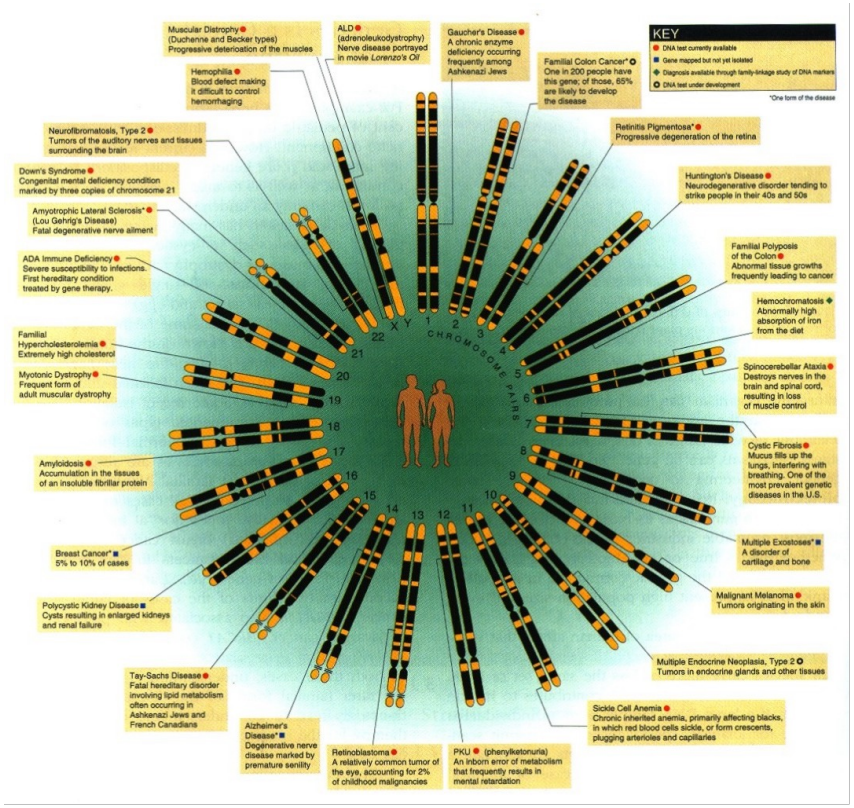
Ethics of Big Data

Yves Moreau

KU LEUVEN

Questions

- You can ask questions at any time


KEY
DNA test currently available
Gene mapped but not yet isolated
Diagnosis available through family-linkage study of DNA markers
DNA test under development
*One form of the disease
Muscular Distrophy
(Duchenne and Becker types)
Progressive deterioration of the muscles
Hemophilia
Blood defect making it difficult to control hemorrhaging
Neurofibromatosis, Type 2
Tumors of the auditory nerves and tissues surrounding the brain
Down's Syndrome
Congenital mental deficiency condition marked by three copies of chromosome 21
Amyotrophic Lateral Sclerosis*
(Lou Gehrig's Disease)
Fatal degenerative nerve ailment
ADA Immune Deficiency
Severe susceptibility to infections. First hereditary condition treated by gene therapy.
Familial Hypercholesterolemia
Extremely high cholesterol
Myotonic Dystrophy
Frequent form of adult muscular dystrophy
Amyloidosis
Accumulation in the tissues of an insoluble fibrilar protein
Breast Cancer*
5% to 10% of cases
Polycystic Kidney Disease
Cysts resulting in enlarged kidneys and renal failure
Tay-Sachs Disease
Fatal hereditary disorder involving lipid metabolism often occurring in Ashkenazi Jews and French Canadians
Alzheimer's Disease*
Degenerative nerve disease marked by premature senility
Retinoblastoma
A relatively common tumor of the eye, accounting for 2% of childhood malignancies
PKU (phenylketonuria)
An inborn error of metabolism that frequently results in mental retardation
Sickle Cell Anemia
Chronic inherited anemia, primarily affecting blacks, in which red blood cells sickle, or form crescents, plugging arterioles and capillaries
Multiple Endocrine Neoplasia, Type 2
Tumors in endocrine glands and other tissues
Malignant Melanoma
Tumors originating in the skin
Multiple Exostoses*
A disorder of cartilage and bone
Cystic Fibrosis
Mucus fills up the lungs, interfering with breathing. One of the most prevalent genetic diseases in the U.S.
Spinocerebellar Ataxia
Destroys nerves in the brain and spinal cord, resulting in loss of muscle control
Hemochromatosis
Abnormally high absorption of iron from the diet
Familial Polyposis of the Colon
Abnormal tissue growths frequently leading to cancer
Huntington's Disease
Neurodegenerative disorder tending to strike people in their 40s and 50s
Retinitis Pigmentosa*
Progressive degeneration of the retina
Familial Colon Cancer*
One in 200 people have this gene; of those, 65% are likely to develop the disease
Gaucher's Disease
A chronic enzyme deficiency occurring frequently among Ashkenazi Jews
ALD
(adrenoleukodystrophy)
Nerve disease portrayed in movie Lorenzo's Oil
CHROMOSOME PAIRS
X Y
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22


