



Ethical considerations in Biomedical & Health Research



- ▶ Research in health sciences often brings up questions of ethics because the study design involves human subjects, some of whom are under age (e.g. primary school children)
- ▶ It is not always easy for young researchers to anticipate where ethical issues might emerge while designing their research project.

Questions that a researcher should consider

- ▶ Will my study cause any harm to the patient?
- ▶ Will it cause any adverse effects?
- ▶ What can I do if, unexpected adverse effects may occur?
- ▶ How am I going to ensure privacy & confidentiality of the participants?



Ethics in Research

- ▶ Designing the Study
- ▶ Interpretation of Data
- ▶ Publication of Research work



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Morals in research

- ▶ Honesty & sincerity
- ▶ Objectivity
- ▶ Carefulness
- ▶ Openness
- ▶ Respect for intellectual property
- ▶ Confidentiality
- ▶ Social respect
- ▶ Animal care

Ethical Principles of Research



Trust in research

- ▶ Scientific research is built on a foundation of trust
- ▶ Scientists trust that the results reported by others are valid
- ▶ Society trusts that the results of research reflect an honest attempt by scientists
- ▶ But this trust will endure only if the scientific community devotes itself to the values associated with ethical scientific conduct.
- ▶ So Research is a responsible job

Why so much talk about ethics in research?

- ▶ Studies involving human participants require careful scrutiny before approval
- ▶ Past mistakes should not be repeated

Several clinical trials in the past have gone horribly wrong



History of Nazi Human Experimentation



Medical experiments by
Nazi physicians

Nazi human experimentation

- ▶ A series of medical experiments on large numbers of prisoners, including children, by Nazi Germany in its concentration camps in the 1940s, during World War II
- ▶ Nazi physicians forced prisoners into participating; they did not willingly volunteer and no consent was given for the procedures.



- ▶ The experiments resulted in death, trauma, disfigurement or permanent disability, considered as examples of **medical torture**
- ▶ After the war, these crimes were tried at what became known as the **Doctors' Trial**, led to the development of the **Nuremberg Code of medical ethics**



The Nuremberg code

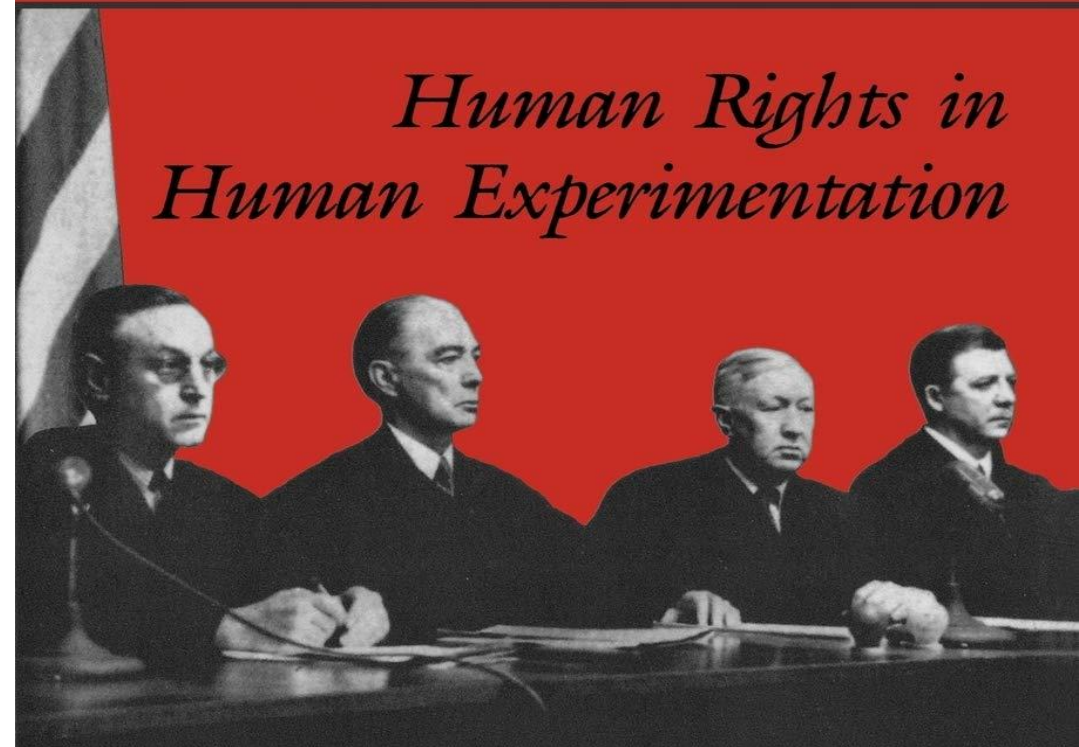
Given in the section of the verdict entitled
"Permissible Medical Experiments"

