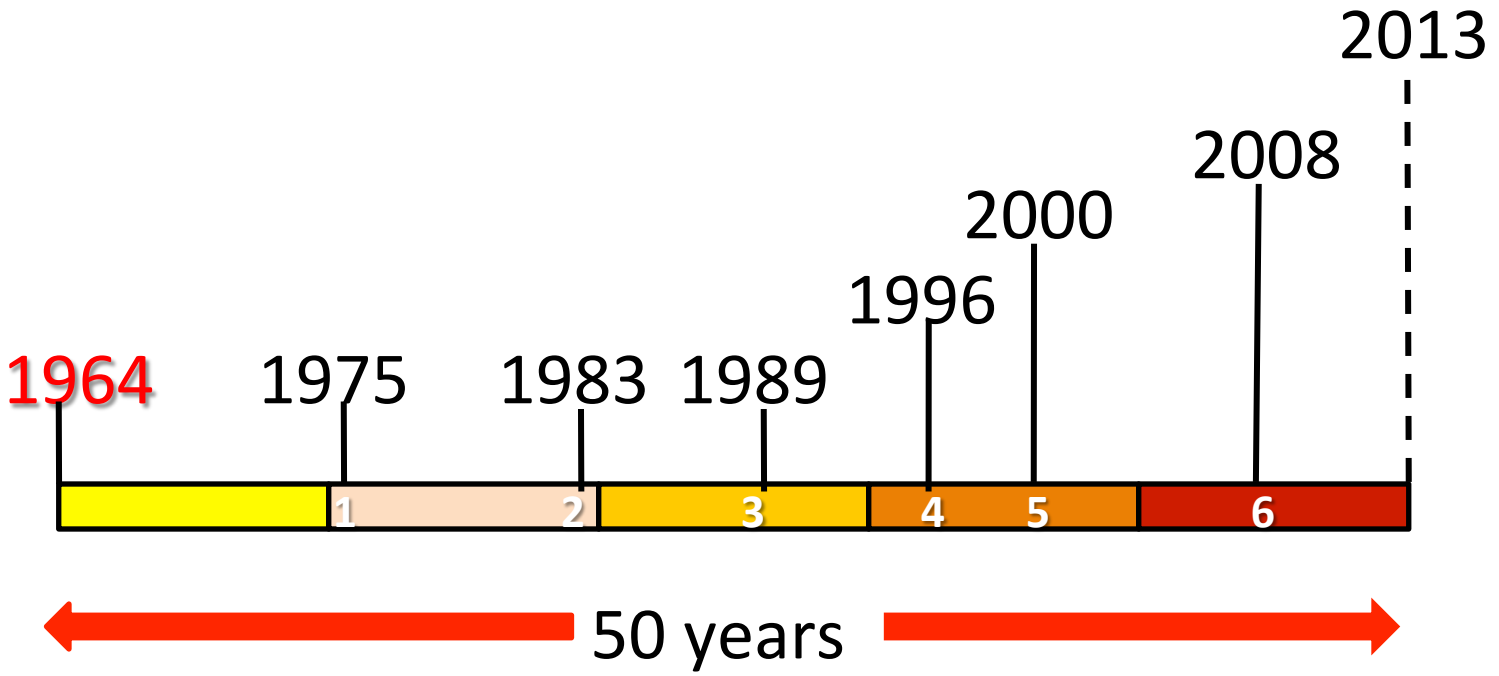
แพทยสมาคมแห่งประเทศไทย ในพระบรมราชูปถัมภ์
The Medical Association of Thailand