دولة الكويت ترحب بكم
Welcome To State Of Kuwait
13 CODIS Core STR Loci
with Chromosomal Positions
TPOX
D3S1358
D5S818
FGA
CSF1PO
D7S820
D8S1179
TH01
VWA
AMEL
D13S317
D16S539
D18S51
D21S11
AMEL
1 2 3 4 5 6 7 8 9 10 11 12
13 14 15 16 17 18 19 20 21 22 X Y
微信号: hmrbs

It’s only data, after all


Bloomberg
Bloomberg
GOOGLE EMPLOYEE RESIGNS OVER CHINA PLANS


Clearview.ai

Overview

- Part 1: Introduction to ethics and bioethics
- Part 2: Ethics and philosophy of AI
- Part 3: Data ethics, the GDPR, and the AI Act

Houston, we have a problem

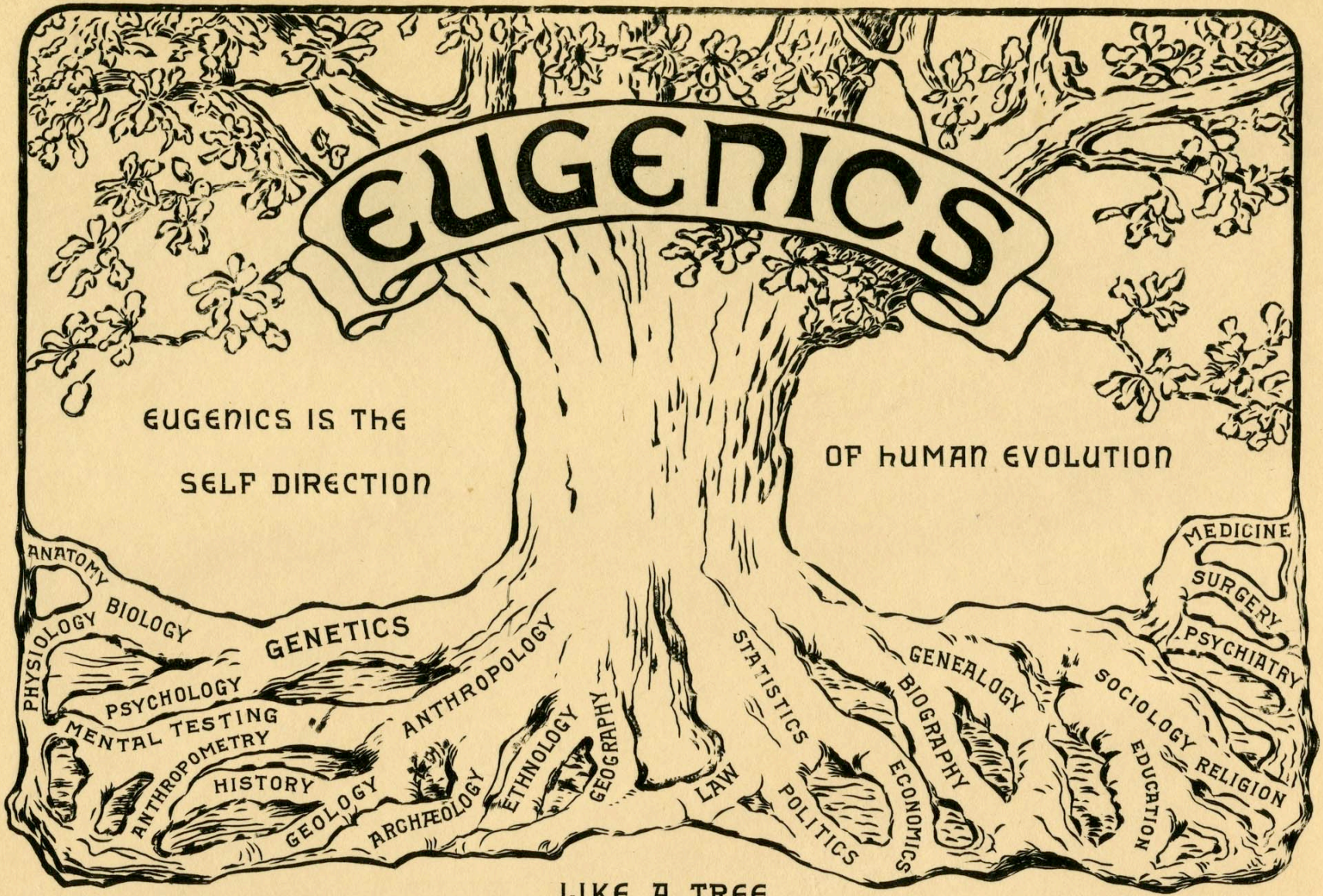
Normative ethics

- (cont'd)
  - Consequentialism
    - Bentham
    - "Judge the morality of actions by their consequences"
    - Utilitarianism: maximize 'happiness' for the greatest number
    - Ethical egoism (self-interest), state consequentialism (state welfare), situation ethics (love), intellectualism (knowledge), etc.
  - Pragmatic ethics
    - With moral progress, ethics evolve

No 'right' theory of normative ethics, but rather competing perspectives

Differences in value systems

- Moral foundations theory
  - Care/Harm
  - Fairness/Cheating
  - Loyalty/Betrayal
  - Authority/Subversion
  - Sanctity/Degradation
  - Liberty/Oppression
- Take the test
  - https://www.idrlabs.com/morality/6/test.php



LIKE A TREE

EUGENICS DRAWS ITS MATERIALS FROM MANY SOURCES AND ORGANIZES THEM INTO AN HARMONIOUS ENTITY.

Eugenics: the original sin?

- Francis Galton (statistician)
  - Coined the term eugenics in 1883
- Alexander Graham Bell (AT&T)
- Winston Churchill (English prime minister)
- Ronald Fisher (statistician)
