

# Ethical Principles For Medical Research Involving Human Subjects

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# Topics

**History**

**Ethical Considerations**

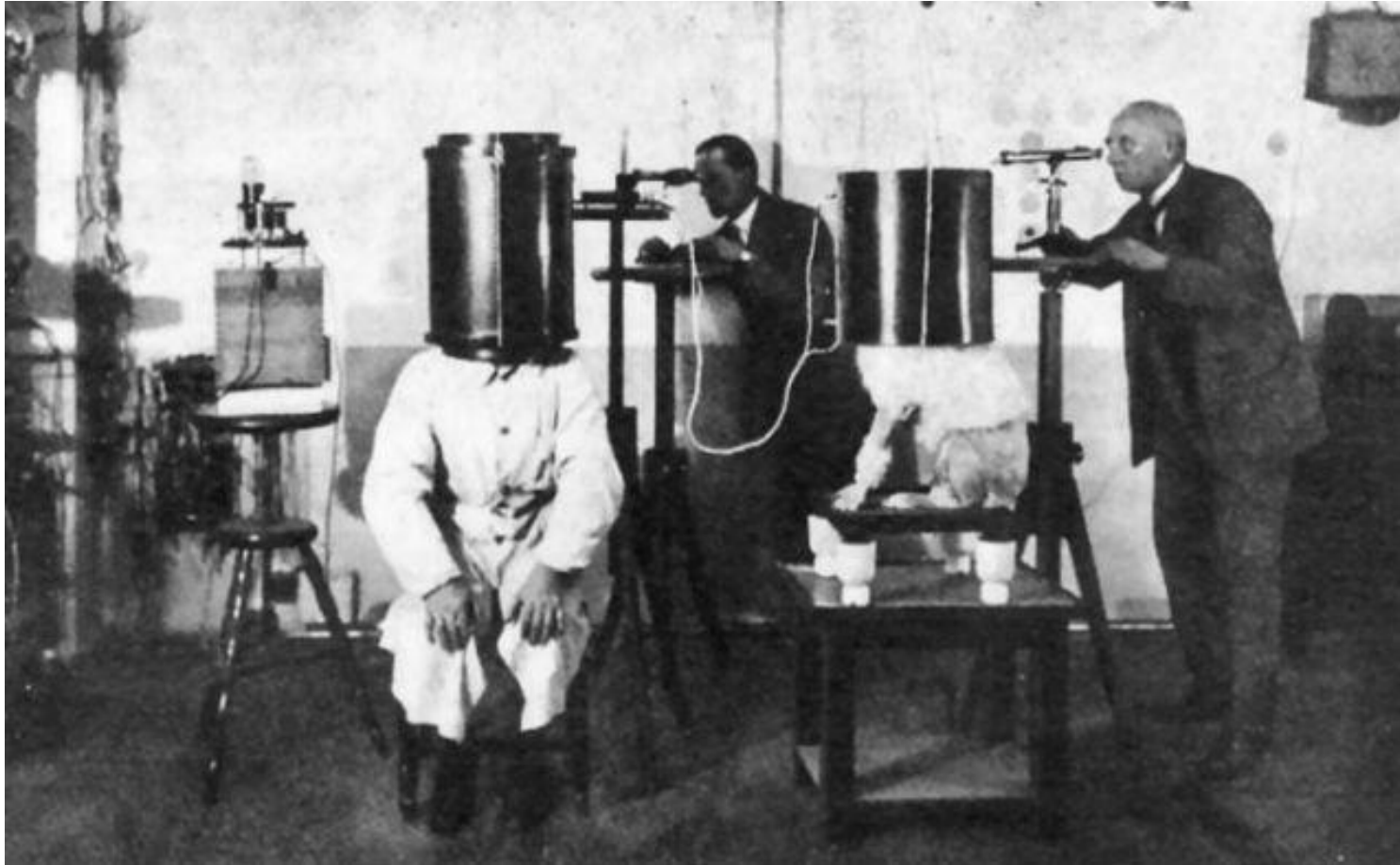
# Nazi Human Experiments

- ❖ Bone, muscle, and nerve transplantation experiments
- ❖ Experiments on twins
- ❖ Freezing experiments
- ❖ Mustard gas experiments
- ❖ Sulfonamide experiments
- ❖ Experiments with poison
- ❖ Blood coagulation experiments
- ❖ Sterilization and fertility experiments
- ❖ Head injury experiments
- ❖ Malaria experiments
- ❖ Immunization experiments
- ❖ Sea water experiments
- ❖ Incendiary bomb experiments
- ❖ High altitude experiments

# Nazi Human Experiments



# Nazi Human Experiments



# Nazi Human Experiments



# Nazi Human Experiments





# Nazi Human Experiments





# Nuremberg Trials

- ❖ Nuremberg, Germany, was chosen as a site for trials that took place in 1945 and 1946.
- ❖ Judges from the Allied powers (USA, UK, SU, and France) presided over the hearings of 21 major Nazi criminals.
- ❖ 12 prominent Nazis were sentenced to death.

