WMA
Declaration of Helsinki

Ethical Principles for Medical Research
Involving Humans Subjects

WMA

- Represents over 8 million doctors
- 85 National Medical Associations
- Non political
- A free open forum for the discussion of matters related to medical ethics, medical education, socio-medical affairs and medical topics generally

WMA - brief history

- 1945, informal conference in London
- 1947, first General Assembly in Paris,
- 1948, Declaration of Geneva, “oath”
- 1949, International Code of Medical Ethics
- 1952, Committee on Medical Ethics
- 2005, WMA Medical Ethics Manual

DoH – Brief History

- Adopted 1964
- Significant additions 1975
- Minor amendments 1983, 1989 and 1996
- Major revision 2000
- ‘Notes of clarification’ 2002 and 2004
- Minor revision 2008

DoH

- Addressed to physicians
- Well-being of the individual
- Purpose of medical research
- Ethical standards
- Legal and regulatory norms and standards

Duty of the physician

- Protect the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of research subject

Research protocol

- Study design and performance
- Ethical considerations
- How the DoH has been addressed
- Funding, affiliations, conflicts of interest
- Post-study arrangements

Research ethics committee

- Consider the protocol before the study begins
- Independent of the researcher
- Consider laws and regulations
- Consider DoH
- Monitor ongoing studies

Database

- Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject

The researcher

- Appropriate training and qualification
- Supervision of a qualified physician
- Responsible for protection of the subject
- Adequately assess risks
- Immediately stop a study

The subject

- Voluntary participation
- Privacy must be protected
- Confidentiality of personal information
- Informed of aims, benefits and risks
- Right to withdraw
- Freely given informed consent

Publication

- Publication of results
- Accuracy of reports
- Guidelines for ethical reporting
- Conflicts of interest

Placebo

- Where no proven intervention exist
- Necessary to determine efficacy/safety
- No risk of serious/irreversible harm
- Avoid abuse

Post study arrangement

- Information about the outcome
- Share any benefits
- Access to interventions identified or other appropriate care