

Bio-Ethical aspects of pre-hospital studies in the emergency area

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Why is new research needed?

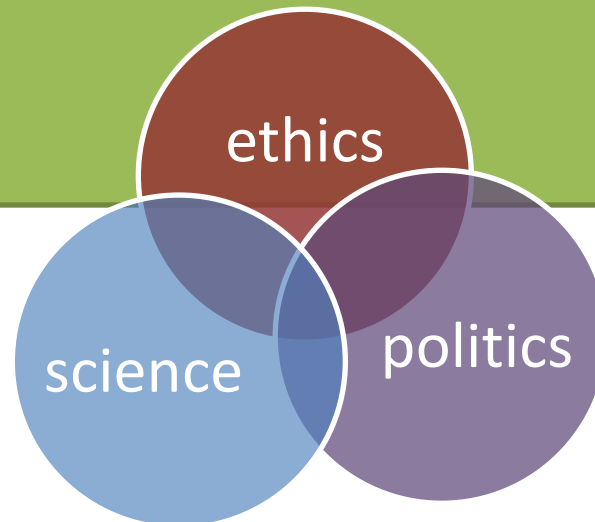
- There is a recognized moral duty to reach the best attainable standards in health through research
- Ethically sounding research projects need to be first of all scientifically sounding (validity) and be recognized as useful mean for the purpose they have been developed for (value)

BIOETHICS: “play fair” in biomedical research

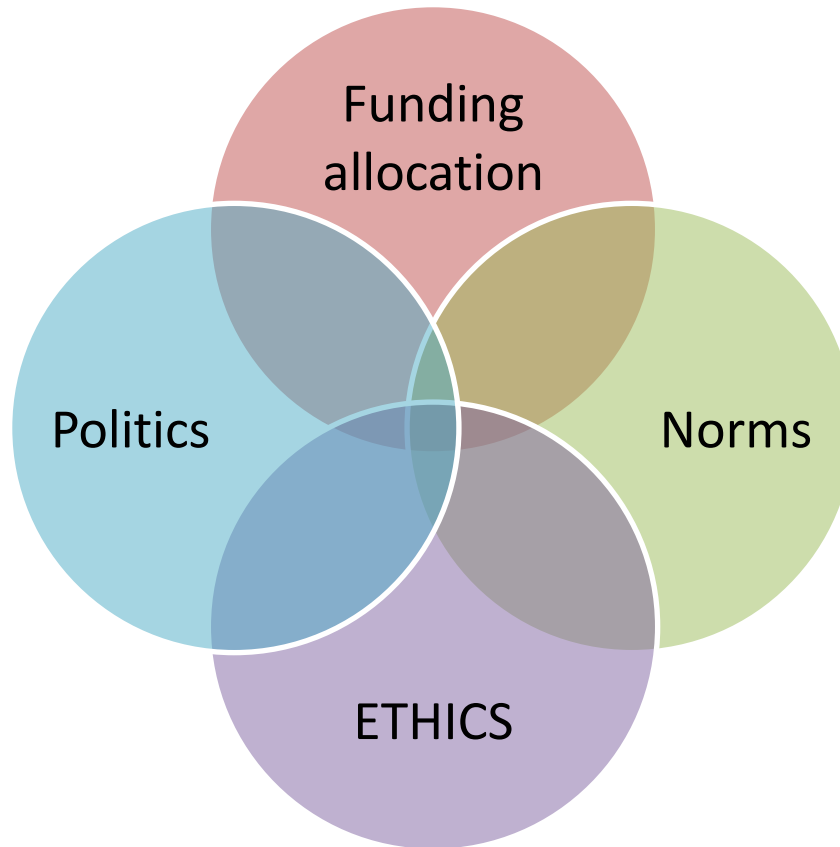
BIOS = LIFE

ETHOS = HABIT

BIO - ETHICS



Just ethics to regulate research fairness?



Theoretical background

Special condition for science. Idea of the republic of science
(progress of humanity as golden aim)

Scientists as the only one able to judge and regulate science
itself



Complete freedom of research

- Defeat of the paradigm of free science and medicine because of great impact on society (nuclear bombs, Tuskegee, etc.)
- Big wave of reflection on science and Society in the World

Main references in the international normative literature

- Oviedo 1997
- CIOMS 1993-2002
- HELSINKI 1964-2008
- Good Clinical Practice (CEE 1991)
- OECD 2004
- UNESCO 2005

Prerequisites for ethical accountancy

- Clear goal
- Value: benefit assessed in the context of use
- Validity: duty for best evidence
- Compliance with ethical standards
- Application for ethical scrutiny

