Ethical Considerations in Research and Clinical Trials

Ethical Considerations in Research and Clinical Trials

1. Introduction

- Research involving human subjects must balance scientific advancement with protection of participants.
- Ethical frameworks arose from historical abuses, leading to codes like the Nuremberg Code and the Declaration of Helsinki.

2. Core Principles (Belmont Report)

- **Respect for persons:** informed, voluntary consent and protection of vulnerable groups.
- **Beneficence:** maximize benefits and minimize harms.
- **Justice:** fair selection of subjects and equitable distribution of risks and benefits.

3. Informed Consent

- Participants must understand purpose, procedures, risks, benefits, and the right to withdraw.
- Consent must be voluntary and free of coercion or undue inducement.

4. Oversight and Safeguards

- **IRB/Ethics committee:** reviews and approves study protocols.
- Privacy, confidentiality, and secure data handling must be ensured.
- Use of placebos and randomization must be ethically justified.

5. Contemporary Issues

- Conflicts of interest and transparent reporting of results.
- Research in low-resource settings and equitable access to benefits.