Ethics in medical (imaging) research

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Content

• Ethics applications

• Responsibilities
Ethics approval

- Declaration of Helsinki
- Local ethics boards
- Animal experiments boards
- Isotope committees (if applicable)
Declaration of Helsinki

• Adopted in Finland 1964 (last revision 2013).

• Ethical principles for medical research involving human subjects, 34 short principles
Declaration of Helsinki

• A physician shall act in the patient’s best interest when providing medical care.

• While 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.

• Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

• The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.
• Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

• The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient’s decision to withdraw from the study must never adversely affect the patient-physician relationship.
Declaration of Helsinki

- The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

  Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

  Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention.
• Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

• In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.
Content of an ethics application

• Informed consent is the key! How, when and what!

• Risks / adverse effects

• Benefits for patients in the study

• Benefit of the project
Animal experiments

• Handled by a different ethics committee.
Randomized clinical trials
Randomized clinical trials

• Importance of randomization
• Placebo effect
• Blinding
• How to determine the primary outcome?
Ebola?
Scapis?

- 30,000 healthy subjects scanned with CT
- Lots of measurements (EKG, spirometry, ...)
- Followed longitudinally over time (10+ years)
Biological tissue

• Can I go to the local butcher and buy a heart to put in the scanner?

• No, formally you need approval from “Jordbruksverket”.

• The rules are that the hearts need to be cut open to check for pathologies.
Who is responsible?

• There is a bug in your software so that the results are wrong?

• The doctor use the software incorrectly?
Confidentiality and sharing data

• Formally when starting to work for / collaborate with a health care provider you should sign confidentially contracts. If not ask for it!

• Respect agreements regarding sharing data. Surprisingly what things may may spread.