# Good Clinical Practice 101: An Introduction

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# **Objectives:**

Define Good Clinical Practice (GCP)
Outline the goals of GCP
Provide a historical perspective on GCP
Outline FDA regulations relating to GCP in medical device research

## What is Good Clinical Practice (GCP)?

GCP is defined as a standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials or studies





## Additional terms defined:

Clinical Investigation
Clinical Investigator
Human Subject
Institutional Review Board

# Why is GCP important?

 GCP compliance provides public assurance that the rights, safety and well-being of human subjects involved in research are protected



## What are the goals of GCP?

- To protect the rights, safety and welfare of humans participating in research
- To assure the quality, reliability and integrity of data collected
- To provide standards and guidelines for the conduct of clinical research
- Good Clinical Practice = Ethics + Quality Data

# What are the foundations for the ethical conduct of clinical research?

The Nuremberg Code (1947)

- The Declaration of Helsinki (1964)
- The Belmont Report (1979)
- International Conference on Harmonisation (ICH-GCP)
- International Standards Organization 14155
- Code of Federal Regulations

# **GCP: A Historical Perspective**

 Nuremberg Code (1947)

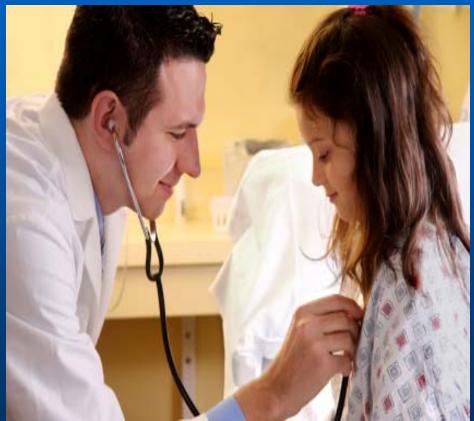
- Voluntary participation
- Informed Consent
- Minimization of risk



# **GCP: A Historical Perspective**

 Declaration of Helsinki (1964)

- Well-being of subject takes precedence
- Respect for persons
- Protection of subjects health and rights
- Special protection for vulnerable populations



# **GCP:** A Historical Perspective

 Belmont Report Ethical Principles (1979)

- Respect for Persons
  - Informed consent
  - Protection of vulnerable populations
- Beneficence
  - Non-malfeasance
- Justice
  - Fairness



## The International Conference on Harmonisation (ICH-GCP)

- GCP is an international quality standard that is provided by the International Conference on Harmonisation (ICH)
- Goals: Harmonize technical procedures and standards; improve quality; speed time to market
- In 1997, the FDA endorsed the GCP Guidelines developed by ICH
- ICH guidelines have been adopted into law in several countries, but used as guidance for the FDA in the form of GCP

### What are the 13 principles of ICH-GCP?

#### Ethics:

- 1. Ethical conduct of clinical trials
- 2. Benefits justify risks
- 3. Rights, safety, and well-being of subjects prevail

#### Protocol and science:

- 4. Nonclinical and clinical information supports the trial
- Compliance with a scientifically sound, detailed protocol

## What are the 13 principles of ICH-GCP? (cont.)

Responsibilities: 6. IRB/IEC approval prior to initiation 7. Medical care/decisions by qualified physician 8. Each individual is qualified (education, training, experience) to perform his/her tasks Informed Consent: 9. Freely given from every subject prior to participation

## What are the 13 principles of ICH-GCP? (cont.)

Data quality and integrity:

- 10. Accurate reporting, interpretation, and verification
- 11. Protects confidentiality of records
- Investigational Products
  - 12. Conform to GMP's and used per protocol
- Quality Control/Quality Assurance
  - Systems with procedures to ensure quality of every aspect of the trial

## A Comparison

#### **DECLARATION OF HELSINKI:**

Ethical principles
 e.g. ethical and scientific

- Focus: Physicians in research
- World Medical Assembly-International medical societies
- Guidance with broad recommendations

ICH-GCP:

- Broader principles e.g. ethical, scientific & operational for designing, conducting, reporting & recording trials
- Focus: Drug sponsors, investigators & IRB
- Representatives from industry and public health
- Guidance document but has the effect of law when put into Regulation

## International Standards Organization

ISO 14155: Clinical Investigation of Medical Devices for Human Subjects - Assists sponsors, monitors, and clinical investigators in the design and conduct of device clinical investigations Assists regulatory bodies and ethics committees in their roles of reviewing clinical investigational plans

## What constitutes Good Clinical Practice in device research?

- IRB-approved protocol
- Valid Informed Consent
- Monitoring Plan

- Adverse Device Effect Reporting [Adverse Event (AE) or Serious Adverse Event (SAE)]
- Proper documentation
- Valid data collection/reporting procedures

# Who is responsible for GCP compliance?

Sponsors

- Clinical Investigators (CIs)
- Independent Ethics Committees (IECs)
   Institutional Review Boards (IRBs)
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- Contract Research Organizations (CROs)
- Research nurses
- Clinical Research Coordinators (CRCs)
- Clinical Research Associates (CRAs)
- Medical monitors
- Data entry personnel
- Others

## How does FDA implement GCP?

• 21 CFR 11 – Electronic Records & Signatures <u>21 CFR 50 – Protection of Human Subjects</u> • 21 CFR 54 – Financial Disclosure • 21 CFR 56 – Institutional Review Boards • 21 CFR 812 – Investigational Device Exemptions 21 CFR 814 – Premarket Approval of Medical Devices

# Summary:

Defined Good Clinical Practice (GCP)
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## For further information:

## FDA Good Clinical Practice Regulations & ICH Guidance

http://www.fda.gov