Ethic on Health Research and Clinical Trials

International Web-Seminar On Biosecurity & Public Health Law in Pandemic

Indonesian Biosecurity Foundation (IBF) – Study Development Program SWCU Salatiga

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University of Sari Mutiara Indonesia – Medan (USM) & Indonesian Center for Health Law and Policy Studies (ICHLAS)
hosted by

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BACKGROUND & DOCUMENTS

Nuremburg Case:

- When World War II ended in 1945, the victorious Allied powers enacted the International Military Tribunal on November 19th, 1945.
- The first trial conducted under the Nuremberg Military Tribunals in 1947 became known as The Doctors' Trial, in which 23 physicians from the German Nazi Party were tried for crimes against humanity for the atrocious experiments they carried out on unwilling prisoners of war. Many of them are Jewish prisoner and was taken place in Auschwitz concentration camp.
- 16 were found guilty and 7 death sentences 9 prison sentences

Cont' Back ground

1931 Guidelines (this document was existed before the Nuremburg Code)

The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury. Not Covered by the 1931 Document

Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury disability or death. Not covered by the 1931 Guidelines.

The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment. Risk benefit analysis covered under Point 4 of the guidelines (1931 Guidelines)

The Nuremberg Code's Ethical Guidelines For Research? Landmark in Medical Research

- Voluntary consent is essential (see also: Nuremberg Code and the Belmont Report)
- The results of any experiment must be for the greater good of society
- Human experiments should be based on previous animal experimentation
- Experiments should be conducted by avoiding physical/mental suffering and injury
- No experiments should be conducted if it is believed to cause death/disability
- The risks should never exceed the benefits (see Belmont Report)

Nuremburg Code

- Adequate facilities should be used to protect subjects
- Experiments should be conducted only by qualified scientists
- Subjects should be able to end their participation at any time
- The scientist in charge must be prepared to terminate the experiment when injury, disability, or death is likely to occur

The Belmont Report: Ethical Principle and Guidelines for the protection of human subjects of research

Risk and Benefit(*) :

The *concept of risk* is generally understood to refer to the combination of the probability and magnitude of some future harm. According to this understanding, risks are considered "high" or "low" depending on whether they are more (or less) likely to occur, and whether the harm is more (or less) serious.(No Harm)

In research involving human participants, risk is the central organizing principle, a filter through which protocols must pass; research evaluated by ECs that presents greater risks to potential research subjects will be expected to include greater or more comprehensive protections designed to reduce the possibility of harm occurring.

* **The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research.**

Department of Health, Education, and Welfare., National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. J Am Coll Dent. 2014 Summer; 81(3):4-13.

The Significance Of The Nuremberg Code

1. The Nuremberg Code is one of several foundational documents that influenced the principles of Good Clinical Practice (GCP).
2. Good Clinical Practice is an attitude of excellence in research that provides a standard for study design, implementation, conduct and analysis. More than a single document, it is a compilation of many thoughts, ideas and lessons learned throughout the history of clinical research worldwide.

3. Several other documents further expanded upon the principles outlined in the Nuremberg Code, including the Declaration of Helsinki, the Belmont Report and the Common Rule.

4. Although there has been updated guidance to Good Clinical Practice to reflect new trends and technologies, such as electronic signatures, these basic principles remain the same. The goal has always been—and always will be—to conduct ethical clinical trials and protect human subjects.

WHAT CONSTITUTES CLINICAL RESEARCH IS A MAJOR QUESTION THESE DAYS

Drug research with special emphasis on Clinical trials, although it literally refers to all types of research involving human participants related to generation of new knowledge for diagnosis, treatment, and prevention in the field of human health and diseases, scanning molecular genetics on one end and epidemiology and public health research on the other end.

A systematic testing of a hypothesis by analyzing data from patients' case records or application of new technologies on stored human biological materials also come under the purview of clinical research.

the present definition of clinical research includes any study conducted on human beings themselves, their biological materials, and human biological data with the potential to improve well being of the human race(*)

*Ethical issues in clinical research<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601715/ > last visited August 18, 2020

THE ETHICAL ISSUES IN CLINICAL RESEARCH PRIMARILY INVOLVES PROTECTION OF RIGHTS, SAFETY, AND WELL BEING OF THE RESEARCH PARTICIPANTS

Reviewing and constant monitoring of the research activities to ensure adherence to the principles laid down in these guidelines or policies or legislations are the main concerns of the Ethics Review Committees (ERC/EC)

The threat posed to the human participants are similar all over the world. There is a need for wider dissemination of these principles to all stakeholders of clinical research including the public at large and the participants in addition to the researchers, sponsors, institutions, members of ethics committees, regulators, and the policy makers, so that the rights of the research participants and the responsibilities of those involved in research are well understood by all concerned. (*)

THE FUNDAMENTAL ETHICAL CONCERN RAISED BY CLINICAL RESEARCH IS WHETHER ANI WHEN IT CAN BE ACCEPTABLE TO EXPOSE SOME INDIVIDUALS TO RISKS AND BURDENS OR THE BENEFIT OF OTHERS

This will lead to constant updating of guidelines, developing new guidelines, proposing new policies, and enacting appropriate regulations, so that the human research participants and the community rest assured that they are well protected while participating in any research(*).

Medical research often involves exposure to minor pain, discomfort, or injury from invasive medical procedures, or harm from possible side effects of drugs. All of these should be considered “risks” for purposes of EC review. (Ethical Clearance)

Research designed to evaluate new drugs or procedures may present more than minimal risk, and, on occasion, can cause serious or disabling injuries. Participation in research may result in undesired changes in thought processes and emotion (e.g., episodes of depression, confusion, or hallucination resulting from drugs, feelings of stress, guilt, and loss of self-esteem)(*)

* Grady C. * JAMA 2000;283:2701-2711
Am J Ophthalmol. 2000 Sep; 130(3):381
What makes clinical research ethical? emanuel EJ, wendler D, grady C. * JAMA 2000;283:2701-2711

Declaration of Helsinki

Ethical approval must have been obtained for all protocols from the local institutional Review Board (IRB) or other appropriate ethics committee to confirm the study meets national and international guidelines for research on humans.

A statement to confirm this must be included within the manuscript, which must provide details of the name of the ethics committee and reference/permit numbers where available.(*)

Non-interventional studies (e.g. surveys), where ethical approval is not required (e.g. because of national laws) or where a study has been granted an exemption by an ethics committee, this should be stated within the manuscript with a full explanation

Non-stigmatizing and non-discriminatory language should be used when describing different groups by race, ethnicity, age, disease, disability, religion, sex, gender, sexual orientation, etc

In addition to the required informed written consent (as stated above) clinical trial protocols must also be registered in a publicly accessible registry prior to participant recruitment. The public registry must be open to all prospective registrants and managed by a not-for-profit organization. A list of eligible registries can be found at the WHO International Clinical Trials Registry Platform (ICTRP). Trials can also be registered at Clinical Trials.gov or the EU Clinical Trials Register.

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Party Involve in Clinical Trial

- Sponsor / Initiator (Pemrakarsa/Penanggung Jawab)
- Executive / Agent Organization (Kimia Farma / UNAIR)
- Review Committee (Scientist / BP POM / Dep-Kes-Community Group-stakeholder)
- Researcher Group (Scientist) (Clinical Trials Agent)
- Participants (Patient)