



Research Training Program (RTP)

GCP Training References / Clinical Trials Research Websites of Interest

[Declaration of Helsinki](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)

[The Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html)

[Good Clinical Practice (GCP) Guideline - Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf)

# [ICH Guidelines](https://www.ich.org/page/ich-guidelines)

# [45 CFR 46 - Protection of Human Subjects](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)

# 21 CFR- FDA Regulations

* [Part 11: Electronic Records; Electronic Signatures](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11)
* [Part 50: Protection of Human Subjects (Consent)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50)
* [Part 54: Financial Disclosure](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54)
* [Part 56: Institutional Review Boards](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56)
* [Part 312: Investigational New Drug Application](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312)
* [Part 600: Biological Products: General](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=600)
* [Part 812: Investigational Device Exemptions](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812)
* [Part 814: Premarket Approval of Medical Devices](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=814)

# [FDA Clinical Trial Forms](https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/clinical-trial-forms)

# [CenterWatch](https://www.centerwatch.com/)

# Books

# Weeks-Rowe, Elizabeth. *The PI’s Guide to Conducting Clinical Research.* 2nd ed., CenterWatch, 2019.

# Sather, Sandra. *The CRC’s Guide to Conducting Clinical Research*. 4th ed., CenterWatch, 2019.

# Weeks-Rowe, Elizabeth. *The CRC’s Guide to Monitoring Clinical Research.* 6th ed., CenterWatch, 2019.

# Chadwick, Gary, et al. Protecting Study Volunteers in Research: A Manual for Investigative Sites. 5th ed., CenterWatch, 2021.

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