Research Ethics

Prof (Dr) Lokesh. S
Scientist ‘E’ (Medical),
ICMR-National Institute of Epidemiology,
Chennai.

Why do Research?

- Understand Disease
- Validate New Therapies
- Understand Physiological Processes
- Study Human Behavior
- Evaluate Curricular Changes
- Evaluate New Teaching Method

Who Gains?

Ethical Issues in Research

- Tuskegee Syphilis Study-USPHS-1930's
  - Not treated even after penicillin discovered
- Jewish Chronic Disease Hospital
  - Patients injected with cancer cells
- Midgeville State Hospital
  - Investigational drugs used without consent

- Willowbrook State Hospital-1970
  - Retarded injected with viral hepatitis
- US Department of Energy-1950s-60s
  - Studies on radioactive fallout
- University of Iowa-1940s
  - Research on stuttering in orphans home
- Johns Hopkins-2001
  - Asthma study with hexamethonium

High Altitude Experiments

- To find out the best means of rescuing pilots from the serious and immediate danger of high altitude when they abandoned craft (with or without oxygen equipment) and were subjected to low atmospheric pressures

High-altitude experiments

March - August 1942. Rascher used a decompression chamber to simulate high altitude conditions.

Dissection of brain while the participants were still alive, to demonstrate that high altitude sickness was a result of the formation of tiny air bubbles in the blood vessels.

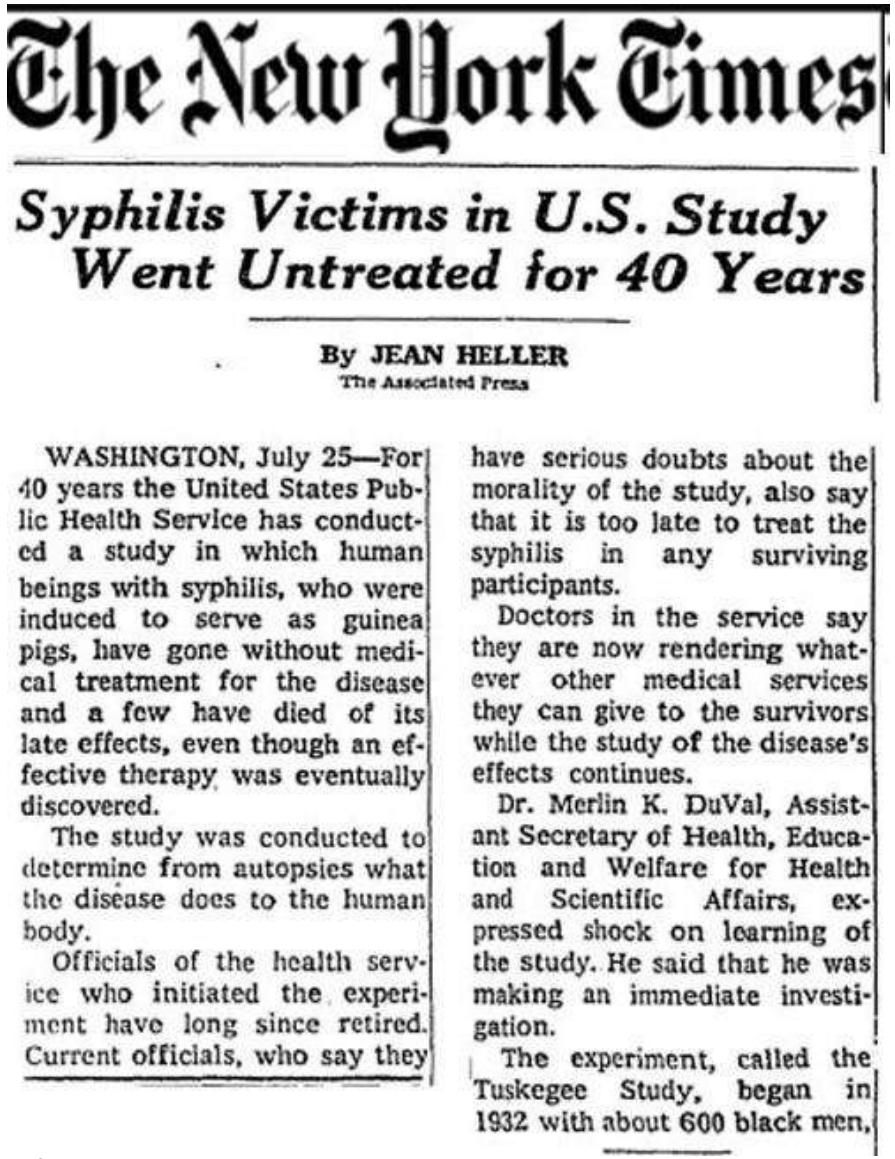
Freezing experiments.

