



UC DAVIS OFFICE OF RESEARCH

# Declaration of Helsinki

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# Introduction

- ❖ Is an international standard for the conduct of clinical research adopted by International Conference on Harmonization(ICH) Good Clinical Practice standards.
- ❖ A global ethical standard for medical research and was approved at the WMA General Assembly by a majority vote of 75%.
- ❖ It is the mission of the clinical research professionals to safeguard the health of the people.

# Historical Overview

- ❖ Prior to 1947 Nuremberg Code, there was no accepted code of conduct governing the ethical aspects of human research.
- ❖ The Declaration more specifically addressed clinical research, reflecting changes in medical practice from the term “Human Experimentation” used in the Nuremberg Code
- ❖ Has undergone six modifications.

# World Medical Association (WMA)

- ❖ It is an international organization of physicians was first established on **September 17, 1947**.
- ❖ First general Assembly of WMA was held in Paris, France.
- ❖ **Mission:-** Serve humanity by endeavoring to achieve the highest international standards in medical education, science, ethics and health care for all peoples of the world.

# Declaration of Helsinki

World Medical Association declaration of Helsinki-2008

(Ethical principles for Medical Research Involving Human subjects)

- ❖ Introduction (Articles 01-10)
- ❖ Principles For All Medical Research (Articles 11-30)
- ❖ Additional Principles For Medical Research Combined With  
Medical Care (Articles 31-35)

# Declaration of Helsinki: Basic Principles

1. Conform to accepted scientific principles.
2. Design formulated in experimental protocol, reviewed by IEC.
3. Conducted by qualified and trained persons.
4. Importance in proportion to inherent risk.
5. Assessment of risks vs. benefits.
6. Safeguard subject's integrity (privacy).
7. Abstain unless hazards are predictable.
8. Preserve accuracy when publishing.
9. Adequately inform or right to withdraw.
10. Obtain true informed consent in writing.
11. Reliance on legal guardian.
12. State compliance with Declaration.

# Declaration of Helsinki: Today

- ❖ Is not a legally binding instrument in international law, but instead draws its authority from the degree to which it has been codified in, or influenced, national and regional legislation and regulations.
- ❖ US FDA rejected the 2000 and subsequent revisions, only recognizing the third (1989) revision, and in 2006 announced it would eliminate all reference to the Declaration.
  - ❖ A final rule was issued on April 28, 2008 replacing the Declaration of Helsinki with Good Clinical Practice effective October 2008.
- ❖ NIH no longer refers to the Declaration of Helsinki

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