- Theodore Roosevelt (US president, New Deal)
- Helen Keller (first deaf-blind person to obtain a university degree)
- Francis Crick (DNA double helix)

- Large-scale sterilization campaigns


Nuremberg doctors trial

The Nuremberg code (1947)

1. Voluntary consent of the human subject is absolutely essential
2. The experiment must yield generalizable knowledge that could not be obtained in any other way and is not random and unnecessary in nature
3. Animal experimentation should precede human experimentation
4. All unnecessary physical and mental suffering and injury should be avoided
5. No experiment should be conducted if there is reason to believe that death or disabling injury will occur

The Nuremberg code (1947)

6. The degree of risk to subjects should never exceed the humanitarian importance of the problem
7. Risks to the subjects should be minimized through proper preparations
8. Experiments should only be conducted by scientifically qualified investigators
9. Subjects should always be at liberty to withdraw from experiments
10. Investigators must be ready to end the experiment at any stage if there is cause to believe that continuing the experiment is likely to result in injury, disability or death to the subject

Declaration of Geneva (1948)

- Modern form of Hippocratic Oath

- As a member of the medical profession
  - I solemnly pledge to dedicate my life to the service of humanity;
  - The health and well-being of my patient will be my first consideration;
  - I will respect the autonomy and dignity of my patient;
  - I will maintain the utmost respect for human life;