- How long German pilots downed by enemy fire could survive the frozen waters of the North Sea?

Freezing experiments.

- August 1942 - May 1943. Doctor Sigmund Rascher attempted to duplicate these cold conditions at Dachau, and used about 300 prisoners in experiments recording their shock from the exposure to cold. About eighty to ninety of the subjects died as a result

- **THE TUSKEGEE SYPHILIS STUDY – 1932 to 1974 Natural History of Syphilis by withholding penicillin**



The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

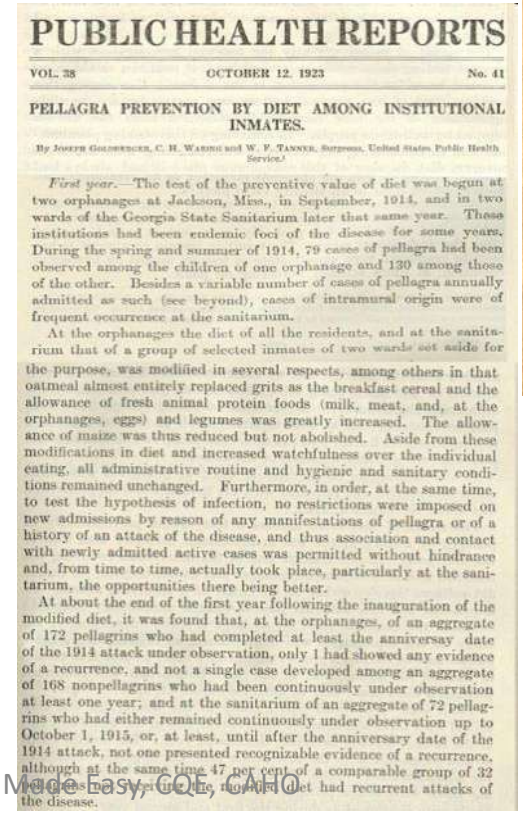
Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,

Other Studies

- Goldberger's study on Pellagra: intervened in the diets of orphanages, asylums, and prisons both to cure and induce pellagra

Goldberger, Joseph
American physician
1874–1929



PUBLIC HEALTH REPORTS

VOL. 38 OCTOBER 12, 1923 No. 41

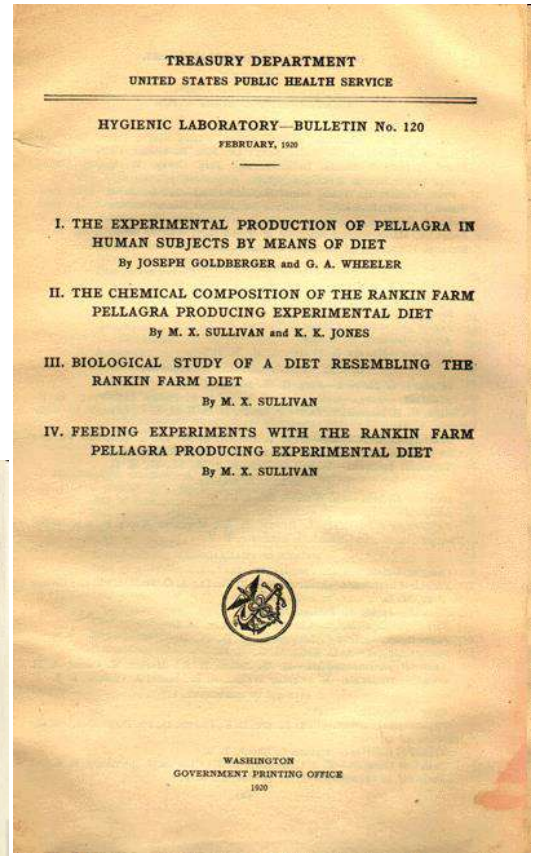
PELLAGRA PREVENTION BY DIET AMONG INSTITUTIONAL INMATES.

