

Educational Resources for Investigators

OHRP created this list of resources to help investigators learn about and succeed in their role in protecting research subjects.



Suggested Resources for Investigators (consider reviewing in the order presented):

- 1. Background information on human research protections
 - Review the set of infographics *Protecting Research Volunteers* to get an overview of the Federal system of protections
 - Review the *Belmont Report*, which provides the ethical foundation for protecting human research subjects in the U.S.

2. Information on when the Common Rule applies to an activity

- Watch the video <u>When Does the Common Rule Apply? Review the Basics Under the Revised Rule</u> to understand the requirements and flexibilities afforded by the regulations for human research protections.
- Human Subject Regulations Decision Charts
- 3. Videos and information on Informed Consent:
 - Informed Consent: What to Expect? (Video for prospective participant of research)
 - General Informed Consent Requirements (Video for investigators)
 - What's New in Informed Consent: Revisions to the Common Rule
 - Information on <u>Clinical Trial Informed Consent Posting Requirement</u>
 - Informed Consent FAQ
 - <u>Revised Common Rule Q&A on Informed Consent</u>
- 4. Videos on Institutional Review Boards (IRBs)
 - Institutional Review Boards
 - What You Should Know About IRB Review of Research (webinar)
- 5. Information on reporting incidents to the IRB and OHRP
 - <u>Guidance on Reporting Incidents</u>
- 6. Videos for investigators who do research primarily with data and biospecimens
 - Regulatory options for Secondary Research with Private Information and Biospecimens Part 1
 - Regulatory options for Secondary Research with Private Information and Biospecimens Part 2
- 7. Materials for investigators doing clinical research
 - Watch videos of the discussions in OHRP's 1-day 2018 Exploratory Workshop entitled
 <u>Meeting New Challenges in Informed Consent in Clinical Research</u>

8. Understanding the HHS Regulations for the Protection of Human Subjects in Research

- Learn more about the regulatory requirements for human subjects research in the **Revised Common Rule**, see the set of **Revised Common Rule Videos**
- Access a collection of <u>Revised Common Rule Resources</u>

Please note that these materials were developed by the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) specifically for HHS-funded research. Their applicability and relevance may differ for research funded by other Federal departments and agencies.

Investigators may also choose to review the following OHRP resources that feature esteemed speakers on thought-provoking topics:

- OHRP's <u>Luminaries Lecture Series</u> covers a broad set of topics including e-consent, big data research and privacy, and personalized medicine, among others
- OHRP <u>Exploratory Workshops</u> provide videos, slides, written materials, and resources form day-long workshops that engage differing viewpoints on topics including informed consent in clinical research, privacy and big data research, and single IRB review



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