

Research with Human Subjects

Helsinki Declaration

World Medical Association

- ✍ Adopted 1964, amended through 2000
- ✍ Purpose was to provide guidance on research involving human subjects, including identifiable human data and materials
- ✍ Duty of the physician to protect/promote the health of the people
 - Well being of people has priority over science
- ✍ Recognize there are some risks inherent in all procedures- therapeutic, diagnostic, prophylactic
- ✍ Vulnerable populations need special protection
 - Economic or medically disadvantaged
 - Unable to give consent/refuse
 - Enlisted under duress
 - Research is linked to care
- ✍ All should be familiar with the ethical, legal, and regulatory requirements of their nation and international rules
- ✍ Protect life, dignity, and confidentiality of patients
- ✍ Protocols must be approved
- ✍ Protocols must have strong scientific rationale
- ✍ Experiments must be stopped if they appear to be harmful – especially consider risk for healthy volunteers
- ✍ Researchers must be scientifically qualified and someone involved must be clinically qualified
- ✍ Study design must be public record
- ✍ Researchers must report findings ethically
- ✍ To consent, subject must be aware of
 - Aims
 - Methods
 - Funding sources
 - Risks
 - Potential benefits
 - Conflicts of interest
 - Right to withdraw from study at any time