By Joseph Goldberger, C. H. Waring and W. F. Tanner, Surgeons, United States Public Health Service.

First year.—The test of the preventive value of diet was begun at two orphanages at Jackson, Miss., in September, 1914, and in two wards of the Georgia State Sanitarium later that same year. These institutions had been endemic foci of the disease for some years. During the spring and summer of 1914, 79 cases of pellagra had been observed among the children of one orphanage and 130 among those of the other. Besides a variable number of cases of pellagra annually admitted as such (see beyond), cases of intramural origin were of frequent occurrence at the sanitarium.

At the orphanages the diet of all the residents, and at the sanitarium that of a group of selected inmates of two wards set aside for the purpose, was modified in several respects, among others in that oatmeal almost entirely replaced grits as the breakfast cereal and the allowance of fresh animal protein foods (milk, meat, and, at the orphanages, eggs) and legumes was greatly increased. The allowance of maize was thus reduced but not abolished. Aside from these modifications in diet and increased watchfulness over the individual eating, all administrative routine and hygienic and sanitary conditions remained unchanged. Furthermore, in order, at the same time, to test the hypothesis of infection, no restrictions were imposed on new admissions by reason of any manifestations of pellagra or of a history of an attack of the disease, and thus association and contact with newly admitted active cases was permitted without hindrance and, from time to time, actually took place, particularly at the sanitarium, the opportunities there being better.

At about the end of the first year following the inauguration of the modified diet, it was found that, at the orphanages, of an aggregate of 172 pellagrins who had completed at least the anniversay date of the 1914 attack under observation, only 1 had showed any evidence of a recurrence, and not a single case developed among an aggregate of 168 nonpellagrins who had been continuously under observation at least one year; and at the sanitarium of an aggregate of 72 pellagrins who had either remained continuously under observation up to October 1, 1915, or, at least, until after the anniversary date of the 1914 attack, not one presented recognizable evidence of a recurrence, although at the same time 47 per cent of a comparable group of 32 [illegible] diet had recurrent attacks of the disease.



TREASURY DEPARTMENT
UNITED STATES PUBLIC HEALTH SERVICE

HYGIENIC LABORATORY—BULLETIN No. 120
FEBRUARY, 1920

I. THE EXPERIMENTAL PRODUCTION OF PELLAGRA IN HUMAN SUBJECTS BY MEANS OF DIET
By JOSEPH GOLDBERGER and G. A. WHEELER

II. THE CHEMICAL COMPOSITION OF THE RANKIN FARM PELLAGRA PRODUCING EXPERIMENTAL DIET
By M. X. SULLIVAN and K. K. JONES

III. BIOLOGICAL STUDY OF A DIET RESEMBLING THE RANKIN FARM DIET
By M. X. SULLIVAN

IV. FEEDING EXPERIMENTS WITH THE RANKIN FARM PELLAGRA PRODUCING EXPERIMENTAL DIET
By M. X. SULLIVAN

WASHINGTON
GOVERNMENT PRINTING OFFICE
1920

Why These were considered wrong

- Performing medical experiments, without the subjects' consent, on prisoners of war and civilians of occupied countries

- Euthanasia of aged, insane, incurably ill and deformed

"Nuremberg Code"

- Informed consent
- Fruitful results
- Based on prior Knowledge
- Avoid Harm
- Pre assessment of risk of harm
- Ensuring no harm is done
- Qualifications of Person conducting the study
- Liberty to Discontinue
- Guidelines for stopping

Unfortunately, codes are not always followed

Ethical Principles for Research

- Beneficence - make a positive contribution

- Non Maleficence-- cause no harm to participants in particular and to people in general.

