



| CHECKLIST-Required Training | | | |
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| NUMBER | VERSION | APPROVED BY | PAGE |
| HRP-422 | 6/12/19 | E. White/C. Hautala-Bateman | 1 of 3 |
| See HRP-001 for definitions of applicable key terms and acronyms. | | | |

The purpose of this checklist is to clarify DOE's expectations for training for those involved in the oversight or conduct of human subjects research. Demonstration of completion of initial and refresher CITI training and understanding of DOE-specific human subjects protection requirements.

Select one of the following groups which best represents your role/training needs.

Training requirements for each group are listed on page 2 of this checklist.

- Biomedical Researcher or Social-Behavioral Researcher**
Required training for all members of the research team who interact with human subjects in research or their identifiable data.
- IRB Member and Administrative Team**
Required training for all members and alternate members of the IRB and members of the Administrative Team
- IRB Chair and DOE Management Team**
Required training for IRB Chairs, Vice-Chairs, and the DOE Management Team including the DOE and NNSA Human Subjects Protection Managers.
- DOE Institutional Official**
Required training for DOE Institutional Officials.

Once training requirements have been met, select the applicable section below to demonstrate completion of initial or refresher training.

Training requirements are specified on page 2 of this checklist.

- Completed Initial Training (both must be checked)**
 - DOE Document Review
Completion Date:
 - CITI Training
Completion Date:
- Completed Refresher Training (both must be checked)**
All training requirements must be completed every three years.
 - DOE Document Review
Completion Date:
 - CITI Training
Completion Date:

Name:

Signature:

Date:

Provide a signed copy of this document and training certificates to the IRB to load in the IRB Electronic System.



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Biomedical Researcher
Social Behavioral Researcher
IRB Member and Administrative Team
IRB Chair and DOE Management Team
Institutional Official

| DOE Document Review | | | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|---|---|---|---|
| DOE requires that each of the below documents be reviewed by all individuals involved in the oversight or conduct of human subjects research. See the DOE Human Subjects Protection Program Website (https://science.osti.gov/ber/human-subjects) for access to these documents for review. | | | | | |
| HRP-101-GENERA-DOE Human Subjects Protection Program Plan | R | R | R | R | R |
| HRP-103-GENERAL-DOE Investigator Manual | R | R | R | R | R |
| DOE-specific requirements outlined in: 1) 10 CFR Part 745 2) DOE O 443.1C | R | R | R | R | R |
| CITI Training | | | | | |
| For more detail on the required and optional CITI modules, see: https://www.citiprogram.org/citidocuments/catalogs/HSR_Catalog.pdf | | | | | |
| Belmont Report and CITI Course Introduction (ID: 1127) | R | R | R | R | |
| Informed Consent (ID: 3) | R | R | | | |
| Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680) | R | R | R | R | |
| Conflicts of Interest in Research Involving Human Subjects (ID: 17464) | R | R | R | R | |
| History and Ethics of Human Subjects Research (ID: 498) | R | | | | |
| Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2) | R | | | | |



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| Defining Research with Human Subjects – SBE (ID:491) | | R | | | |
| Assessing Risk – SBE (ID: 503) | | R | | | |
| Privacy and Confidentiality – SBE (ID: 505) | | R | | | |
| The IRB Member Module – What Every New IRB Member Needs to Know (ID: 816) | | | R | R | |
| Informed Consent – (ID: 504) | | | R | R | |
| Privacy and Confidentiality – (ID: 505) | | | R | R | |
| The Federal Regulations – (ID: 502) | | | R | R | |
| History and Ethical Principles – (ID: 490) | | | R | R | |
| Roles and Responsibilities of an IRB Chair (ID:15386) | | | | R | |
| IRB Chair Meeting Responsibilities (ID:15387) | | | | R | |
| The IRB Chair’s Role Outside the IRB Meeting (ID:15388) | | | | R | |
| Introduction to Being an Institutional Official (ID: 16640) | | | | | R |
| IO Knowledge Requirements: Human Subjects Protections (ID: 16641) | | | | | R |
| Expectations of the IO (ID: 16642) | | | | | R |
| Challenges of Being an IO: Human Subjects Protections (ID: 16643) | | | | | R |

Note that the sponsor(s) may have additional specific training requirements (e.g., for some of the DOE-VA joint research, HIPAA training is required), and it is up to the PI to verify those requirements. Demonstration of completion of comparable training may be an acceptable alternative to CITI.