Resources for Exploring the Common Rule

* Common Rule, Subpart A (current version): <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html>
* Annotated Comparison of the Pre-2018 Common Rule with the Revised Common Rule: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/annotated-2018-requirements/index.html>
* Belmont Report <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>
* US Federal Agency interpretations of the Common Rule
  + VHA Directive 1200.05 Requirements for the Protection of Human Subjects in Research: <https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171>
  + Department of Defense (DOD) Instruction 3216.02 Protection of Human Subjects and Adherence to Ethical Standards in DOD-Conducted and -Supported Research: <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf>
  + Department of Energy (DOE)-Specific Requirements: <https://science.osti.gov/ber/human-subjects/Regulations-and-Requirements/DOE-Specific-Requirements>
  + Department of Justice (not a signatory to the revised Common Rule as of June 2023): <https://www.ojp.gov/sites/g/files/xyckuh241/files/media/document/ResearchDecisionTree.pdf>
  + Environmental Protection Agency (EPA): <https://www.epa.gov/sites/default/files/2016-06/documents/2016_policy_order_revision_6-10-16.pdf>
  + Department of Education
    - The Family Educational Rights and Privacy Act (FERPA): <https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html?src=rn>
    - Protection of Pupil Rights Amendment (PPRA): <https://studentprivacy.ed.gov/content/ppra>
* Office for Human Research Protections (OHRP)
  + Decision Charts: <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html>
  + Guidance: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/alphabetical-list/index.html>
  + FAQs: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/index.html>
  + Expedited Review: Categories of Research that may be Reviewed Through an Expedited Review Procedure (1998): <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>
  + Webinars on 45 CFR 46: <https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/ohrp-webinars-on-45-cfr-46/index.html>
  + Mini Tutorials: <https://www.hhs.gov/ohrp/education-and-outreach/online-education/mini-tutorials/index.html>
  + Reporting incidents: <https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html>
  + Registering IRBs and Obtaining FWAs: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/index.html>

Subparts

* Subpart B — Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html>
* Subpart C — Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html>
* Subpart D — Additional Protections for Children Involved as Subjects in Research: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html>
* Subpart E — Registration of Institutional Review Boards: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-e/index.html>

Additional Resources

* Secretary's Advisory Committee on Human Research Protections (SACHRP) Recommendations: <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/index.html>
* IRB Management and Function, 3rd Edition: <https://www.jblearning.com/catalog/productdetails/9781284181159?_ga=2.243219714.1058173199.1608128616-198625547.1608128615%23productInfo#productInfo>
* IRB Member Handbook, 4th Edition: <https://www.jblearning.com/catalog/productdetails/9781284197143>

Comparison of the Common Rule and FDA Regulations

* <https://www.fda.gov/science-research/good-clinical-practice-educational-materials/comparison-fda-and-hhs-human-subject-protection-regulations#:~:text=1%20In%201991%20FDA%27s%20regulations%20were%20harmonized%20with,parts%20312%2C%20812%2C%20and%20814.%20...%20More%20items>

Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations

* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/impact-certain-provisions-revised-common-rule-fda-regulated-clinical-investigations>

Differences between the Common Rule and the HIPAA Privacy Rule

* <https://aihc-assn.org/do-you-know-the-difference-between-hipaa-versus-the-common-rule/>