library, 175 West 18th Avenue

May 17, 3pm – 4pm

[Data and Specimen Repositories \(Medical Research\)](#)

Clinical Skills Education and Assessment Center, Room 620, 6th Floor Prior Health Sciences Library

June 21, 8am – 9am

Save the Date

July 14th, 4pm - Secondary Analysis of Data and/or Specimens (Research Commons)

August 12th, 8am - Secondary Analysis of Data and/or Specimens (Prior Health Sciences Library)

Contact Sandra Meadows at meadows.8@osu.edu for more information or to schedule a workshop for your college or department.

ORRP Staffing Updates

Please join us in welcoming new members of the ORRP team:

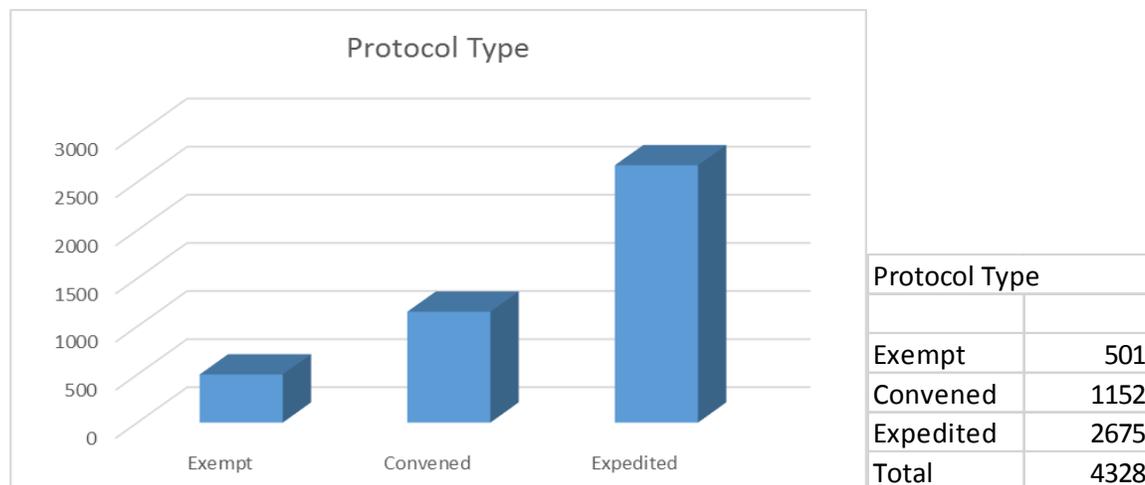
Kim Toussant, MBOE, MA, CRA, Director

Jessica Mayercin-Johnson, MA, IRB analyst

Aaron Seddon, MA, IRB analyst

Kirsten Thomas, MA, IRB analyst

IRB by the Numbers



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