Training Checklist for Someone Working with IRBs

OHRP created this list of resources to provide basic training for someone who will be working with an IRB:

New IRB members (including community members)

Investigators wanting to know what to expect when submitting a protocol for review

IRB administrators

Existing IRB members who want to brush up on the basics

The checklist covers 5 main areas with a recommendation to review in the order provided.

Basic Information about Human Research

Review the material in this section to get a general understanding about research, research participation, and the framework for protecting research participants:

- [ ] 1. Read a simple explanation of what it means to do research involving humans (www.hhs.gov/ohrp/education-and-outreach/about-research-participation/additional-resources/index.html) (scroll down to *Commonly Asked Questions Explained* and select "*What is Human Subjects Research?*").
- [ ] 2. Watch videos from the *About Research Participation (ARP)* series (www.hhs.gov/ohrp/education-and-outreach/about-research-participation/informational-videos/index.html) to learn:
    - The basics of medical research: *Part 1: What is Medical Research?*
    - How research is different from routine care: *How is Medical Research Different from Medical Care?*
    - Details of medical research: *Part 2: Deciding to Participate in Clinical Trials*
    - Other types of research: *Participating in Social and Behavioral Health Research*

Brief History of the Formation of Ethical and Regulatory Frameworks for Protecting Humans in Research

Learn about research ethics and the history of "why" and "how" the U.S. regulations were developed:

- [ ] 1. Review the set of infographics *Protecting Research Volunteers* (www.hhs.gov/ohrp/education-and-outreach/about-research-participation/protecting-research-volunteers/index.html) to get an overview of the Federal system of protections. These provide an easy-to-follow introduction to human subjects' research protections that covers topics such as why we have regulations to protect human research participants and the framework for protecting human research participants in the U.S.
- [ ] 2. Watch the video *Evolving Concern: Protection for Human Subjects* (www.youtube.com/watch?v=_8Ku4b1fW18) to understand the historical events that provoked public concerns and led to the development of regulations and policies to protect human research participants in the U.S.
- [ ] 3. Review the *Belmont Report* (www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html), which provides the ethical foundation for protecting human research subjects in the U.S. The Report lists and explains three principles (respect for persons, beneficence, and justice) that act almost as a "Bill of Rights" for human research participants. Following these tenets helps ensure ethical research.

Understanding the Framework of the Federal Regulations for Human Research Protections and IRB Review of Research

Explore how to protect human research participants through application of the federal regulations, particularly the Common Rule:

- [ ] 1. OHRP's *Human Research Protection Foundational Training* (www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/human-research-protection-foundational-training/index.html). Complete this five-lesson training for an overview of the regulatory framework to protect human research participants in research funded by the U.S. Department of Health and Human Services (HHS) and most other Federal departments and agencies. This training explains what the federal regulations are, how they apply, and who bears the responsibility for protecting research participants.

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2. Watch short videos (http://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html) explaining the 2018 version of the Common Rule, its applicability, and what changes were made to the "old" version of the Common Rule.
3. Review the regulations at 45 CFR 46 (http://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html) including the Common Rule in subpart A.

Institutional Review Boards (IRBs) Basics, What Are They and What Do They Do?

Review the Common Rule requirements for IRBs operations:

1. *Institutional Review Boards* (www.youtube.com/watch?v=U8fme1boEbE) – This short video provides background on what an IRB is and the role it plays in protecting human research participants.
2. *Membership Requirements for Institutional Review Boards* (www.youtube.com/watch?v=sk5CXXLafQQ) – This short video explains the membership requirements for IRBs to facilitate appropriate representation for adequate and meaningful review of human research protections.
3. *Quorum and Voting in IRB Review Meetings* (www.youtube.com/watch?v=Lu3Nsl8dYYY) – This short tutorial explains the quorum requirement for IRB meetings and how members' attendance and votes are counted.
4. Watch video *Balancing Society's Mandates: IRB Review Criteria* (www.youtube.com/watch?v=Ec1BqLP7ZUQ) for a comprehensive perspective of the IRB review process.
5. Watch webinar *What Investigators Should Know about IRB Review* (www.youtube.com/watch?v=Mtf0K2Kpt-w&t=3060s) to better understand the IRB review criteria at 46.111.
6. Complete the OHRP *interactive training programs on IRB Considerations* (www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/considerations-for-reviewing-human-subjects-research/index.html) to consolidate your knowledge about IRB reviews.

Communicating with Participants through Informed Consent

Learn about the importance of respect for research participants, what constitutes informed consent, and what needs to be in a quality consent document:

1. Watch the *Informed Consent for Research: What to Expect* (www.hhs.gov/ohrp/education-and-outreach/about-research-participation/informational-videos/index.html) introductory video to understand the basics of informed consent.
2. Put yourself in the shoes of potential participants by watching the ARP video *Part 3: Questions to Ask Before Volunteering in Clinical Trials* (www.hhs.gov/ohrp/education-and-outreach/about-research-participation/informational-videos/index.html) and read the questions possible volunteers should ask (www.hhs.gov/ohrp/education-and-outreach/about-research-participation/questions-to-ask/index.html). A good, informed consent document would address many of these questions in plain language.
3. Learn what goes into a meaningful consent process by watching *Simplifying Informed Consent* (www.hhs.gov/ohrp/education-and-outreach/online-education/videos/informed-consent/index.html), which also includes practical examples (please note that this video is approximately 105 minutes).
4. Read some of the Frequently Asked Questions (FAQs) (www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html #informed-consent) about Informed Consent and watch *What's New in Informed Consent: Revisions to the Common Rule* (www.hhs.gov/ohrp/education-and-outreach/online-education/videos/informed-consent/index.html) to enhance your understanding of some of the recent changes to the regulations for consent.
5. Enrich your vocabulary and better understand the scientific terms in a consent document (or protocol) by browsing NIH's glossary of commonly used terms (www.hhs.gov/ohrp/education-and-outreach/about-research-participation/additional-resources/index.html), as necessary.