Declaration of Geneva (1948)

- I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient;
- I will respect the secrets that are confided in me, even after the patient has died;
- I will practice my profession with conscience and dignity and in accordance with good medical practice;
- I will foster the honour and noble traditions of the medical profession;

Declaration of Geneva (1948)

- I will give to my teachers, colleagues, and students the respect and gratitude that is their due;
- I will share my medical knowledge for the benefit of the patient and the advancement of healthcare;
- I will attend to my own health, well-being, and abilities in order to provide care of the highest standard;
- I will not use my medical knowledge to violate human rights and civil liberties, even under threat;
- I make these promises solemnly, freely and upon my honour.

Declaration of Helsinki (1964)

- Extends Nuremberg code
  - Minimize harm to the environment
  - Ensure respect for all human subjects
  - Provide appropriate access to underrepresented groups
  - Respect the welfare of animals used for research
  - Submit research protocol to the research ethics committee for approval
  - Protect the privacy of research subjects
  - Adequately inform subjects of aims, methods, and funding
  - Seek freely-given informed consent


skegee Experiment | Genealogy Roadshow
The Tuskegee experiment (1932-1972)

The Tuskegee experiment (1932-1972)

- John C. Cutler (assistant Surgeon General 58-60, Prof. U. Pittsburgh)
  - https://www.youtube.com/watch?v=3I3vPgJNFwg (03:30, 34:52, 42:03, 49:02)

- Raymond A. Vonderlehr (CDC director 1947-51)
- John R. Heller (NCI director 48-60, CEO Memorial Sloan-Kettering Cancer Center 60-63)
- Thomas Parran Jr. (Surgeon General 36-48)
- Eugene Dibble, Eunice Rivers

Moral disengagement

- Albert Bandura
- Cognitive dissonance
  - Misalignment between behavior and values
  - Cognitive strategies to reduce dissonance