# Nuremberg Trials



# Nuremberg Trials





# **World Medical Association Declaration of Helsinki**

**Members are typically represented by National Associations of  
Physicians from different countries in the world**

# Ethical Principles for Medical Research Involving Human Subjects

- ❖ Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
- ❖ 29th WMA General Assembly, Tokyo, Japan, October 1975
- ❖ 35th WMA General Assembly, Venice, Italy, October 1983
- ❖ 41st WMA General Assembly, Hong Kong, September 1989
- ❖ 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
- ❖ 52nd WMA General Assembly, Edinburgh, Scotland, October 2000
- ❖ 53rd WMA General Assembly, Washington, USA, October 2002
- ❖ 55th WMA General Assembly, Tokyo, Japan, October 2004
- ❖ 59th WMA General Assembly, Seoul, South Korea, October 2008
- ❖ 64th WMA General Assembly, Fortaleza, Brazil October 2013

# Declaration of Helsinki 2013

<b>1-2</b>	<b>• Preamble</b>
<b>3-15</b>	<b>• General Principles</b>
<b>16-18</b>	<b>• Risks, Burdens, and Benefits</b>
<b>19-20</b>	<b>• Vulnerable Groups and Individuals</b>
<b>21-22</b>	<b>• Scientific Requirements and Research Protocols</b>
<b>23</b>	<b>• Research Ethics Committees</b>
<b>24</b>	<b>• Privacy and Confidentiality</b>
<b>25-32</b>	<b>• Informed Consent</b>
<b>33</b>	<b>• Use of Placebo</b>
<b>34</b>	<b>• Post-Trial Provisions</b>
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<b>37</b>	<b>• Unproven Interventions in Clinical Practice</b>

# Declaration of Helsinki 2013

## ❖ Preamble #1

- Ethical principles for medical research involving
- Human subjects
- Identifiable human material and data



# Declaration of Helsinki 2013

## ❖ General Principals #3

- The health of my patient will be my first consideration.

# Declaration of Helsinki 2013

## ❖ General Principals #8

- The primary purpose of medical research is to generate new knowledge.
- This goal can never take precedence over the rights and interests of individual research subjects.

# Declaration of Helsinki 2013

## ❖ General Principals #9

- It is the duty of physicians to protect the research subjects'
  - Life
  - Health
  - Dignity
  - Right to self-determination
  - Confidentiality
  - Privacy

# Declaration of Helsinki 2013

## ❖ General Principals #10

- Physicians must consider:
  - Declaration items
  - Ethical norms
  - National laws and regulations
  - International norms and standards

# Declaration of Helsinki 2013

## ❖ General Principals #11

- Medical research should be conducted in a manner that minimizes possible harm to the environment.

# Declaration of Helsinki 2013

## ❖ General Principals #12

- Medical research involving human subjects must be conducted only by individuals with
- appropriate ethics and scientific education, training and qualifications

# Declaration of Helsinki 2013

## ❖ General Principals #15

- Appropriate compensation and treatment for subjects who are harmed as a results of participating in research must be ensured.



# Declaration of Helsinki 2013

## ❖ Risks, Burdens, and Benefits #16

- Medical research involving human subjects may only be conducted if potential benefits outweigh the risks and burdens

# Declaration of Helsinki 2013

## ❖ Risks, Burdens, and Benefits #17

- The risks must be continuously monitored, assessed and documented by the researcher.
- Secondary outcomes

# Declaration of Helsinki 2013

## ❖ Vulnerable Groups and Individuals #19

➤ All vulnerable groups and individuals should receive specifically considered protection.

- Children
- Elderly
- Pregnant women
- Mentally retarded subjects

# Declaration of Helsinki 2013

## ❖ Vulnerable Groups and Individuals #20

- Medical research with a vulnerable group is only justified if the research is responsive to the health or priority of this group.

# Declaration of Helsinki 2013

## ❖ Scientific Requirements and Research Protocols #21

- The welfare of animals used for research must be respected.

# Declaration of Helsinki 2013

## ❖ Scientific Requirements and Research Protocols #22

- The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

# Declaration of Helsinki 2013

## ❖ Research Ethics Committees #23

- The research protocol must be submitted to the committee for:
  - Consideration
  - Comment
  - Guidance
  - Approval
  - before the study begins
- ❑ No amendment to the protocol may be made without consideration and approval by the committee.



