



OFFICE OF RESEARCH AND SPONSORED PROJECTS

Federal Regulation Updates: Summary of Changes

The Federal regulations regarding the protection of human subjects in research have been updated. These changes are effective beginning January 19, 2019 for all new applications reviewed and approved by the UWG Institutional Review Board (IRB).

Below are the changes that are most likely to impact UWG researcher for IRB applications approved **after January 19, 2019:**

1. Consent
 - a. Consent must start with a “clear and concise summary” of information a reasonable person would want to know. This has been added to the Consent templates.
 - b. If the research involves the collection of identifiable private information or identifiable biospecimens, a statement on whether the identifiers might be removed and information or biospecimens could be used for future research without additional informed consent must be included in the informed consent document.
2. Continuing Review
 - a. Expedited studies no longer require annual Continuing Review.
 - b. Expedited or Full Board that have progressed to data analysis only, no longer require annual Continuing Review.
3. Exempt Determinations
 - a. The IRB will make a determination of whether or not the study is exempt from IRB review. The IRB will issue a determination letter, not an approval letter.
 - b. Several existing categories have been revised or expanded. A new category for benign behavior interventions has been added. Please see the [Exempt Category summary](#) for additional information.
4. New Definitions
 - a. Vulnerable - no longer includes pregnant women or handicapped or physically disabled individuals as examples of populations that are potentially vulnerable to coercion or undue influence. The new language describes vulnerable as "individuals with impaired decision-making ability" rather than "mentally disabled persons."
 - b. Human subject - references "information and biospecimens" (replacing "data") and adds "obtaining, using, analyzing, or generating identifiable private information or identifiable biospecimens."
5. IRB oversight of research where the research institution and the sight institution where data is collected. §11.103(e) requires that for nonexempt research involving human subjects (or exempt research that requires limited IRB review) that takes place at an institution for which an IRB not operated by that institution exercises oversight, the institution and the organization operating the IRB must document the institution’s reliance on the IRB for its research oversight.

The final rule also requires that this documentation include the responsibilities of each entity to ensure compliance with the requirements of the rule.

6. The elimination of the requirement that institutional review boards (IRBs) review grant applications or other funding proposals related to the research.

The IRB is in the process of updating all IRB applications and consent form templates. Existing projects that have IRB approval prior to January 19, 2019 will not be impacted by these changes. They will continue to operate under their existing approvals and expiration dates. Projects that require modification or continuing review may be required to update to the new Consent Forms at the time of modification or continuing review.

Please send any questions or concerns to the UWG IRB office at irb@westga.edu.