

OHRP Office for Human Research Protection

OHRP created this list of resources to help IRB members and administrators learn about and succeed in their roles in protecting research subjects.

Suggested Resources for IRB Members & Administrators (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. Short Videos on Institutional Review Boards (IRBs)

- Institutional Review Boards
- Membership Requirements for Institutional Review Boards
- Quorum and Voting in IRB Review Meetings
- 3. Short videos on IRB Review and Other Responsibilities
 - IRB Review Criteria
 - Prisoner Research Series: Part 1
 - Prisoner Research Series: Part 2
 - OHRP Reporting Requirements: Part 1
 - OHRP Reporting Requirements: Part 2
- 4. 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 <u>Revised Common Rule Videos</u>
 - Access a collection of <u>Revised Common Rule Resources</u>
- 5. Find OHRP guidance documents
 - Review commonly used guidance documents:
 - » Human Subject Regulations Decision Charts
 - » Draft guidance on Activities Deemed Not to be Research: Scholarly and Journalistic Activities
 - » Draft guidance on Elimination of IRB Review of Research Applications and Proposals
 - » Exempt Research Determination FAQs
 - » Institutional Review Board Written Procedures: OHRP Guidance (2018)
 - » Approval of Research with Conditions: OHRP Guidance (2010)
 - » Continuing review guidance (2010)
 - » Informed Consent FAQs
 - » Information on Clinical Trial Informed Consent Posting Requirement
 - » Research with Children FAQs
 - » Unanticipated Problems Involving Risks and Adverse Events Guidance (2007)
 - » Reporting Incidents to OHRP
 - » Access Revised Common Rule Q&As

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.

IRB members and administrators 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



