Health and technology: ethical issues related to behavioral observation and experimentation

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What is ethics?

- branch of philosophy that involves systematizing, defending, and recommending concepts of right and wrong behavior.
  - *Metaethics* investigates where our ethical principles come from, and what they mean.
  - *Normative ethics* try to define standards that regulate behavior: virtues, duties and the consequences of our behavior on others.
  - *Applied ethics* involves examining specific controversial issues,

http://www.iep.utm.edu/ethics/

In “SMART”summer-school framework

1. Research in Ethics
   - convergence of technics and human behavior
   - Example of ethical controversies
2. Ethics in research
   - deontology of research
   - regulation of human experimentation

1-Research in ethics

- Three examples of contemporary ethical issues:
  - Transhumanism.
  - Control and surveillance
  - Ethics of robotics
  - Example: a social dilemma of autonomous vehicles.

Human Enhancement

- Transhumanism
  - Liberal ideology
  - Convergence of NBIC technologies for enhancing human performance “beyond the species-typical level »
  - Technology is an opportunity for human to act on his own evolution.
- Bioperservationists
  - “human enhancement technologies will undermine our human dignity”
  - For preservation of basic human rights and autonomy.
  - But distinctions “artificial’’ versus ‘‘natural’’ or “therapy” versus “enhancement” problematic.
- Bioethics: use of enhancement should be regulated (Allhoff 2011)
  - Freedom, but Responsibility
  - Risk of external pressure by peers.
  - Possible risk for health
  - Risk for equality and Justice (enhancement enabling for the few, disabling for many)
- Social issues (Ledevedec, 2013)
  - Transhumanism is in a logic of medicalization of society and instrumentalization of human
  - Disrupt social values and social progress

Control and surveillance

biometry, videosurveillance, RFID

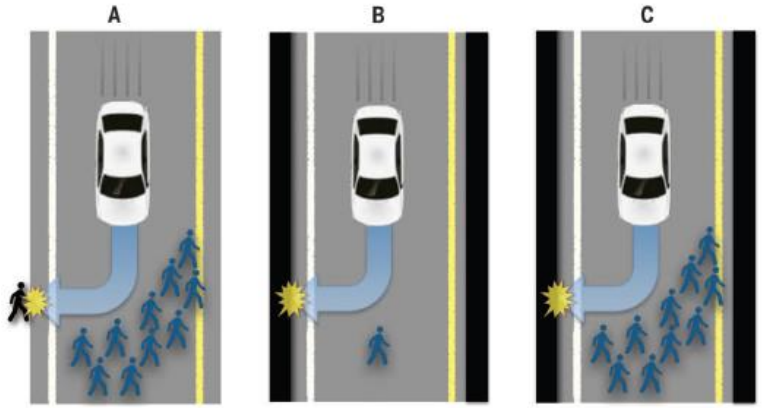
- Risks of surveillance
  - Security versus privacy and autonomy of citizens
  - Centralized (« big brother ») or private and diffuse.
  - May threaten social values instead of protect them.
- Major ethical issues (Boucher 2014)
  - Deploiement proportional to the insecurity
  - vigilance on the finality (terrorism, crime then commercial..)
  - Protection of individual data but difficult: technologies are intimate and indiscreet.
  - Human or automatic data processing?
  - Information of the citizens and participation to the decisions.