Resource poor settings / Post-study arrangements: Thailand's experience

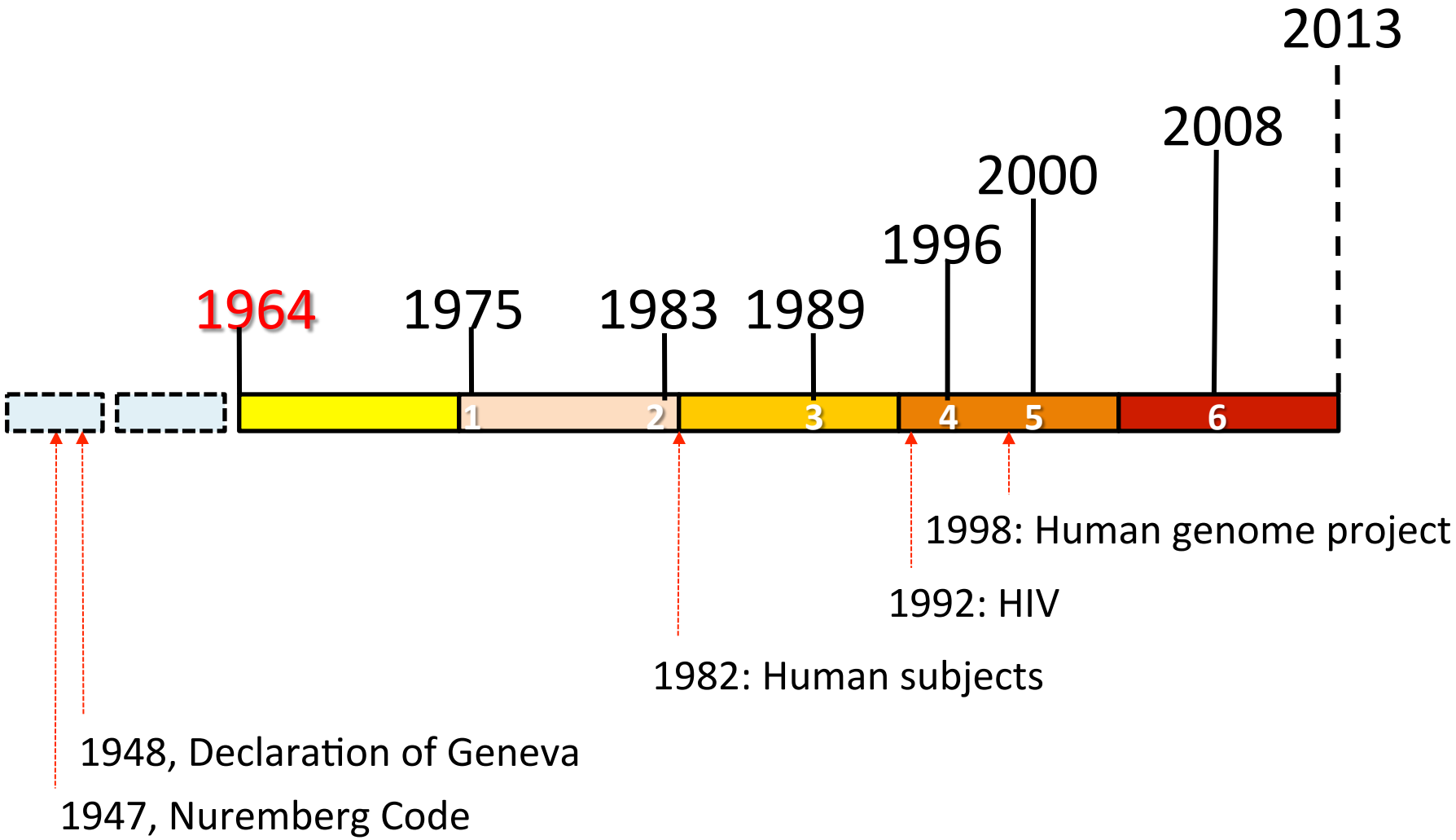
Expert Conference on Revision of Declaration of Helsinki
Tokyo, Japan. On March 1, 2013

Professor Somkiat Wattanasirichaigoon, MD, FRCST
Chairman, Medical Education Section,
Medical Association of Thailand