Science and social understanding

- Co-production of science and social needs/uses (see reproductive technologies)
- Coproduction of science and regulation (Jasanoff)
- Changing Rational of costs share (who pays, who buys? who are the real stakeholders? Who decides?)
- Redefinition of what is accepted and perceived as risk and as benefit

Special Ethical considerations for prehospital studies

- Sensible ratio risk vs. expected benefit/efficacy
- Correct use of the new method/molecule/tool vs. standards
- **Correct tests in the pre-human phase that also includes validation with animal-models to get best evidence**
- **Informed consent of the subject (especially sensitive and difficult to obtain in case of emergency situations)**



According to international ethical guidelines, pre-clinical research is not only useful but ethically required for minimize risks in the human setting

Research with animal models

Regulation on the welfare of animals and on the use of them for research changed dramatically in the last decades and requires now fair conditions (food, space, veterinary care etc.) especially in certain countries

Cow sleeping on it's matt in the south part of Lillehammer, Norway.



Regulation

- Animals including vertebrate can be used proven there is not other methodology to obtain the same result
- The use must be proportioned to the goal
- The animal chosen must reflect the best model for specific reseach goal
- If it is possible to use different models the one to be chosen is the less neurologically developed species
- Endangered species or primates can only be used if a special permission is granted

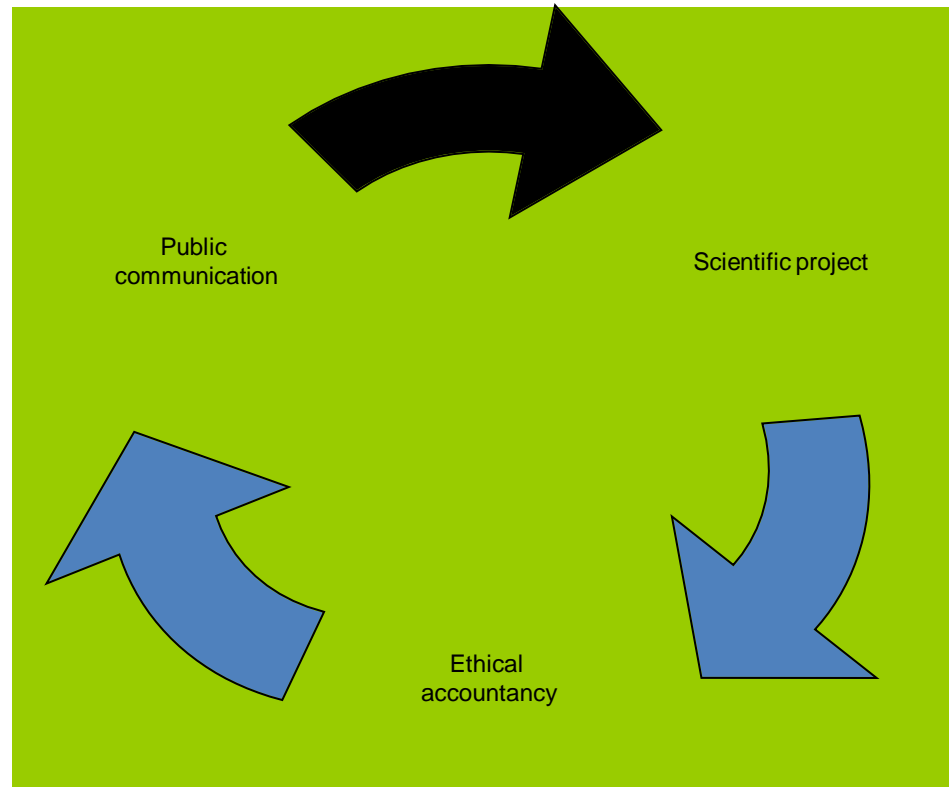
The 3 R's

Recognized as best practice for preclinical studies have been accepted and translated into law in Europe and in several other countries (Dir CEE 86/79; DLgs n.116/92)

- **Replacement** refers to the preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aim
- **Reduction** refers to methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals
- **Refinement** refers to methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals still used*including keeping conditions

*Russell, W.M.S. and Burch, R.L.. "The Removal of Inhumanity: The Three R's". Archived from the original on 2007-04-03

