

Revised Common Rule
for
Biomedical and Behavioral Research Involving Human Subjects

The **Common Rule** is a 1981 **rule** of ethics in the United States regarding biomedical and behavioral research involving human subjects.

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 effective date of the revised Common Rule is July 19, 2018.

What are the changes?

- Requirement for consent forms – The consent form should provide research subjects with a clear project’s scope including risks and benefits. As a result participants can make a more fully informed decision on their participation
- Requirements, in many cases, to use a single institutional review board (IRB) for multi-institutional research studies.
- For studies on stored identifiable data or identifiable biospecimens, researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement. As under the current rule, researchers will still not have to obtain consent for studies on non-identified stored data or biospecimens.
- The establishment of new exempt categories of research based on the level of risk they pose to participants.
- Removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects.
- Requirement that consent forms for certain federally funded clinical trials be posted on a public website.

For more information please go to:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>

https://regionalseminars.od.nih.gov/neworleans2017/wp-content/uploads/2017/04/Overview_of_Common_Rule-May_2017.pdf

The list below displays the 16 agencies and departments that have signed onto the Common Rule and their CFR numbers.

1. [Department of Agriculture](#) (7 CFR Part 1c)
2. [Department of Energy](#) (10 CFR Part 745)
3. [National Aeronautics and Space Administration](#) (14 CFR Part 1230)
4. [Department of Commerce, National Institute of Standards and Technology](#) (15 CFR Part 27)
5. [Consumer Product Safety Commission](#) (16 CFR Part 1028)
6. [Agency for International Development](#) (USAID) (22 CFR Part 225)
7. [Department of Housing and Urban Development](#) (24 CFR Part 60)
8. [Department of Justice, National Institute of Justice](#) (28 CFR Part 46)
9. [Department of Defense](#) (32 CFR Part 219)
10. [Department of Education](#) (34 CFR Part 97)
11. [Department of Veterans Affairs, Office of Research Oversight, Office of Research and Development](#) (38 CFR Part 16)
12. [Environmental Protection Agency](#), Research and Development (40 CFR Part 26)
13. [Department of Health and Human Services](#) (45 CFR Part 46)
14. [National Science Foundation](#) (45 CFR Part 690)
15. [Department of Transportation](#) (49 CFR Part 11)
16. [Social Security Administration](#) (20 CFR 431)