Revision of Declaration of Helsinki



Revision of Declaration of Helsinki

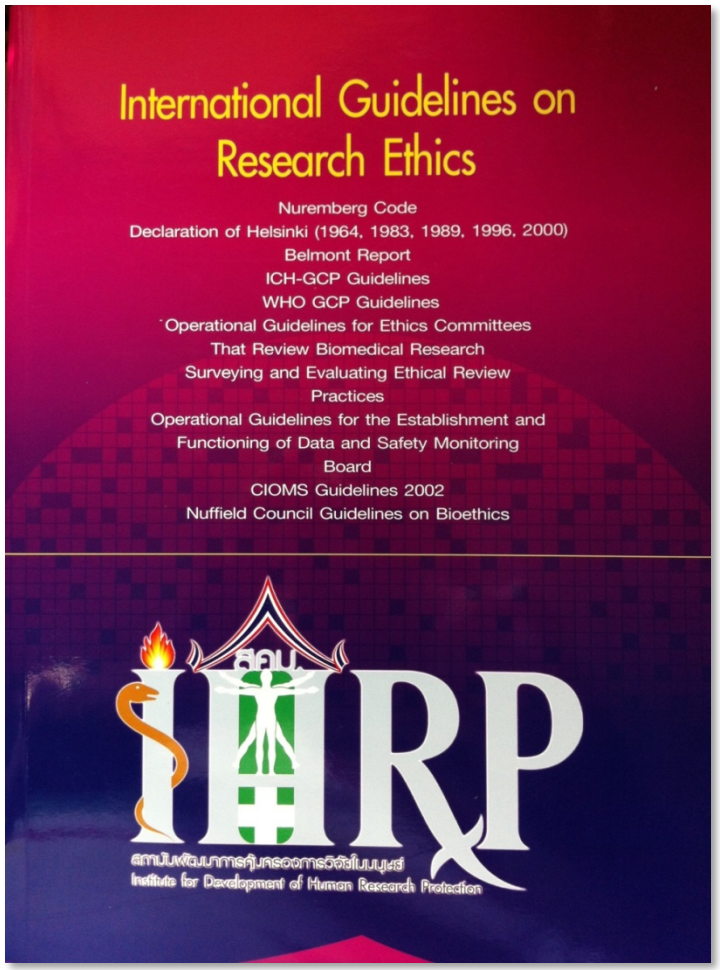


The National Bioethics Advisory Commission; NBAC

Executive Branch
Departments / Agencies

All Federal Government's work

Scientific Research and
Biomedical Regulation and Policy



Health System Research Institute (HSRI)

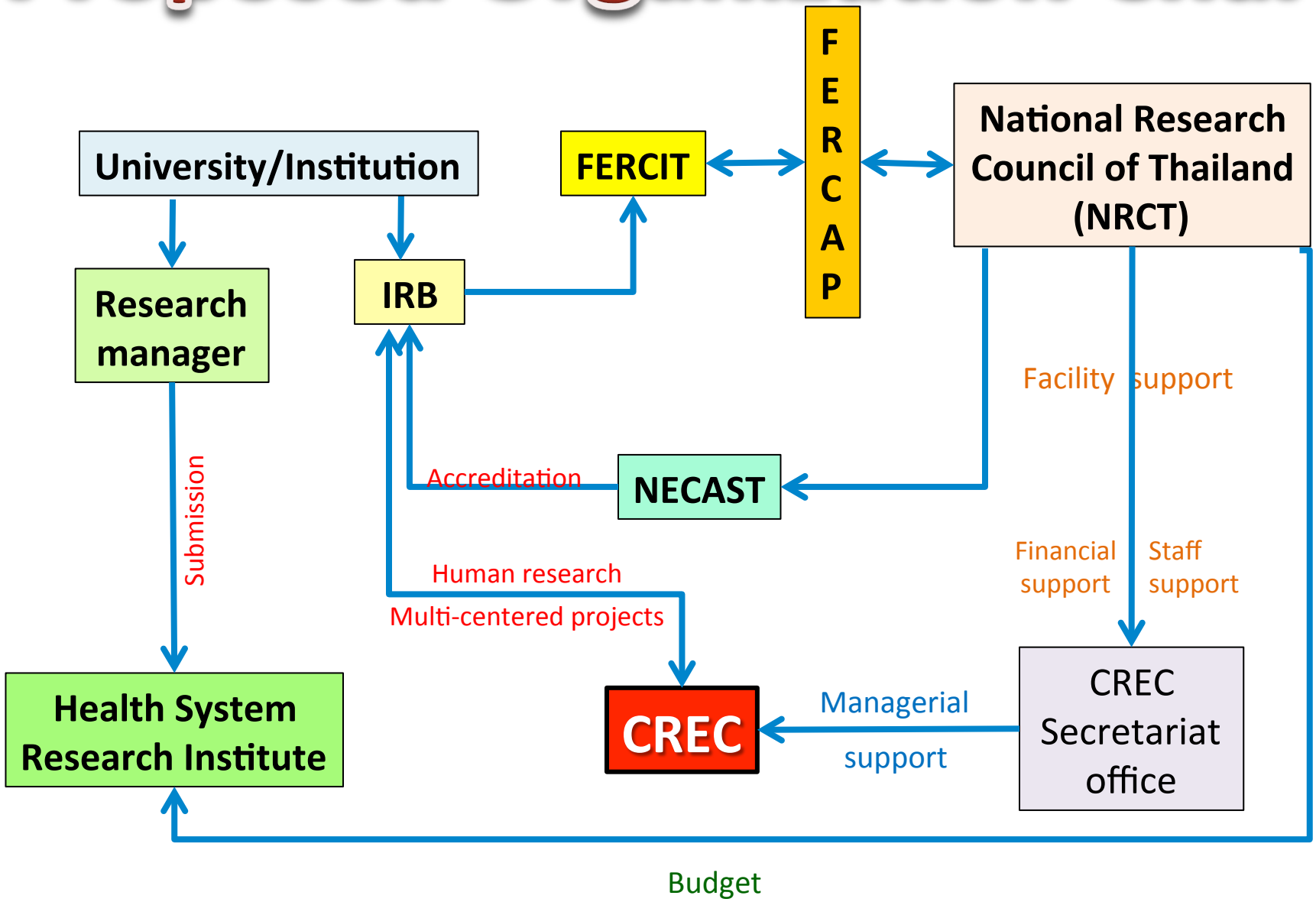
Institute for Development of Human Research Protection (IHRP)