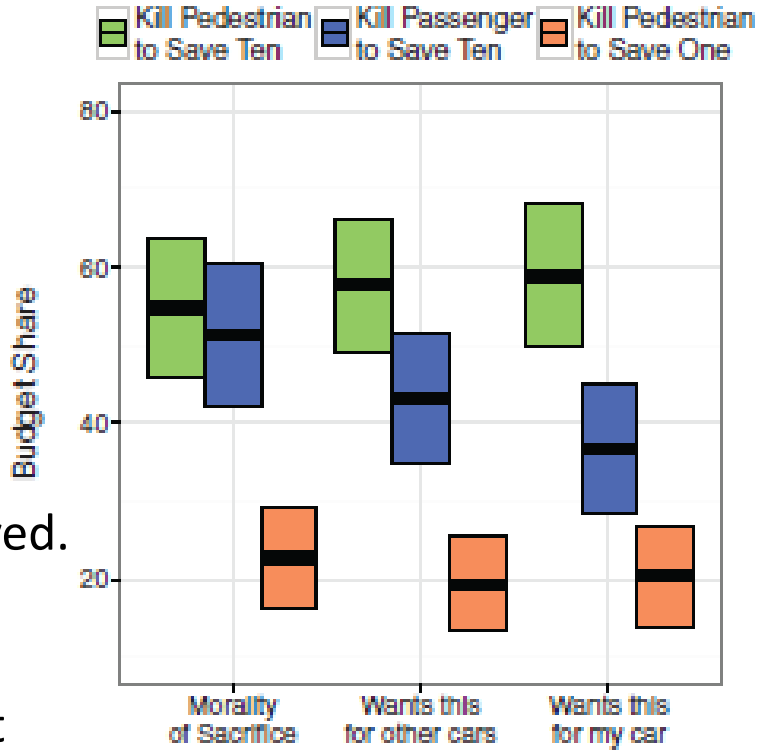
Ethics of robotics

- CERNA (Allistène) 2015: Ethical issues should be part of research activity.
- Ethics committee
- robots interacting with humans,
  - Blurring frontiers between humans and machine and acting on emotion.
- Robots in a medical context
- ecur

The social dilemma of autonomous vehicles

- Avs “should reduce traffic accidents, but they will sometimes have to choose between two evils, such as running over pedestrians or sacrificing themselves and their passenger to save the pedestrians” (Bonnefon et al Science 2016)





Known thought experiment for human decision.
Utilitarian ethics: maximize the number of lifes saved.
The programming of AV has to account for moral value.
People judge utilitarian algorithms more moral but would not buy it. Counterproductive despite the risk to postpone a safer technology.

2-Ethics in research

- Deontology
  - French chart in January 2015

- International regulations for human experimentation

Declaration of Helsinski

« Ethical principles for medical research involving human subjects »

- World Medical Association (WMA 1964, 7th revision 2013)
- A set of ethical principles regarding human experimentation developed in direct response to **research abuses** in the 20th century.
  - "health of my patient is my first consideration",
  - "informed consent",
  - protocols should be examined by ethics committees.
- Universal moral authority,
- But recent updates debated.
- Other international textes:
  - CIOMS (Council for International Organizations of Medical Sciences, UN) International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993-2002)
  - UNESCO Universal Declaration on Bioethics and Human Rights. 2005.

Belmont report

- US National Commission (1974–1978)
  - Protection of Human Subjects of Biomedical and Behavioral Research
  - Belmont report issued in 1978.
- The Commission was directed to consider the boundaries between biomedical and behavioral research
- Agreement with other federal agencies and departments
  - **Common Rule** ”Code of federal regulations, protection of human subjects”.
  - Creation of the Office for Human Research Protections (US Department of Health and Human Services HHS).
  - Defines requirements for Institutional Review Board (IRB): membership, function, operations, review of research, and record keeping.

Common rule for ethical research

Research produces benefits valued by society. Institutions engaged in research should foster a culture of ethical research.

ETHICAL RESEARCH rests on three principles

1. RESPECT for persons' autonomy, meaning the researcher gives adequate and comprehensive information about the research and any risks likely to occur, understandable to the participant, and allows them to voluntarily decide whether to participate.
2. BENEFICENCE, meaning the research is designed to maximize benefits and minimize risks to subjects and society.
3. JUSTICE, meaning that the research is fair to individual subjects and does not exploit or ignore one group (e.g., the poor) to benefit another group (e.g., the wealthy).

- *http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html*

International review Board, IRB

- Must be agreed by Office for Human Research Protections
- Their role is to examine research protocol by reference to the common rule.
- BEFORE the beginning of the project

- Formal approval is most often needed
  - In USA: approval by an IRB is mandatory if federal funding.
  - Approval of an ethic committee may be mandatory to submit some projects.
  - Publications: journals may impose approval by a local ethics committee or an US IRB.

