



Common Rule Agencies & Departments

Research Funded and/or Supported Federal Agencies

The “Common Rule” is the set of federal regulations (Code of Federal Regulations-CFR) that protects the rights and welfare of human research participants. The U.S. Department of Health and Human Services is the federal agency by which the Common Rule was developed and maintained. The Common Rule, initially published in 1991 and codified as 45 CFR part 46 with four subparts protecting the rights of vulnerable populations (i.e. pregnant women, human fetuses, neonates; children; and prisoners). Revisions to the Common Rule occurred with an intended general compliance and effective date of January 19, 2018. However, there was a delay in the revised rule, resulting in a final general compliance and effective date of January 21, 2019.

Research Funded and/or Supported

Currently, there are 19 agencies that are signatories to the Common Rule. Research that is funded or supported by agencies that have signed on to the Common Rule are governed by the Common Rule and its subparts.

Common Rule Agencies

Department of Health and Human Services	Department of Homeland Security	Social Security Administration
Social Security Administration	Department of Veterans Affairs	Department of Agriculture
Agency for International Development	Environmental Protection Agency	Department of Energy
Department of Housing and Urban Development	National Aeronautics and Space Administration	Department of Labor
National Science Foundation	National Institutes of Health	Department of Defense
Department of Transportation	Department of Education	Department of Commerce
Consumer Product Safety Commission		

Food and Drug Administration

The Food and Drug Administration (FDA) is a Health and Human Services agency that has its own set of regulations for drugs, biological products, and medical devices. The FDA is not considered a Common Rule agency as the FDA regulations differ from the Common Rule.

References:

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