Forum for Ethical Review Committee in Thailand (FERCIT)

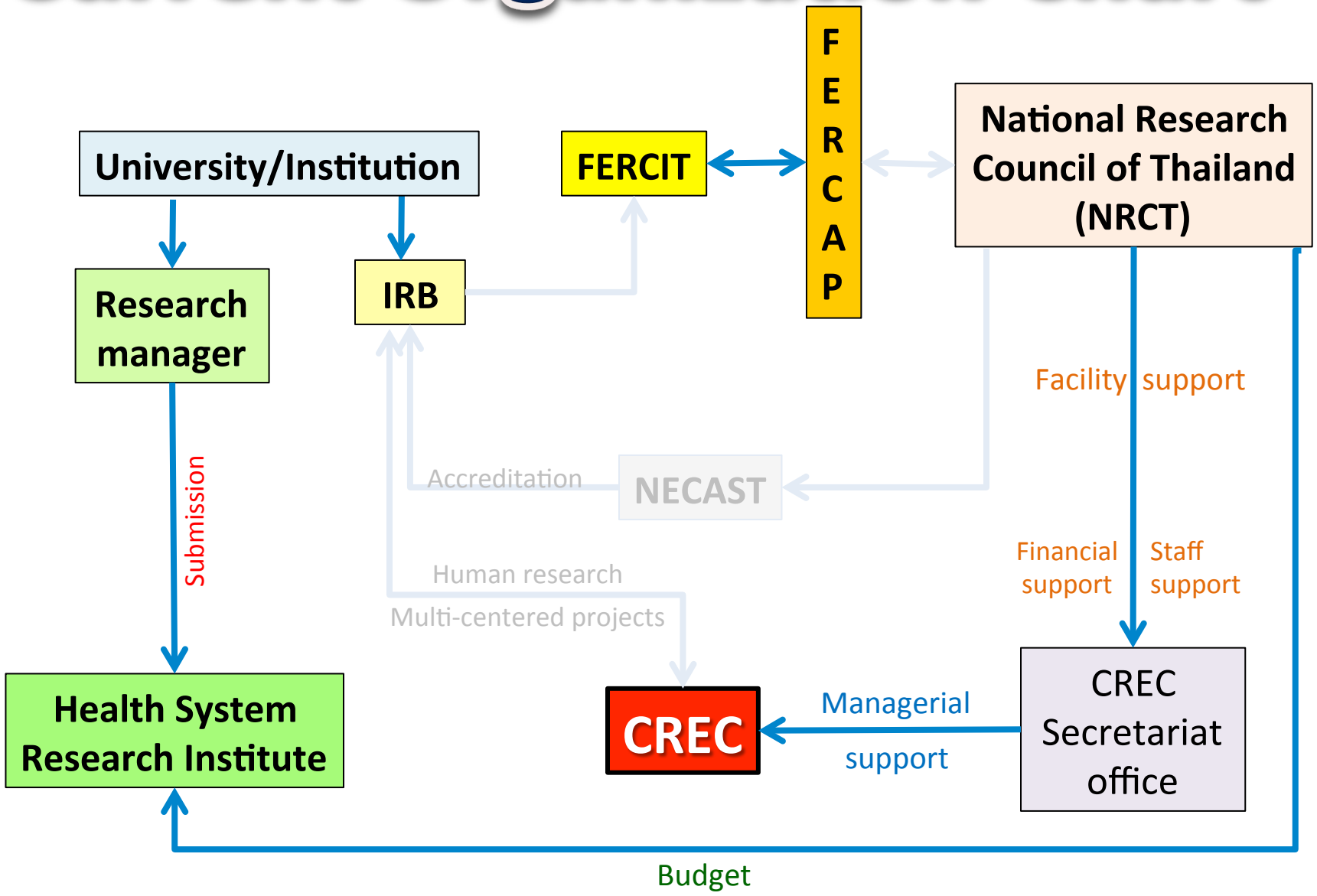
Established in 2001

http://www.fercit.org

Proposed Organization Chart



Current Organization Chart

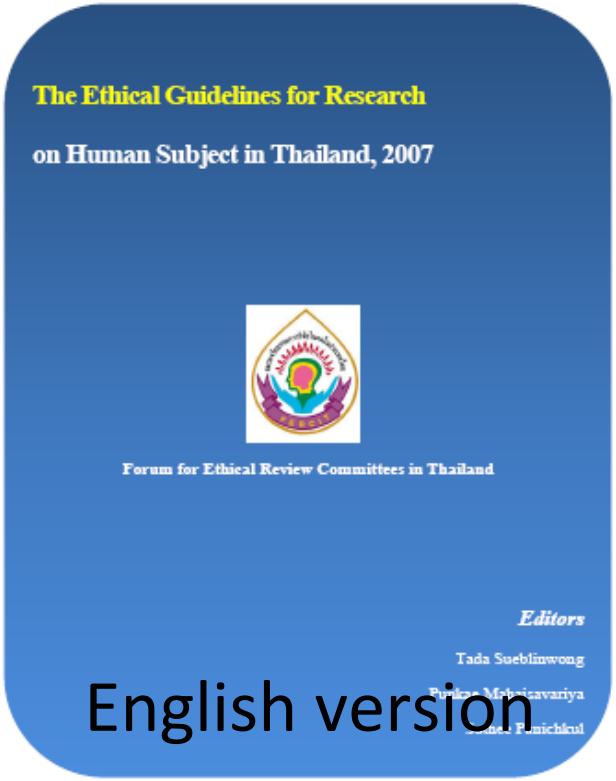


BASIC FACT: THAILAND

- No National IRB established
- No legal National Bioethic Advisory Committee (NBAC)
- There is a well-recognized human ethics association, Forum for Ethical Research Committee in Thailand (FERCIT)
- FERCIT: Ethical practice guidelines

FERCIT: The Ethical Guidelines for Research on Human Subject in Thailand, 2007

Thai version



English version

adapted from the revised edition of the National Guidelines for Ethical Research on Human Subject, 2002

Current Situation in Thailand

- 24 Institutional Review Boards (IRBs): 14 Medical schools and 10 Medical centers.
- Multi-institutional Review Board
  1. Central Research Ethics Committee (CREC), sponsored by National Research Council of Thailand
  2. Ministry of Public Health
  3. Thai Medical Council (only stem cell research project)

17

FERCIT: Research studies in vulnerable subjects

- *"…… including those who in need to depend on others, and are unable to express their opinion freely or to make their own decisions.*
  - *Hospitalized patients, prisoners, children, the mentally impaired, critically ill patients, psychotic patients, pregnant woman, and the economically disadvantaged."*

Questionnaires to 14 IRBs

We provided space for open-ended answers responsible to the following questions:

1. Changes in some parts of DoH.
2. Post-study arrangements
3. Best *vs* Optimal treatments

   (To confirm Item No. 1)

Q1. Changes in some parts of DoH.