Exceptions (US regulation)

- Research in conventional educational settings
  - if subjects cannot be identified or exposed to risks.
- Research involving the analysis of existing data/material
  - if they are already publicly available, or if an individual subjects cannot be identified in any way.
- Studies intended to assess the performance of public service programs, or to evaluate consumer acceptance.

Decisions about exemption should be made by an IRB representative, not by the investigators.

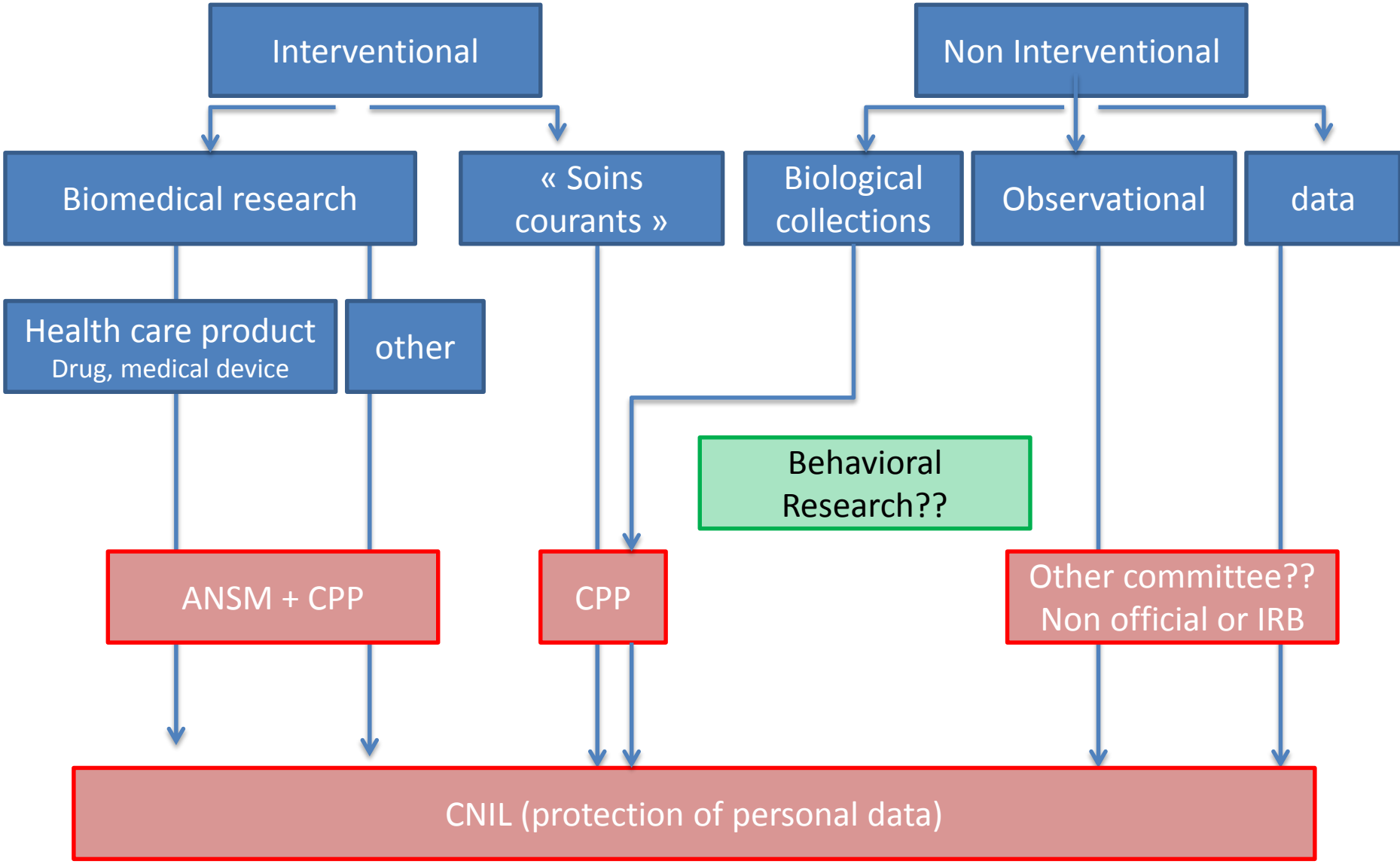
Social sciences and the « common rule »

