Ethical Aspects

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Research ethics

- research with human subjects

  ➡ *today's focus*

- ethics in data collection

  ★ research must have clear aims & appropriate risk - benefit ratio

  ★ research must be conducted in methodologically rigorous manner & produce reliable data

  ★ participants cannot be excluded without scientific reason

- ethics in publishing

- sustainable data archiving

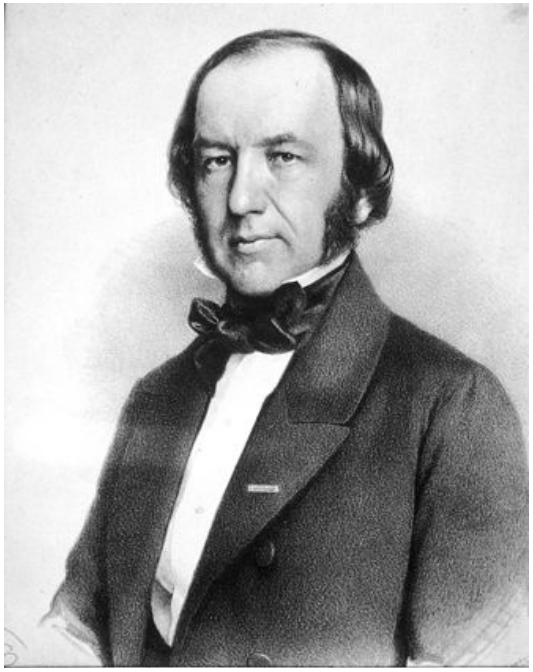
Research with human subjects

- respect their rights
- protect their health & well-being
- safeguard their data
- guarantee their privacy

Research with human subjects

„Among the experiments that may be tried on man,
those that can only harm are forbidden,
those that are innocent are permissible,
and those that may do good are obligatory.“

(Claude Bernard. 1865. *Introduction à l'étude de la médicine experimentale*. Paris. / translated by N.C. Greene. 1957. *An Introduction to the Study of Experimental Medicine.* Dover Publications.)



Claude Bernard (1813-1878).
Source: G. Terry Sharrer,

Background

- abuse of human subjects in biomedical experimentation
  - Nuremberg code (1947)
  - Neisser trial (Breslau, 1898) - anti-syphilis serum therapy
  - …

Nuremberg trial. Photograph: Eddie Worth/AP

Declaration of Helsinki (1964/2008)

- ethical principles for medical research involving human subjects
- world medical association (WMA)
- „addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.“ (Preamble, §2)

General Principles

- „to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research“ (§4)
- „The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions […] Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.“ (§6)
- „Medical research is subject to ethical standards that promote and ensure respect for all human subjects“ (§7)

General Principles

- „It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.“ (§9)

- „Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards.“ (§10)

- „Medical research should be conducted in a manner that minimises possible harm to the environment.“ (§11)

Risks, Burden & Benefits

- „In medical practice and in medical research, most interventions involve risks and burdens. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.“ (§16)

- „All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.
  Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.“ (§17)

Vulnerable Groups

- „Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection.“ (§19)

- „Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.“ (§20)

Scientific Requirements & Research Protocols

- „Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation.“ (§21)

- „The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.
  The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.“ (§22)

Research Ethics Committees

- „The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. […]
  The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.“ (§23)

Privacy & Confidentiality

- „Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.“ (§24)

Informed Consent

- „Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary.“ (§25)

- „each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.“ (§26)

Informed Consent

- „After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.
  All medical research subjects should be given the option of being informed about the general outcome and results of the study.“ (§26)

- „When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.“ (§27)

Informed Consent

- „For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.“ (§28)

- „When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject’s dissent should be respected.“ (§29)

Informed Consent

- „For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse.“ (§32)

Publication & Dissemination of Results

- „Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.“ (§36)

Human subjects protection

- minimize harms & risks
- maximize benefits
- respect human privacy & dignity
- take special precautions with vulnerable populations
- retain data responsibly

Do I need ethics approval?

- DFG (www.dfg.de/foerderung/faq/geistes_sozialwissenschaften/index.html)
  - ★ invasive methods
  - ★ clinical studies
  - ★ participants < 18 & > 65 years of age
- but publishers may have a more rigid position
- in any case, participants must be informed and give consent

Ethical standards

- informed consent
  - ★ information about task
  - ★ potential risks & benefits
    - ➡ often: no direct benefit for participant
  - ★ right to ask questions
- confidentiality
  - ★ data stored & reported anonymously
- voluntary participation
  - ★ right to withdraw

Participant information sheet

- What is the purpose of the study?
  - ✦ background, aims, duration
- What is the task of the participant?
- What are the risks and benefits?
- Why has participant been selected?
  - ✦ inclusion criteria, other groups
- Does participant have to take part?
  - ✦ voluntary participation, withdrawal at any time
- How is participant compensated?