# Declaration of Helsinki 2013

## ❖ Privacy and Confidentiality #24

- Every precaution must be taken to protect
  - The confidentiality of their personal information
  - The privacy of research subjects

# Declaration of Helsinki 2013

## ❖ Informed Consent #25

- The consent must be
  - Informed
  - Freely-given
  - Right to refuse to participate
  - Right to withdraw at any time without reprisal

# Declaration of Helsinki 2013

## ❖ Informed Consent #26

➤ Each potential subject must be adequately informed of the

- Aims
- Methods
- Anticipated benefits
- Potential risks
- Institutional affiliations of researcher
- Sources of funding
- Any possible conflicts of interest

# Declaration of Helsinki 2013

## ❖ Informed Consent #26

- Preferably in writing
- If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

# Declaration of Helsinki 2013

## ❖ Informed Consent #28

- For a potential research subject who is incapable of giving informed consent
  - Children
  - Unconscious patients
  - Mentally retarded subjects
  - Prisoners
- The physician must seek informed consent from the legally authorized representative.
- The potential subject's dissent should be respected.

# Declaration of Helsinki 2013

## ❖ Informed Consent #32

- For medical research using identifiable human
  - Material
  - Data
- Physician must seek informed consent for
  - Collection
  - Storage
  - Reuse
- If impossible or impractical
  - Research may be done only after consideration and approval of a research ethics committee

# Declaration of Helsinki 2013

## ❖ Informed Consent

- Explicit (written) consent
  - Interventional studies
- Implicit (verbal) consent
  - When written consent is impossible



# Declaration of Helsinki 2013

## ❖ Use of Placebo #34

- The benefits, risks, burden and effectiveness of a new intervention must be tested against those of the best proven interventions, except:
  - No proven intervention exists
  - The use of placebo is acceptable
  - The patients must not subject to serious or irreversible harm

# Declaration of Helsinki 2013

## ❖ Research Registration and Publication and Dissemination of Results #35

- Every clinical trial must be registered
- In a publicly accessible database
- Before recruitment of the first subject
- ICD-10 code

## International Clinical Trials Registry Platform (ICTRP)

No.	<b>ANZCTR</b>	Australian New Zealand Clinical Trials Registry
1	<b>ReBec</b>	Brazilian Clinical Trials Registry
2	<b>ChiCTR</b>	Chinese Clinical Trial Registry
3	<b>CRiS</b>	Clinical Research Information Service (Korea)
4	<b>CTR-I</b>	Clinical Trials Registry - India ()
5	<b>RPCEC</b>	Cuban Public Registry of Clinical Trials
6	<b>EU-CTR</b>	EU Clinical Trials Register
7	<b>DRKS</b>	German Clinical Trials Register
8	<b>IRCT</b>	Iranian Registry of Clinical Trials
9	<b>ISRCTN</b>	International Standard Randomized Controlled Trials Number (UK)
10	<b>JPRN</b>	Japan Primary Registries Network
11	<b>NTR</b>	Netherlands National Trial Register
12	<b>PACTR</b>	Pan African Clinical Trial Registry
13	<b>REPEC</b>	Peruvian Clinical Trial Registry
14	<b>SLCTR</b>	Sri Lanka Clinical Trials Registry
15	<b>TCTR</b>	Thai Clinical Trials Registry

# Iranian Registry of Clinical Trials

[Home](#)[« فارسی](#)

Welcome to Iranian Registry of Clinical Trials. This is a [Primary Registry in the WHO Registry Network](#) set up with the help from the Ministry of Health and Medical Education (MOHME) and hosted by Iran University of Medical Sciences (IUMS).

[Read more »](#)

## Learning about trials

[Read more »](#)

15407 trials registered.

### Search for Trials

[Advanced search](#)

### Search Help

- [How to search](#)
- [How to refine your search](#)
- [How to export data](#)

## What is a Clinical Trial?

According to the international committee of medical journal Editors (ICMJE) any research study that prospectively assigns human participants or groups of humans to one or more health-related

## How do I register a trial?

You need to take the following steps:

- You need to register with IRCT web-site and set up an account.
- IRCT staff will get back to you when the

## Key points about IRCT

- IRCT is a not for profit website.
- Search within the content of this website is allowed for members of public.
- All researchers can register their trials in this

Trial dashboard

General information

Secondary Ids

Ethics committees

Health conditions studied

Primary outcomes

Secondary outcomes

Intervention groups

Recruitment centers

Sponsors / Funding sources

Person responsible for general inquiries

Person responsible for scientific inquiries

Person responsible for updating data

Protocol summary

Sharing plan

Back

The effect of intravenous sodium valproate versus dexamethasone on headache relief in patients with acute migraine headache: a double blinded randomized clinical trial

Draft

Trial Id 34592

IRCT Id empty

Registration date empty

Registration date empty

Membership number 9014

Progress



Activate Windows

Go to Settings to activate Windows.

If you have a feedback for the referee or an explanation regarding referee messages/entered data, please leave it here.

# Declaration of Helsinki 2013

## ❖ Research Registration and Publication and Dissemination of Results #36

- Results of must be publicly available
- Negative and positive results must be published
- Sources of funding and conflicts of interest must be declared
- Reports of research NOT in accordance with the principles of this Declaration should NOT be accepted for publication.

# THANK YOU