- Oral histories, unstructured interviews, collecting anecdotes, and similar free speech activities often do not constitute "human subject research" .. and are not intended to be covered by clinical research rules.
- The NSF guidelines assure IRBs that the regulations have some flexibility and rely on the common sense of the IRB to focus on limiting harm, maximizing informed consent, and limiting bureaucratic limitations of valid research.
- http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp#top

The case in France

- Biomedical research: Hurriet-Sérusclat law (1988, revised 1994, 2004)
- CPP (committee for the protection of persons) more constraining than IRB.
  - Promoter (company, institution, individual ..), Insurance
  - The principal investigator should be MD
  - The room should be agreed.
- Submit in parallel to ANSM (agence national de sécurité du médicament et des produits de santé) and CNIL (protection of personal data).

France: current classification (2004)



Jardé law in France

- 2012, but the decrees to implement act are not yet published (EU harmonization).
- Advice of a CPP should be mandatory for all «research implying humans», including behavioral researches and social sciences.
- Risk-based approach :
  - Interventional (biomedical risk)
  - Interventional with minimal risk
  - Observational (no constraint at all)
- "*Ordonnance*" June 2016
- Future organization unknown.

Borders no easy to define

- Minimal risk: “The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests..” US
- Examples (CNRS)
- Invasive → CPP
  - Crossing the skin barrier
  - Administration of medicine or other product (oral, cutaneous, experimental diet..)
  - Penetration of focal physical signal (e.g. X rays)
- Non invasive :
  - EEG, EMG, Photos, recordings of sound..
  - Presentation of images..
  - Moderate physical activity
- Observational
- Coming to an experimental room can be considered as a constraint.

Research Ethic Committees in France

- Comité Consultatif National d'éthique (CCNE)
  - General report and recommandations (bioethics).
  - 1993: report on behavioral research…
- Recommandations COMETS CNRS
- Ethic Committees, other than CPP
  - Inserm CEEI, agreement IRB
  - University Paris Descartes (CERES, associated to CPP)
  - University of Provence, Université Lille 3, University Reims..
  - Specialized e.g. SFTAG for gerontechnology
  - function on a voluntary basis

Some recomandations before submitting a protocol!

Informed consent

The participants must need to know :

- all of the inconveniences and risks,
- what will happen to the information after the research
- be informed of the outcome.
- The risk to detect a pathology
- phone or email of the contact person.

Allow subjects to drop out without consequences.

The style and format of the information and consent form should be adapted to the participant (age, cultural context..).

Specific information and consent needed

for further re-use of data.

for image and video (de-identified)

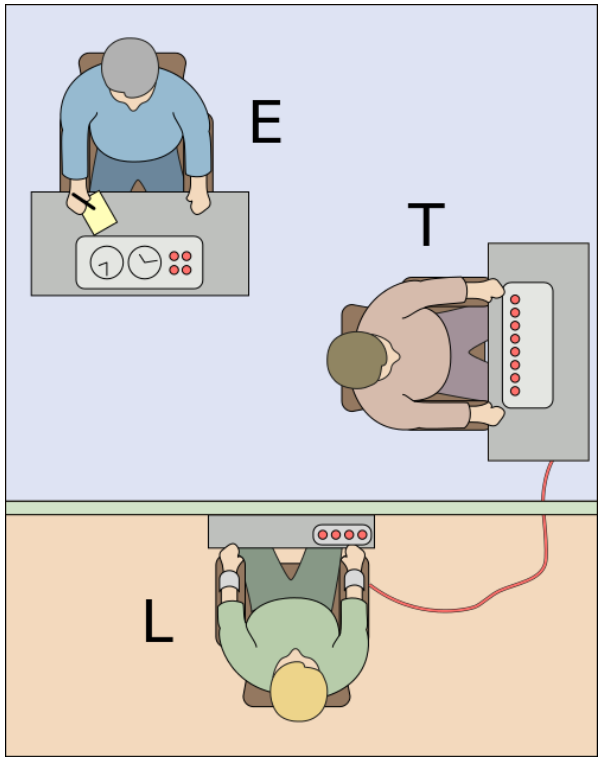
No deceit!

