

Special Notice

Changes to Instructor Assurances as a Result of the New Common Rule

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule). The Final Rule was published in the Federal Register on January 19, 2017. It implements new steps to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

The rule adds to and modifies existing Exemptions. This includes modifying previous Exemptions to allow use of identifiable information with limited IRB review (which is a new category of review that requires an IRB member); inclusion of benign behavioral interventions; and storage, maintenance and secondary use of identifiable private information and identifiable biospecimens where broad consent is obtained.

The changes to the Exemption categories, while trying to reduce overall burden, are significantly more complicated requiring related experience and training in making appropriate Exemption determinations. Therefore, we will be retiring the Instructor Assurance process.

Locally and nationally, the majority of classroom projects are not considered research by Federal definition and do not require IRB review. If the intention of the class project meets the following criteria, then the project would not meet the definition of research and would not require IRB submission.

- It is an activity designed as part of a course requirement for purposes of learning research methods and;
- The results and data will not be used for any presentation, conference, publication, thesis, dissertation, or report outside of the course for which it is assigned.

If the student's required classroom project does not meet the criteria above, an IRB submission is necessary. There will no longer be an option for the Instructor to make Exemption determinations for their student's class project. A student project felt to be research defined by Federal regulations will need to be submitted to the IRB for review. See attached Student Class Guidance for your responsibilities as the Class Instructor in these instances.

This new requirement does not apply to the Spring 2018 semester classes currently in progress. However, Investigators will need to look ahead at any Summer and Fall classes to ensure student class projects that are research are submitted to the RPO Office.

Additional information on class projects including examples of projects not requiring review can be found under [Student Class Project Guidelines](#).