



EXPERT CONFERENCE ON THE REVISION OF DECLARATION OF HELSINKI

**IMPERIAL HOTEL, TOKYO
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DECLARATION OF HELSINKI

RESOURCE POOR SETTING

&

“POST STUDY ARRANGEMENT”

BY

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Introduction

I would like to thank the WMA Organizing Committee for allowing me this opportunity to share my insights on the need to revise the Declaration of Helsinki.

The advancement of technology in the practice of medicine has already provided cure to some diseases. This advancement of technology, however, has equally unlocked the vault of problems that pose challenges for medical practitioners. These challenges take the form of serious ethical issues which are now brought into the open by several sectors of the community.

It used to be that the innovative medicines are first tested on animals before they are tested on humans. Now, it's the other way around because it is the stem cells of animals that are now tested on humans. This is the era of stem cell therapy. Genetic engineering was first applied with the intention of improving yield for plants, but now genetic manipulation is equally applied to humans.

What are the risks in these so called medical advancement that were not existing before and more importantly what are the new breakthrough of hope of cure that these new trends in the treatment of disease can really offer? In my country alone there is right and left employment of the use of stem cell procedures. Even those in the non-medical field are involved in the treatment with use of stem cells. Even some doctors, sad to say, are themselves injecting stem cells into their veins in the hope of achieving eternal youth!

Are we to ignore the fiction movie entitled “X-MEN”. But of course the world will be lucky if the result of the medical advancement are the Avengers! We must remember that the fiction of yesterday has become the realities of today. Are these new trends or situation covered by the Declaration of Helsinki?

Thus, I join the WMA in its serious intention to revise the Declaration of Helsinki and make it more responsive to the latest developments in the practice of medicine. There must be a re-defining of what is safe practice of medicine in the light of all these new medical development. More importantly, the right of the patient must be reinforced with these so called new scientific breakthrough. Medical practitioner must be involved with fresh ethical principles in their effort to cure the illnesses of their patients.

Let me walk you through a short history of the Revision of Declaration of Helsinki and its perspective.

WMA DECLARATION OF HELSINKI

- ❖ History
- ❖ Relevance
- ❖ Future

DECLARATION OF HELSINKI (Past, Present & Future)

The Declaration of Helsinki was adopted year 1964 on the 18th WMA General Assembly in Helsinki, Finland and underwent several revisions. It is the supreme declaration pertaining to international ethical standard in human medical research. History would reveal that after its first major revision done in Tokyo in 1975 and series of revision done in Italy, Hong Kong, South Africa, Edinburgh and Seoul, South Korea. We are now in the process of doing the 8TH Revision of the Declaration.

WMA DECLARATION OF HELSINKI

Adopted by the 18th WMA General assembly; Helsinki, Finland; June, 1964 and amended by the:

29th WMA General Assembly Tokyo, Japan; Oct., 1975

35th WMA General Assembly; Venice, Italy; Oct., 1983

41st WMA General Assembly; Hong Kong; Sept., 1989

48th WMA General Assembly; South Africa; Oct., 1996

52nd WMA General Assembly; Edinburgh, Scotland; Oct. 2000

53rd WMA General Assembly; Washington 2002

55th WMA General Assembly; Tokyo 2004

59th WMA General Assembly; Seoul, South Korea; Oct. 2008

DECLARATION OF HELSINKI

ISSUES

- ❖ Resource Poor Setting
- ❖ Post Study Arrangement
- ❖ Informed Consent
- ❖ Use of Placebo

DECLARATION OF HELSINKI (Resource Poor Setting)

ARTICLE 9

“Medical Research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and needs special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.”

In a resource poor setting, extra caution must be taken in the selection of human subjects, making sure that the subjects do not give their consent because of economic duress.

DECLARATION OF HELSINKI (Resource Poor Setting)

ARTICLE 13

“Appropriate caution must be exercised in the conduct of medical research that may harm the environment.”

In a resource poor setting, a research finding organization must also provide appropriate funding for the disposal of the research drugs or materials.

DECLARATION OF HELSINKI (Resource Poor Setting)

ARTICLE 15

The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be

In a resource poor setting, wherein there is no research, ethics committee in the physician's institution, the physician must seek approval from other institution where there are research ethics committee, whether private or government.

DECLARATION OF HELSINKI (POST STUDY ARRANGEMENT)

- ❖ Patient access to best proven prophylactic, diagnostic and therapeutic method identified by the study?
- ❖ What happens to patient once study is over?
- ❖ Who owes to whom and why?
- ❖ Patient compensation for research related injury?
- ❖ Patient access to result of research subject?
- ❖ Which way the result of clinical treatment, shall be reported? (Internet, Private or Public Publication and International Society or PROCTOR)
- ❖ How they must be used for developing clinical standard for medical care?

ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

“36 No mode of treatment that has no proven safety and efficacy, or when it is publicly known to be of no benefit or doubtful benefit, shall be employed and where the adverse results of the intended mode of treatment are irreversible and unpredictable.” (Dr. Jose Asa Sabili), Philippine Medical Association Declaration of Helsinki 2013, Tokyo, Japan

At this point, let me quote from a dear friend Dr. Bu Castro, a doctor lawyer President of the Philippine Hospital Association and Past President of the Philippine Medical Association when he says,



**“ In medical research, we treat not the
present but the future...
but we must likewise protect the future
by protecting the present.”**



**THANK YOU SO MUCH,
I LOVE YOU ALL!!!**