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
  o 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
  o Economic or medically disadvantaged
  o Unable to give consent/refuse
  o Enlisted under duress
  o 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
  o Aims
  o Methods
  o Funding sources
  o Risks
  o Potential benefits
  o Conflicts of interest
  o Right to withdraw from study at any time