



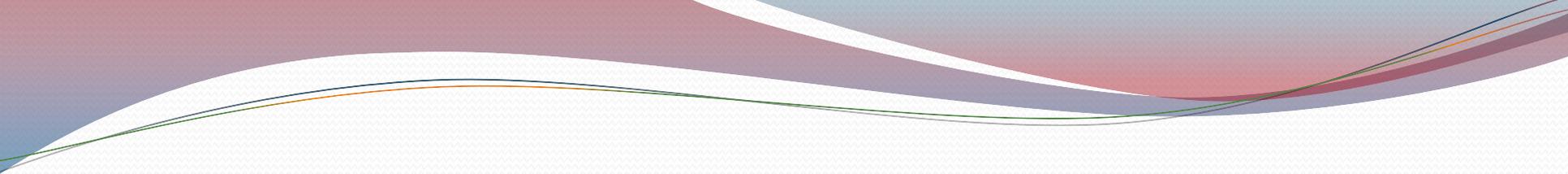
Shiksha Mandal's Jankidevi Bajaj College of Science, Wardha

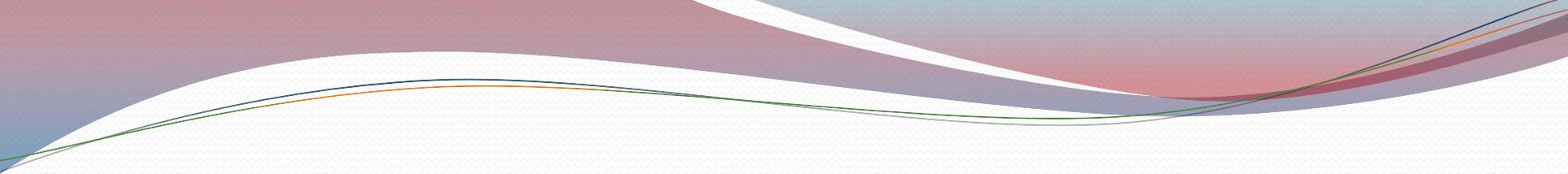
Guest Lecture on Bioethics and Biosafety.

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Under DBT supported STAR College Scheme

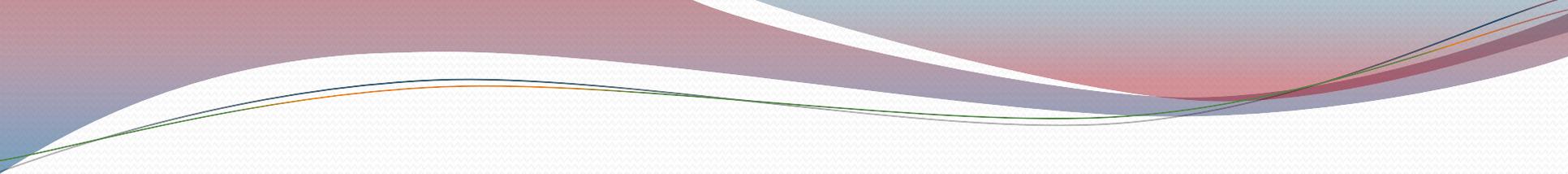
Date: September 16, 2013

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- An Introduction to Bioethics



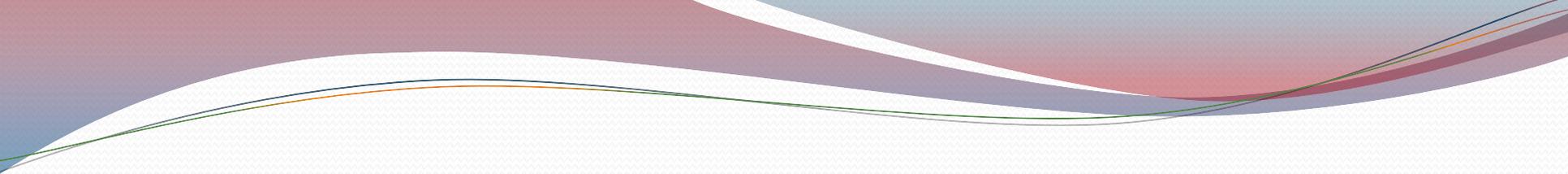
Learning outcomes

- Introduce bioethics through an overview of the tools of the trade
- Develop ability to identify, analyse, and solve ethical dilemmas in the biomedical sciences



Why do we need and what is bioethics?