Participant information sheet

- How will data be treated? / Who has access to data?
  - ✦ personal information & collected data
  - ✦ confidentiality & anonymity
- What will happen to the results?
  - ✦ publication & possibility to access research report
- Who is funding the project?
- Who is the head of the project?
  - ✦ contact details

Data handling

- data should not reveal the participant's identity
- use pseudonyms during data collection
- who has access to code list (participant ID ~ pseudonym)?
- for how long?
- how long can participants request data deletion?

- if you have a participant database, participants should be informed, give consent & have the right to refuse (separate consent form)

DGfS Ethics Committee

- if your university doesn't have an ethics committee
- submit project proposal, information on experiments, demands, recruitment, etc., participant information, consent forms
  - ✳ single pdf file

- fees
  - members of DGfS: 100€
  - non-members: 300€
  - lab approval (members only): 500€
    - ✳ non-invasive methods, typical population only

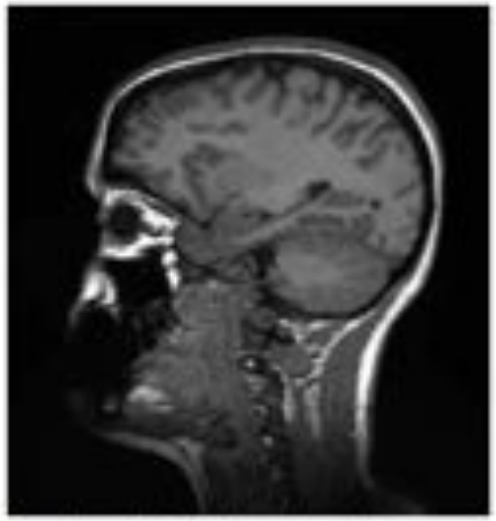
- more info: www.dgfs.de/de/inhalt/ueber/ethikkomission.html

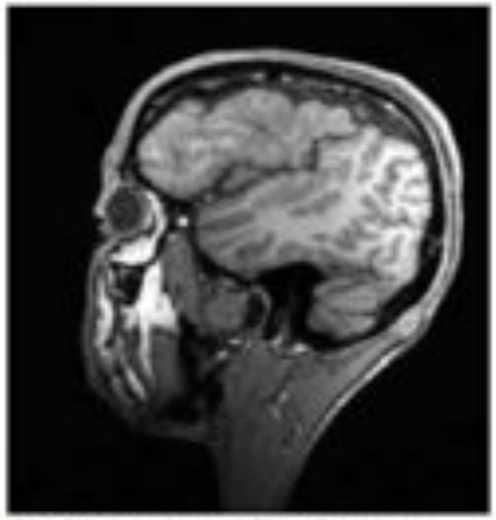
Further issues

Incidental findings

- our research typically does not aim at diagnosis or treatment
- yet incidental findings may occur (—> neuroimaging)

- no harm principle / duty of care (Hippocratic maxim): participants should be informed when incidental findings occur
  - ➡ explanation of researcher-participant relationship
  - ➡ explanation of incidental findings
  - ➡ inform participants that possible incidental findings will be reported
  - ➡ participants must give written consent





- Heinemann et al. (2007). Zufallsbefunde bei bildgebenden Verfahren in der Hirnforschung. *Deutsches Ärzteblatt, 104,* 1982-1987.

Audio & video recording

- anonymity may be in danger
  - obtain separate consent
  - also obtain separate consent for permission to use data in the classroom / lectures

Internet-based studies

- participant briefing and informed consent online
- information on internet security
- how are participant inclusion criteria implemented?

Hidden purposes

- in case participants cannot be informed a priori about the actual purpose of the study, they have to be informed during debriefing

Student participation

- recruiting students in class?
  - voluntary participation (when for course credit, offer alternatives)
  - no added benefit for teacher-student interaction (grades, …)
  - advertise for participants in general terms, rather than recruit students individually

Links

- Declaration of Helsinki: www.wma.net/en/30publications/10policies/b3/
- Ethics statement of the LSA: www.linguisticsociety.org/files/Ethics_Statement.pdf
- Ethics committee of the DGfS: www.dgfs.de/de/inhalt/ueber/ethikkomission.html
- DFG FAQ: www.dfg.de/foerderung/faq/geistes_sozialwissenschaften/index.html