10 points Moral code of ethics

- ▶ Introduced after the Doctor's trial
on August 9, 1947

The Nazi Doctors and the Nuremberg Code

*Human Rights in
Human Experimentation*



George J. Annas Michael A. Grodin

Helsinki Declaration

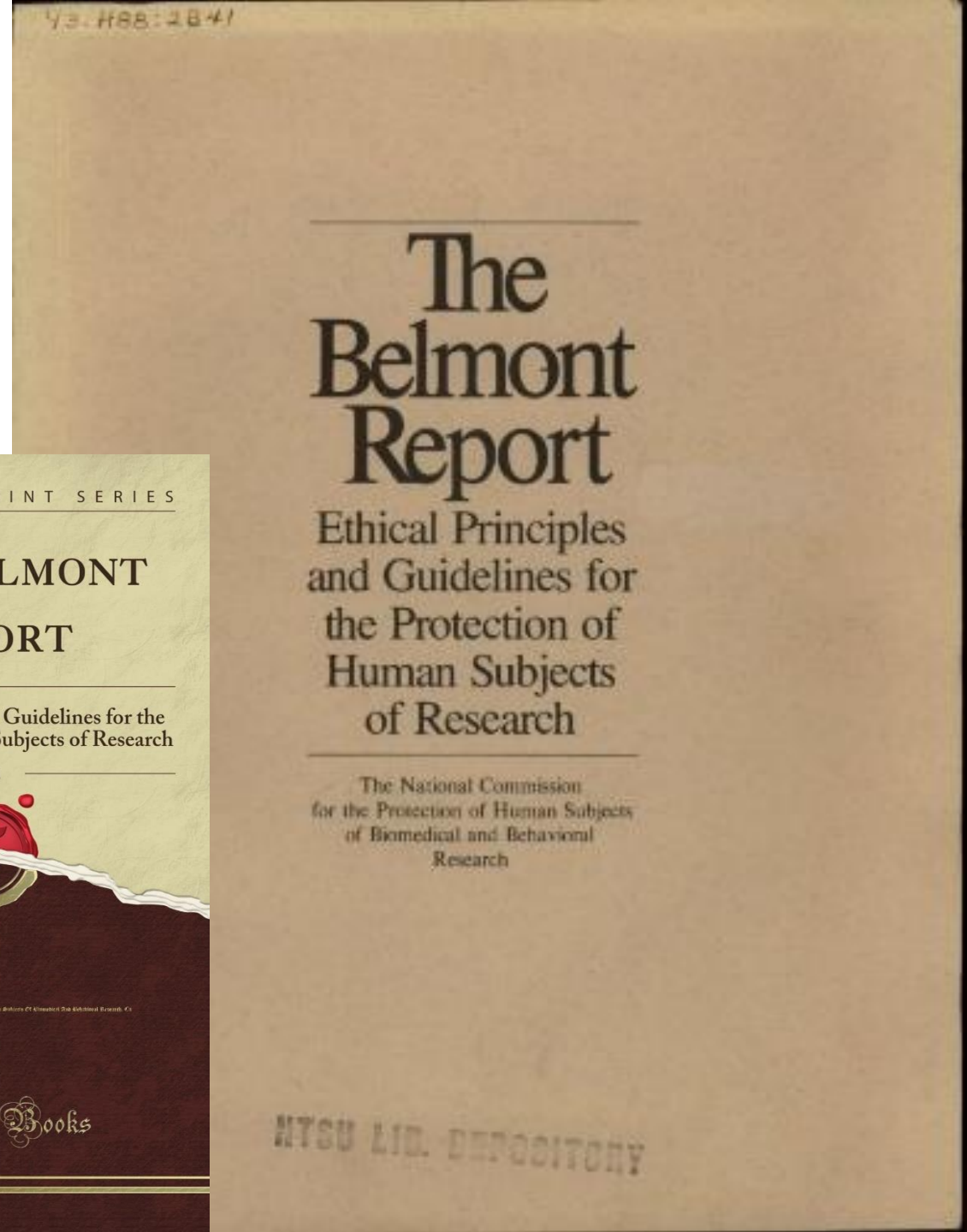
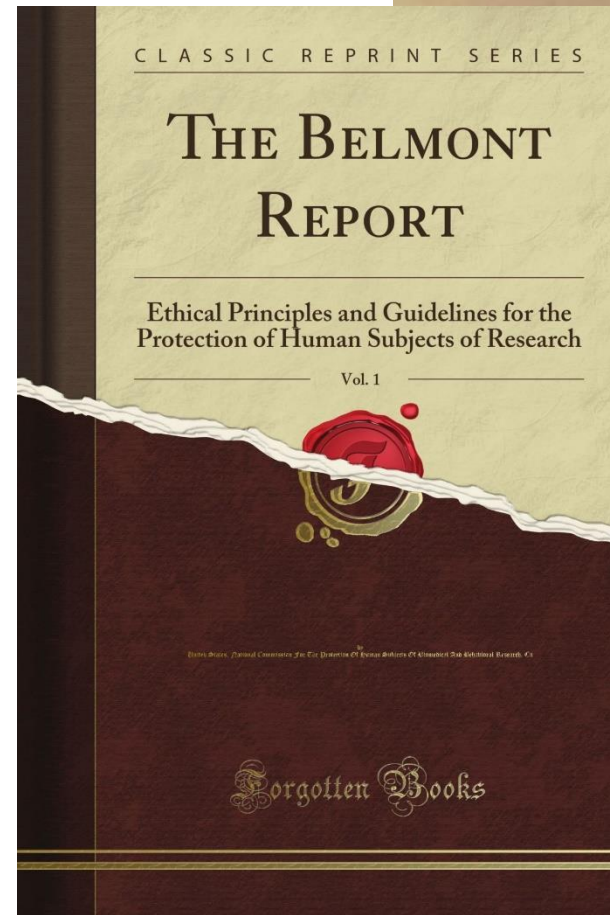
- ▶ Developed by the World Medical Association (1964)
- ▶ The Declaration was originally adopted in June 1964 in Helsinki, Finland, and has since undergone seven revisions (the most recent at the General Assembly in October 2013)
- ▶ Designed to promote responsible research with human subjects



WORLD MEDICAL
ASSOCIATION'S
**Declaration
of Helsinki**
7TH REVISION, 2013

Belmont Report

- ▶ United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979)



Indian Council of Medical Research (ICMR) Guidelines

- ▶ ICMR designed the policy statement on ethical considerations involved in research on human subjects in February 1980
- ▶ Recommended the constitution of institutional ethical committees to scrutinize research studies before approval