The social setting



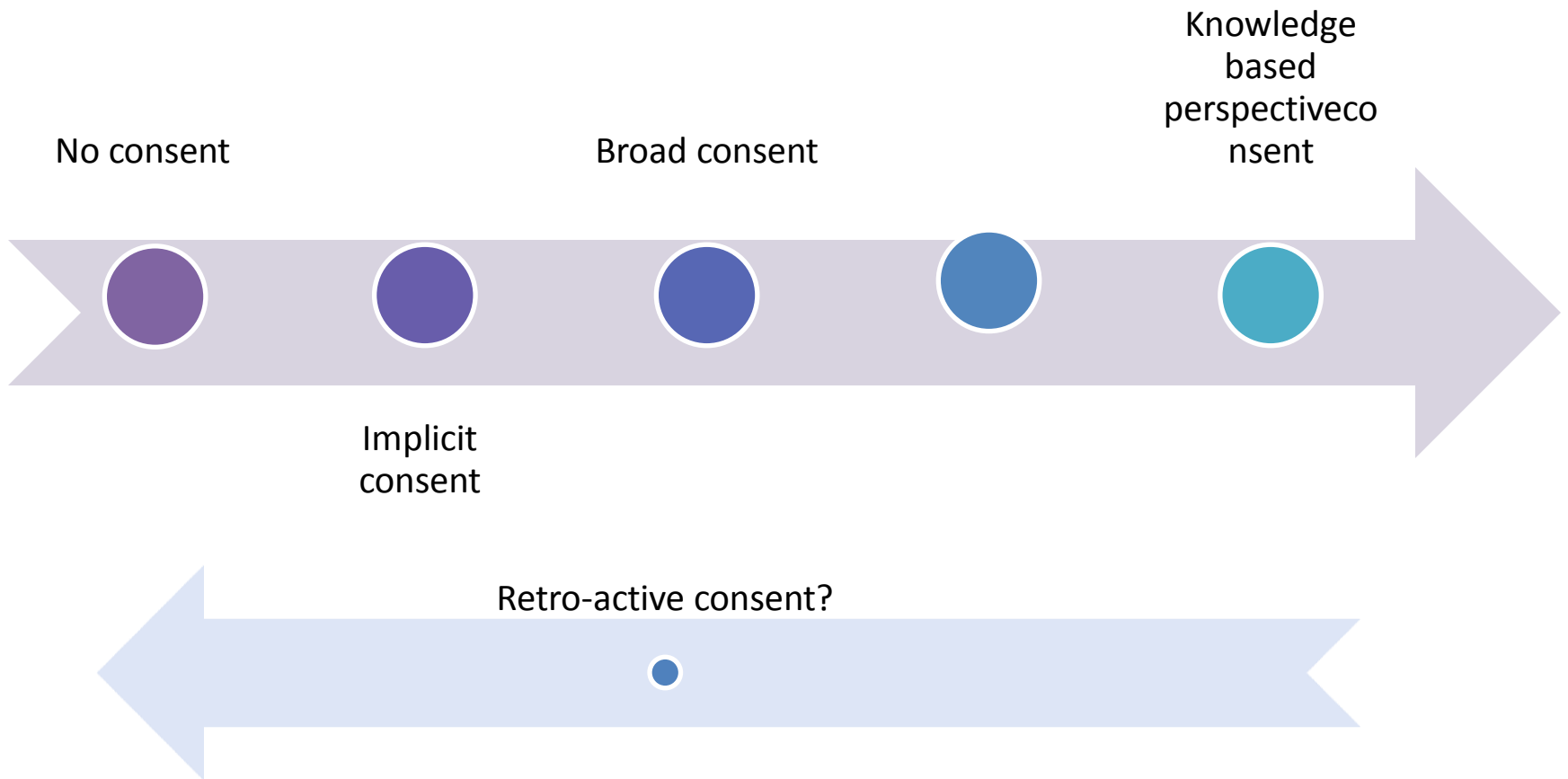
Principle of Autonomy in the human phase “research” in emergency setting

- Often Informed Consent cannot be required in the emergency situation:
 - need of immediate action in order to rescue
 - subject not able to interact (unconscious state and state of life-threatening.)
- Consent for research can be required afterwards?

Consenting equal IC?

- Consenting to take part in a research protocol is not equal to paperwork”informed consent”
- It has to do with the autonomy of the subject and the chance to make an informed choice

Consent types in research



Elements for retrospective” consent

- Intervention cannot be object of consent because has been already performed
- collection of clinical and personal data or samples
- Permission to follow up or monitor the conditions of the rescued person
- Re-contact permission

Advantages for research

- Be able to follow up patient conditions over time and to ask for re-contact permission
- Possibility of follow up studies
- Datasharing and publications in a more extensive way
- Transparency and social acceptance



Communication the first tool for policy and ethics in every phase of research

- transparency in policy research and communication in the community
- declared policy
- sensitivisation of official organization to support