NIMICT
NATIONAL INITIATIVE FOR MINORITY INVOLVEMENT IN NEUROLOGICAL CLINICAL TRIALS

Human Subjects Research

Regulations, Rules, and Research Oversight

Funding Source

Knowing the requirements of your funding source dictates the protocol and regulations.

US Department of Health and Human Services (DHHS)

National Institutes of Health (NIH)

Office of the Assistant Secretary for Health (ASH)

Food and Drug Administration (FDA)

NIH Institutes and Centers

Office for Human Subject Protection (OHRP)

45 CFR 46 subpart A: Basic HHS Policy for Protection of Human Research Subjects (The Common Rule)

45 CFR 46 subpart B: Protection for Pregnant Women, Human Fetuses & Neonates

45 CFR 46 subpart C: Protection for Prisoners

45 CFR 46 subpart D: Protection for Children

45 CFR 46 subpart E: Registration of IRBs

21 Code of Federal Regulations (CFR)

21 CFR 50: Protection of Human Subjects

21 CFR 54: Financial Disclosure

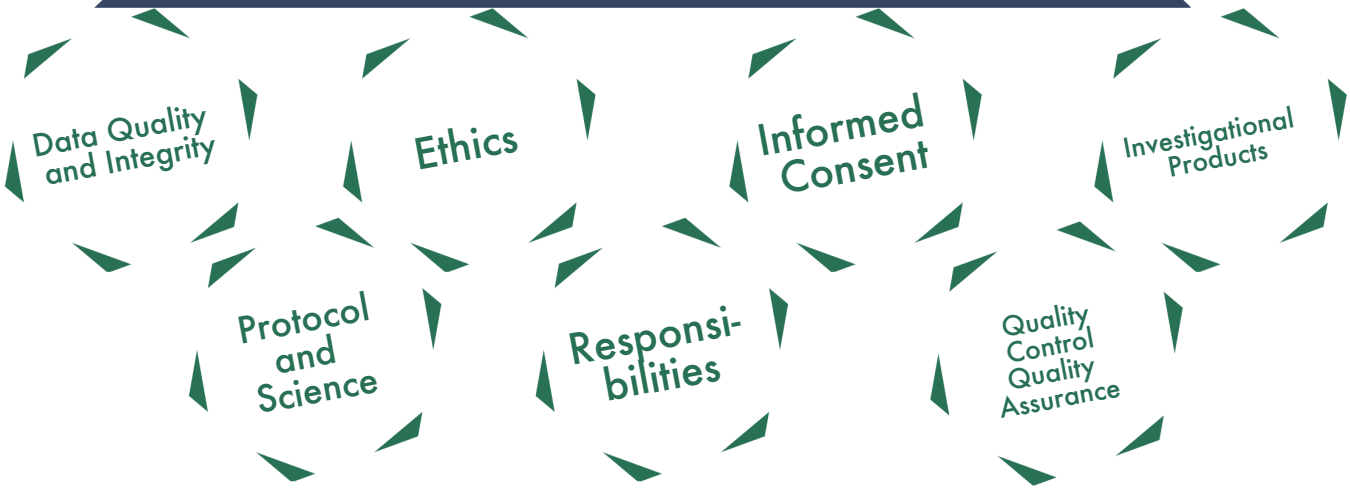
21 CFR 56: Institutional Review Boards

21 CFR 312: Investigational New Drug Application (IND)

21 CFR 803, 812: Devices

Per International Conference on Harmonization (ICH) E6, Good Clinical Practice is defined as an "...ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects".

7 key principles of ICH E6



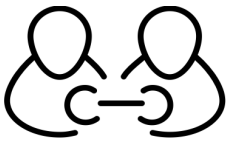
Good Clinical Practices Forms

Sponsor responsibilities

21 CFR 312 & 812

Investigator responsibilities

21 CFR 312 & 812 (IND & IDE)
FDA information sheets
Financial Disclosure – 21 CFR 54



Drug/Device quality standards

Drugs – 21 CFR 210 & 211
Biologics – 21 CFR 600 & 606
Tissue – 21 CFR 1271
Devices – 21 CFR 820

Protocol standards & requirements

Standards – 21 CFR 312 & 812
IRB review requirements – 21 CFR 56

Participant

Informed Consent – 21 CFR 50
Medical care – 21 CFR 312
Protection of human subjects 21 CFR 50; 45 CFR 46

Documentation

Essential & source documents – 21 CFR 312 & 812
Electronic records & signatures – 21 CFR 11

Safety reporting

To IRB – 21 CFR 56 & 812
To Sponsor – 21 CFR 312 & 812
To FDA – 21 CFR 312, 812, & 803
To manufacturer – 21 CFR 803

Monitoring (Quality Assurance & Quality Control)

21 CFR 312 & 812

Content adapted from Training Elements of Human Subjects Research Coordination CTSA Research Coordinator Taskforce Overview of the Regulatory Environment in Academic Health Centers Version 5/31/12