Before the experiment, the information may be uncomplete but not false and must be completed afterward.

Milgram experiment on obedience to authority figure **was unethical**.

WE WILL PAY YOU $4.00 FOR ONE HOUR OF YOUR TIME

Persons Needed for a Study of Memory



Risk / benefit

A research interaction may cause emotional or psychological harm.
Do the maximum to minimize harm,

- Fields investigators must be qualified, in particular with vulnerable participants.
- The investigator must anticipate longer term psychological reactions : a counsellor or psychologist should be available for consultation.
- If a pathology could be detected: anticipate medical advice.

Breaches of confidentiality may induce risks : social harm (stigma), physical, financial, legal or moral harm (e.g. when studying illegal behaviors such as drug abuse, violence..).

Confidentiality and privacy

PRIVACY refers to persons; and to their interest in controlling the access of others to themselves.

CONFIDENTIALITY refers to data
information should be restricted to certain people.

The level of confidentiality should be adapted with the level of risk applicable to all identified persons.
Minimum : coding the ID.
Images and video should be de-identified.

DATA REPOSITORY
The participants **should be informed and consent** to ananymous storing and re-use of data.

Secondary analysis of public de-identified data does not requires IRB

Vulnerable participants.

- Children
  - may participate to « behavioral research with minimal risk ».
  - Both the participant and the legal guardian must give an informed consent.
- Participants with pathology, handicap…
  - may participate to « behavioral research with minimal risk » with appropriate caution.
  - They must not be discriminated.
- Vulnerable population without basic rights need specific ethical consideration.

Compensation

- The payment must not be coercive if the study is at risk.
  - Reimbursement of fares
  - Compensation for time, not a salary.
- The amount may depend on the performance.

- participants should be protected by appropriate insurance.

Thank you for your attention!

Helsinski Principles

Primarily for physicians (2).

- “health of my patient is my first consideration” (3). Medical progress is based on research (4). Purpose: understanding illnesses and evaluate medical intervention (6)

General principles:

- The scientific goal (new knowledge) cannot take precedence on the rights and interest of subjects (8).
- Duty: protection of life, health, dignity, integrity, right to self-determination, privacy and confidentiality of research subjects (9)
- Research conducted by a person with appropriate education and qualification, supervised by a qualified health care professional (12).
- Appropriate compensation if the subject is harmed (13)

Risks burdens and benefits:

- Assess and minimize risks (17)
- only if benefits outweigh the risks (16)

Vulnerable groups

- specially protected (19)
- included only if benefits for this group (20)

Helsinski Principles –bis

Research protocols

- Should conform to scientific principles (21).
- Protocol clearly written and justified. With all information (i.e. concerning funding, conflict of interest…) (22)
- Respect of privacy and confidentiality (24).

Ethics committees

- Protocol should be approved by an ethics committee: transparent, independent and qualified (23).

Informed consent

- Participation must be voluntary (25)
- Information must be adequate and adapted, the subject must be informed of the right to refuse or withdraw . The consent must be freely given, preferentially in writing (26) or if unable by the legal representative (28)
- Caution if dependant relationship (27).
- The refusal must not affect patient-physician relationship (31).
- Seek informed consent for storage or re-use of material or data (32).

Research registration

- Clinical trials should be registered (35) and results publicly available (36)