Following public outcry after the discovery of the Tuskegee Syphilis Study and complaints that the Nuremberg Code and Helsinki were difficult to interpret and inadequate to cover complex situations, the US Government drafted the National Research Act of 1974. This act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. They created the Belmont Report, which remains the basis for the US Department of Health and Human Services human subject protection regulations.

<u>3 Core Principles:</u>

1. Respect for Persons
   - Individuals should be treated as autonomous agents and vulnerable individuals should be protected
   - Autonomy through informed consent, voluntariness, and understanding
2. Beneficence
   - Maximize benefits and minimize risks
   - Do no harm
3. Justice
   - Individuals should receive fair and equal distribution of clinical research burdens
   - Selection of subjects is equitable

U.S. Department of Health and Human Services (DHHS) regulations based off the Belmont Report. The Office for Human Research Protections (OHRP) is responsible for the implementation of 45 CRF 46.

- Subpart A – The Common Rule – Fundamental guidelines for ethics of all human research; Governed IRBs
- Subpart B – Additional protections for research with pregnant women and fetuses
- Subpart C – Additional protections for research with prisoners
- Subpart D – Additional protections for research with children
- Subpart E – Requirements for IRB registration

International Conference on Harmonization Good Clinical Practice (ICH-GCP) was developed as an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involved the participation of human subjects. The goal was to facilitate the mutual acceptance of credible and ethical clinical trial data on an international level so that applications for marketing to various regulatory agencies around the wd e

End(e)7.ised b the FDA in 1997, ICHidelines aveleen adopted into law in several countries. Al.]T4.004 (o)-5 (u)2.998 (g)3.9
(GCP) and should be strictlyllwed.

<u>GCP training is requiD r for all pers 11.04998ons participating in NIH-nded or FDA 11.04998egula</u>ted clinical trials.