

Common Rule Changes – Notification about initial changes

There are three burden-reducing provisions in the new Common Rule (45 CFR 46) have been officially approved to be implemented on or after **July 19, 2018** (so they are now in force). The IRB webpage will be updated to reflect any relevant changes needed in policies and procedures for research involving human participants that will be put into place as a result of these preliminary changes and of changes in the final version of the Common Rule, scheduled to take effect on **January 21, 2019**. In addition, there will be training documents available in the Office of Research's Canvas Community with additional information.

The Specific changes to the existing Common Rule are listed below:

1. Elimination of the Continuing Review requirement for qualifying studies, such as:
 - Studies with minimal risk, including studies eligible for Expedited review
 - Studies (even if initially requiring review by a full IRB board meeting) where intervention has already occurred and all that remains to complete the study is one of the following:
 - “Analyzing data (including identifiable private information);” and/or
 - “Accessing follow-up clinical data from procedures that subjects would undergo as part of standard care for their medical condition or disease.”
2. Elimination of congruency checks between grant applications and IRB applications. This relates to the fact that IRBs no longer need to approve research studies involving human participants prior to submission of a grant to fund those studies.
3. The definition of Research now makes explicit four activities which do not count as research and therefore do not require IRB review. Principal Investigators are still welcome to submit these types of studies for review if they address sensitive issues or raise other potential risk issues. The four activities are:
 - Scholarly and journalistic activities that focus directly about whom the information is collected;
 - Public health surveillance activities authorized by a public health authority in high-stakes situations where timeliness is imperative;

- Activities authorized by a court of law for the sole purpose of criminal justice or investigative purposes; and
- Authorised operational activities in support of national security.

Definition of Research from 45 CFR 46.102(l)

“Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For the purposes of this rule, the following activities are deemed not to be research:

(i) Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly about whom the information is collected.

(ii) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onset of disease outbreaks, or conditions of public health performance.

(iii) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by a law or court order solely for criminal justice or criminal investigative purposes.

(iv) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.”

Link to OHRP’s website with full information on Common Rule changes:

<https://www.hhs.gov/ohrp/final-rule-delaying-general-compliance-revised-common-rule.html>