POLICY STATEMENT ON ETHICAL CONSIDERATIONS INVOLVED IN RESEARCH ON HUMAN SUBJECTS

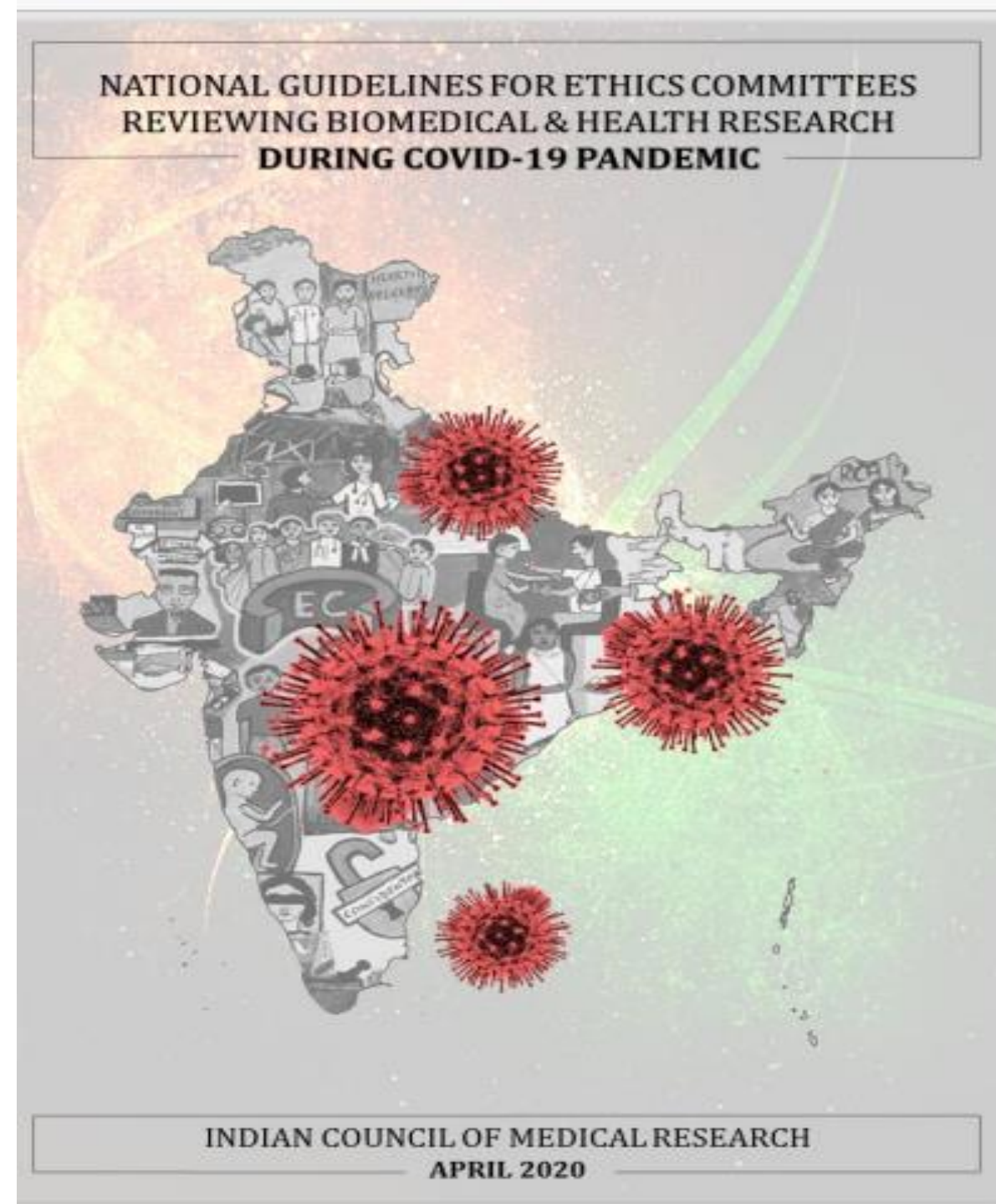


INDIAN COUNCIL OF MEDICAL RESEARCH
New Delhi 110 016
February 1980

ICMR Guidelines

April 2020

- National Guidelines for Ethics Committees reviewing Biomedical & Health Research during **COVID -19** pandemic



Our agenda for today

Topic	Speaker
Ethical Guidelines	Dr. Radhika M B
Clinical trial of drugs and other interventions	Dr. Joann Pauline George
Common forms of submission	Dr. Gayathri

Life in the labs

Are you going
to get vaccinated?

You're crazy!,
they haven't finished
human trials!