Behavior

1. Moral justification
2. Advantageous comparison
3. Euphemistic labelling

Moral disengagement

Effects

4. Disregarding or misrepresenting injurious consequences

Victim

5. Dehumanization

6. Blaming the victim

Link between behavior and effect

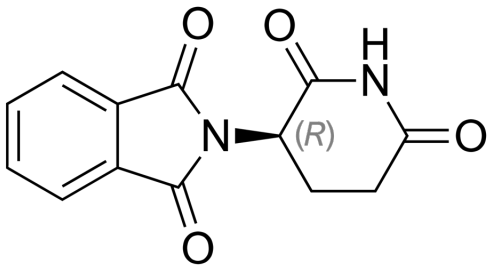
7. Displacement of responsibility

8. Diffusion of responsibility

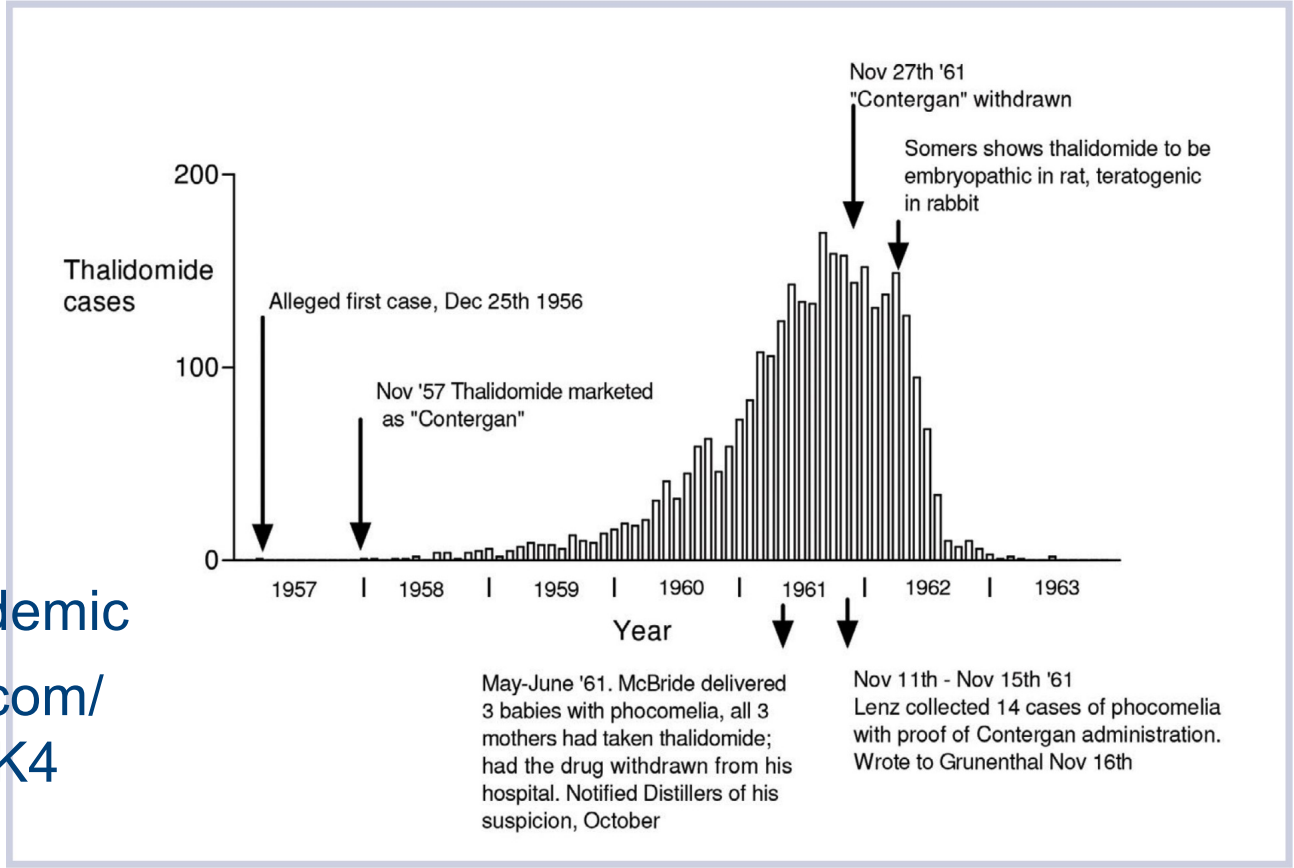
Thalidomide

- Sedative (non-addictive, hard to overdose), anti-convulsive, anti-emetic (morning sickness)

Thalidomide



- Grünenthal Co., Germany (Mückter, Ambros [sArin], Baumkötter, Staemmler, Schenck)
- 1954 patent by Keller and Kunz (contested origin)
- Marketed 1957
- Withdrawal 1961
- >10,000 births?
- Currently used against leprosis and myeloma



- The Thalidomide Epidemic

  https://www.youtube.com/watch?v=_ZXb3PF-4K4

'Heroine' of FDA Keeps Bad Drug Off of Market: Vital FDA Delay Keeps Bad Drug Off of Market
By Morton Mintz Staff Reporter
The Washington Post, Times Herald (1959-1973); Jul 15, 1962;
ProQuest Historical Newspapers: The Washington Post
pg. A1

Linked to Malformed Babies

'Heroine' of FDA Keeps Bad Drug Off of Market

By Morton Mintz
Staff Reporter

This is the story of how the skepticism and stubbornness of a Government physician prevented what could have been an appalling American tragedy, the birth of hundreds or indeed thousands of armless and legless children.

The story of Dr. Frances Oldham Kelsey, a Food and Drug Administration medical officer, is not one of inspired prophesies nor of dramatic research breakthroughs.

She saw her duty in sternly simple terms, and she carried it out, living the while with insinuations that she was a bureaucratic nitpicker, unreasonable — even, she said, stupid. That such attributes could have been ascribed to her is, by her own acknowledgement, not surprising, considering all of the circumstances.

The Washington Post

DR. FRANCES O. KELSEY
. . . skepticism wins

What she did was refuse to be hurried into approving an application for marketing a new drug. She regarded its safety as unproved, despite considerable data arguing that it was ultra safe.