Belmont Report **1978**

Ethical Principles for Research

- Respect & autonomy-- protect the rights and dignity of participants.

"What fits your busy schedule better, exercising one hour a day or being dead 24 hours a day?"


Respect for Persons
Beneficience
Justice
Human Research Protections

TWELVE BASIC PRINCIPLES (common to all areas of biomedical research)

1. Principle of Essentiality:

- All biomedical research in human subjects should be absolutely essential after a due consideration of all alternatives for the advancement of knowledge.

Research on Vulnerable Groups

- prisoners,
- Children,
- Pregnant women,
- Crime-stricken communities
- and those with disabilities especially mentally challenged

2. Principle of voluntariness and Informed Consent:

- The concept of voluntariness and informed shall apply to the community as a whole and to each individual member who is subjected for research.
- The right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time, is paramount.
- The informed consent process ensures that participants rights are safeguarded.

Informed Consent

i. Purpose of research

ii. Identity of the researchers

iii. Identity of others associated with the research

iv. Why selected:

v. Harms and benefits:

vi. Privacy, anonymity and confidentiality:

vii. Future use of information:

viii. Right not to participate and withdraw:

ix. Right to get help:

3. Principle of Non-Exploitation:

- Irrespective of the socio-economic status and educational levels, research subject should be fully appraised of all risks arising as a result of research.
- The research participants are equitably selected so that the benefits and burdens of the research are distributed fairly and without discrimination.
- Sufficient safeguards to protect vulnerable groups are to be ensured.

4. Principle of Privacy and Confidentiality:

- Privacy is the right of an individual to control or influence the information that can be collected and stored and by whom and to whom that the information may be disclosed or shared.
- Confidentiality is the obligation of the researcher to the participants to safeguard the entrusted information.
- Privacy of the participant, his / her identity and records are to be kept confidential and access limited to only those authorized.

- The identity of records of human subjects should be kept confidential and should not be disclosed without valid scientific and legal reasons.
- However, under certain circumstances privacy of the information can be breached in consultation with EC for valid scientific or legal reasons as the right to life of individual supersedes the right to privacy of the research participant.

5. Principle of Precautions and Risks Minimisation:

- Due care and caution has to be taken by all stake holders at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.

6. Principle of Professional Competence

- The research is conducted at all times by the competent and qualified persons with relevant training or experience.

7. Principle of Accountability and Transparency:

The research is committed in a fair, honest, impartial and transparent manner and records and data are maintained for a reasonable period.

The stake holders involved in research should disclose any existing conflict of interest and manage it appropriately.

The outcomes of research must be brought in to public domain through registries, reports and scientific and other publications while safeguarding the right to privacy of the participants.

8. Principle of Maximization of Public Interest

The research is conducted to benefit all human kind and not just socially better off.

9. Principle of Institutional Arrangements:

Institution must have policies for appropriate research governance and take the responsibility to facilitate research by providing infrastructure, manpower, funds and training opportunities.

"Sometimes, if I smack it here real good, it will start back up."

