Priorities of the National Programme for Research & Technology

- Food and Agriculture
- Energy (biofuel & alternative energy)
- Transportation (land, sea and air)
- Information technology & Telecommunication
- Pharmaceuticals (incl. biologicals) and Health
- Biotechnology

(National Five Year Plan 2009-2014)
Subsystems of National Health System

- Health Delivery System
- Health Research and Development
- Health Financing
- Health Human Resources
- Supply of Pharmaceuticals, Medical equipment & Food
- Management information and Regulation
- Community Empowerment
Objectives of Health Research & Development

To obtain information, technology and products for health development and increase the health status & quality of life of the population

(Law No.36/2009 on Health)
Institutions conducting Health Research & Development

- Universities and its research centres
- Research/R&D Institutions
- Health facilities / hospitals
- Corporations
- Private foundations
- Other institutions
Health R & D Networks

- National Committee of Health R&D Network established by the Minister of Health
- National Research Council (has Section on Health & Food) established by the Minister of Research & Technology
- Health Technology Consortium (for development of vaccines and drugs) established by the Minister of Research & Technology
- Consortium for Basic Health Surveys (Ministry of Health and Statistics Indonesia)
- Consortium for Influenza & other Emerging Infections (MOH, WHO, US-CDC)
Indonesian Association of Health Researchers (APKESI)

- Prepared an Ethical Code for Health Researchers in 2012, consisting of 30 articles
- Several articles refer to the protection of human subjects in research, e.g. the requirement to respect the rights and dignity of subjects, priority for safety and welfare of subjects, give proper inducement/compensation for participation in research, obtain informed consent, approval from an ethics committee, feedback of the research results to subjects/communities
Section Four on Technology and technological products for health has four articles and two are related to the protection of human subject in research.

Article 44 stipulates that human subjects involved in research should be based on three basic ethical principles, namely respect for persons, beneficence, and justice. The health and safety of human subjects should be safeguarded and informed consent should be obtained.

The use of human subjects in research should be further regulated by a Government Regulation.

The Minister of Health is responsible for the protection human subjects in research.
This Government Regulation (based on Law No. 23/1992 on Health) has 22 articles related with informed consent, the sending of biological specimens abroad, international collaboration in research, confidentiality, the use of vulnerable populations (children, pregnant women, psychiatric patients, mentally retarded persons, etc), compensation for injury, disability and death caused by faults or negligence of researchers, the use of animals before trials in humans, etc.

This Government Regulation will be amended to conform with Law No. 36/2009 on Health
The Commission has been established by the Minister of Health in 2002 and has the following tasks:

1. Promote ethics in health research
2. Develop capacity in ethical review
3. Prepare national guidelines for ethics in health research
4. Develop networking of ethics committees
5. Conduct discussions and consultations on ethics of health research
6. Give an opinion on research which require special ethical consideration
7. Submit annual reports to the Minister of Health

The Commission has 25 members representing disciplines of medicine, philosophy, ethics, law, biology, veterinary science, environmental science, nursing, public health, social science/journalism.
There are at present 52 institutional ethics committees: 24 in medical schools, 4 in dental schools, 1 in school of public health, 6 in poly-technical colleges (for training of paramedical personnel), 8 in research institutions, and 9 in teaching hospitals.

A total of 6 ethics committees have been recognized by FERCAP.

It is planned that national accreditation system will be in place in 2015.
The National Guidelines was prepared by the National Commission in 2003 and was put into effect by a Decree of the Minister of Health: requiring all researchers to follow the guidelines.

Several Supplements to the National Ethical Guidelines have been published: Use of Animals in Research, Use of Archived Biological Materials, Ethics of Epidemiological Research, Genetics Research, Stem Cell Research.

In the latest edition of the National Guidelines of 2011 all these supplements have been incorporated into one book.

The National Commission has also published a Textbook on Ethics in Health Research to be used in teaching at the undergraduate as well as postgraduate level of health professions.
This Guideline, based on the ICH-GCP was prepared by the Clinical Trial Working Group established by the National Agency of Drug and Food Control.

All pre-marketing clinical trials requires approval from the NADFC.

Before submitting to NADFC, the protocol should have been approved by an Ethics Committee which has reviewed the protocol ethically as well as scientifically. If there is a Scientific Committee, the scientific review can be done by the Scientific Committee.

Post-marketing clinical trials and clinical trials for educational purposes have to be reported to NADFC but do not require permits from NADFC.
Thank You

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