It was not until last April, 19 months after the application was filed with the FDA, that the terrible effects of the drug abroad were widely reported in this country. What remains to be told is how and why Dr. Kelsey blocked the introduction of the drug before those effects were suspected by anyone.

Dr. Kelsey invoked her high standards and her belief that the drug was "peculiar" against these facts:

The drug had come into widespread use in other countries. In West Germany, where it was used primarily as a sedative, huge quantities of it were sold over the counter before it was put on a prescription basis. It gave a prompt, deep, natural sleep that was not followed by a hangover. It was cheap. It failed to kill even the would-be suicides who swallowed massive doses.

And there were the reports on experiments with animals. Only a few weeks ago the American licensee told of giving the drug to rats in doses 6 to 60 times greater than the comparable human dosage. Of 1510 offspring, none was delivered with "evidence of malformation."

In a separate study, one rat did deliver a malformed offspring, but the dosage had been 1200 times the usual one. Rabbits that were injected with six times the comparable human dose also were reported to have produced no malformed births.

Recently, the FDA publicly

See DRUG, A8, Col. 1

Frances Oldham Kelsey
"said she could not help regarding thalidomide as a "peculiar drug." It troubled her that its effects on experimental animals were not the same as on humans – it did not make them sleepy."

Thalidomide

- 1968 criminal trial in Germany
- 1970 settlement
- In Germany, most compensations paid by government (2400 victims alive) – compensation waives right to sue
- IN UK, 1972 article by the Sunday Times led to change in settlement from £3.25m to £32.5m (400 victims alive)
- 2012: “We also ask for forgiveness for not reaching out to you from human to human for almost 50 years... We ask that you see our long speechlessness as a sign of the silent shock that your fate has caused us.”
- Victims argue that they are not able to access all promised compensations

Double effect fallacy

- Double effect principle
  - Under what circumstances is it morally acceptable to carry out an action that has both morally positive and negative effects?

- Double effect fallacy
  - Conditions for the double effect principles are not met
  - False dilemma

Seven pillars of clinical research

1. Autonomy
2. Non-maleficence
3. Beneficence
4. Fidelity
5. Truthfulness
6. Confidentiality
7. Justice

The Belmont report (1979)

- Birth of bioethics
- Respect for persons
  - Individuals should be treated as autonomous agents
  - Persons with diminished autonomy are entitled to additional protections
- Beneficence
  - Do no harm
  - Maximize possible benefits and minimize possible harm
- Justice
  - Requires that individuals and groups be treated fairly and equitably in terms of bearing the burdens and receiving the benefits of research

IRB & ethics committee

- EU: research ethics committee
- US: institutional review board

- The major roles of IRBs (US) in oversight of research are
  - Initial review and approval or disapproval of the proposed research activity
  - Ensuring that the proposed informed consent process meets all of the requirements of 45 CFR 46.116
  - Providing continuing oversight for progress reports and protocols for ongoing research studies

US IRB: 45 CFR 46

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, […]

US IRB: 45 CFR 46

[…] the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

US IRB: 45 CFR 46

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

US IRB: 45 CFR 46

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Areas of review (UK NHS)

- Relevance of trial
- Trial design
- Risks and benefits
- Protocol
- Suitability of investigator and supporting staff
- Investigator brochure
- Quality of the facilities
- Recruitment procedures
- Subject information
- Consent procedure
- Justification for including minors or adults unable to give informed consent
- Insurance/ indemnity
- Rewards or compensation for investigators and subjects

Further areas of review

- Confidentiality and data protection
- Retention and future uses of tissue samples
- Sub-studies (e.g. genetics)
- Radiation exposure
- Arrangements for notifying other care professionals
- Criteria for subject withdrawal
- Criteria for early termination
- Data monitoring arrangements
- Exit strategies – continued care of subjects outside trial
- Patient/public involvement in trial design
- Publication/dissemination of results
- Sponsorship arrangements
- Sources of funding

The New York Times

Biogen Abandons Its Controversial Alzheimer's Drug Aduhelm

The pharmaceutical company will give up its ownership rights to the drug and stop a clinical trial that had been aimed at confirming whether it works.