10. Principle of Public Domain:

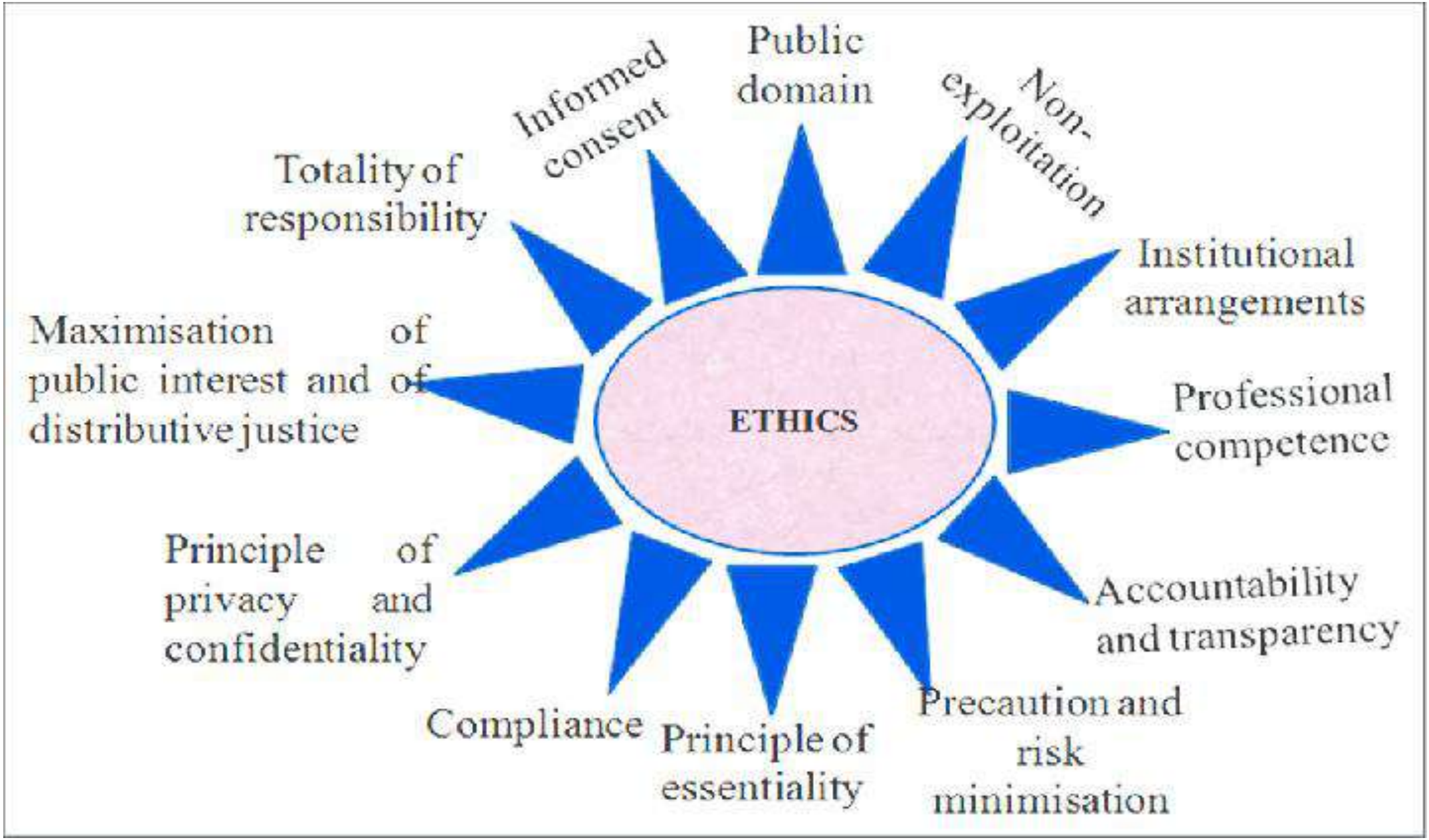
After due experimentation and due evaluation are brought in to public domain through scientific and other publications under the law in force at that time.

11. Principle of Totality and Responsibility:

It is the responsibility of all directly and indirectly involved with the research to monitor, review constantly and take remedial action at all stages of research.

12. Principle of Environmental protection:

All researchers are accountable for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.


Informed consent
Public domain
Non-exploitation
Totality of responsibility
Institutional arrangements
Maximisation of public interest and of distributive justice
ETHICS
Professional competence
Principle of privacy and confidentiality
Accountability and transparency
Compliance
Principle of essentiality
Precaution and risk minimisation

Introduction:

"Ethics Guidelines for Biomedical Research on Human Subjects-2000"

"Ethical Guidelines for Biomedical Research on Human Participants-2006"

"National Ethical Guidelines for Biomedical and Health Research Involving Human Participants-2017"

{In line with the "Council for International Organizations of Medical Sciences (CIOMS)}

"National Ethical Guidelines for Biomedical Research Involving Children-2017"

Traditional Ethical Theory

Rule of reciprocity:

Do unto others as you would have them do unto you

Reflects "*concern for others*"

Ethical sensitivity leads to professional commitment

Thank you