2008 Version	Proposal	Commentary
The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstance	The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention, except in the following circumstance	We suggest to remove "current" because it is difficult to precisely define what it means (a period of time, and if so what?)
The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists: or Where for compelling and scientifically sound methodological reasons, the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subjected to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.	Where for compelling and scientifically sound methodological reasons, the use of any intervention less effective than the best proven one, placebo or no treatment is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no treatment, will not be subjected to additional risks of serious or irreversible harm. The use of any intervention less effective than the best proven one, placebo, or no treatment, is acceptable in studies where both conditions above apply and research is necessary to develop a treatment option adapted to local health care resources and health priorities	"any" should be deleted and "additional" should be added, because "risk of serious or irreversible harm" is unavoidable in some cases of clinical research regardless of question of placebo control However, we have allowed biomedical research to test an intervention in resource poor setting countries. It is limited to cases where there are scientifically sound methodological reasons to do so, where there would be no additional risk of serious or irreversible harm. These criteria would not be fit for resource rich countries.

Q2

Clinical trial Phase III

Drug A *vs* Placebo

Drug "A" is more effectively than placebo.

In regards to post-study arrangement, which of the following did your IRB likely opt to do?

a) No further suggestion.
b) Suggest a negotiation of free drug "A" to both treatment and control groups for a certain period of time.
c) Suggest a negotiation of free drug "A" only to the treatment group for a certain period of time.

Q2. Post-study arrangements → Most - agree

Even though we have no SOP which states the practice of Post-study arrangements.

Q2: Post-study arrangements

FERCIT: Principle of Justice

"Principle of distributive justice can also be applied at community and country levels."

- A common problem examples: *"the trial are conducted in developing countries, but after the end of the trials, drugs or vaccines or medical devices under the studied cannot be made beneficial to the participating populations or countries" due to their high cost or lack of disease/illness for such drugs or vaccines in those communities in developing countries"*

- *"Thus, the principle must be carefully and thoroughly considered to bring justice to all levels from the individuals to the society."*

Q3

Disease "B" → Bone marrow transplantation → CURE + 50% Death rate

Disease "B" → Life-long treatment with expensive drug → Not CURE → No mortality

New Protocol

Disease "B"

One -year treatment with expensive drug

Better condition → Bone marrow transplantation → CURE + 10% Death rate

Yes or No

Results: 9/14 Medical schools

	IRB	1	2	3	4	5	6	7	8	9
Question No.	1. Changes in some parts of DoH.	√	√	NA	X	NA	NA	NA	√	X
	2. Post-study arrangements	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.1
	3. Best *vs* Optimal treatments	√	√	√	√	√	√	√	√	√

→ 1/3 - yes

→ 8/9 - 2.2

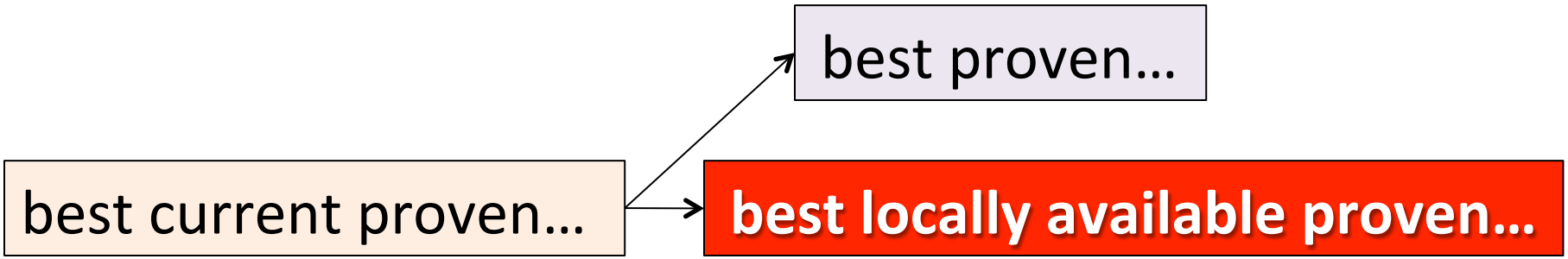
→ All - yes

Q3. Best *vs* Optimal treatments → All - agree

FERCIT: PLACEBO-CONTROLLED TRIAL

"It is generally unacceptable to use placebo in a control group in a trial where standard treatments or medically proven medicines are available, because patients will loose medical benefit entitled from participating in the clinical trial. However, the use of a placebo in a control group may be allowed in the following cases.

(1) no standard drug medically recognized for the treatment of the disease is available"




Thank you for your a