- Many (or all?) people feel the need to justify their behaviour
 - to explain why their behaviour is (un)acceptable
- Bioethics: how scientists and health professionals ought to behave in the biomedical sciences

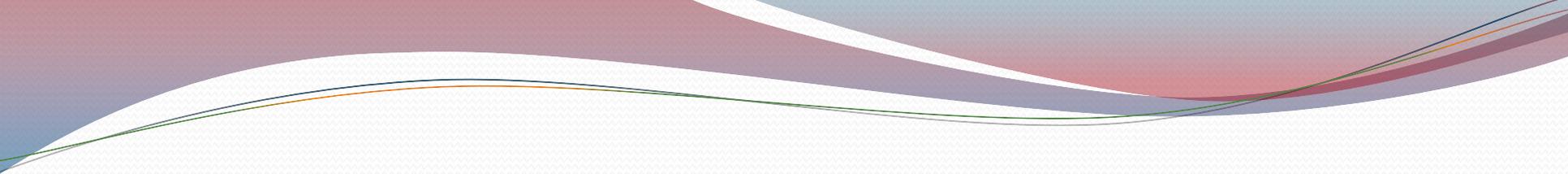


What is bioethics?

- the attempt to understand and justify the link between values (fundamental principles) and actions

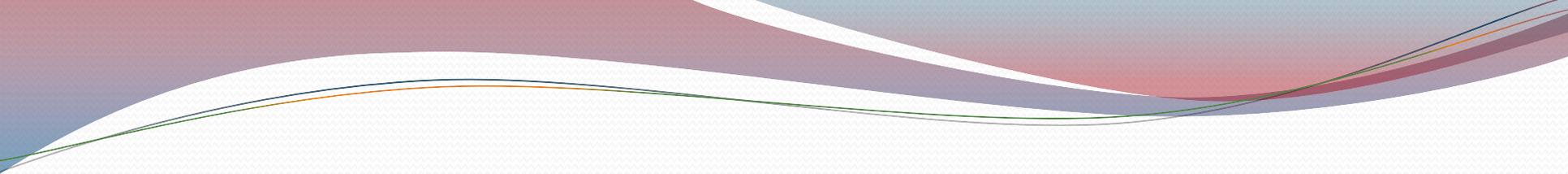
Why is bioethics important?

- Realisation that ‘not everything goes’, e.g.
 - Tuskegee Syphilis Experiment
 - Nazi human experimentation (Nuremberg Trials, 1945-1949)
 - TGN1412 trial: Did something go wrong?
 - Dr Shipman
 - DDT (Rachel Carson’s ‘Silent Spring’)
- Therefore: need for justification



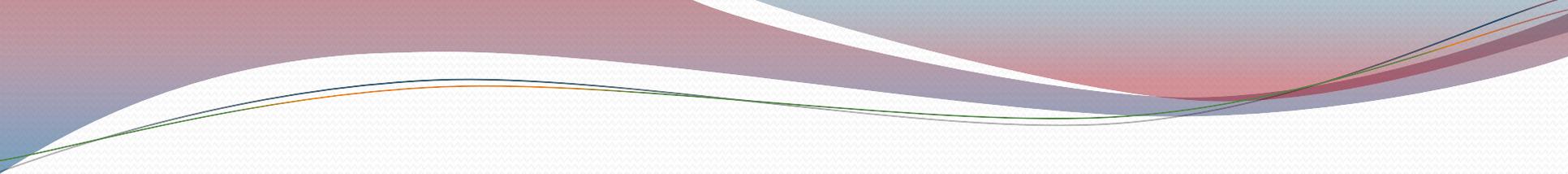
Bioethics and environmental ethics

- Both developed significant momentum in last quarter of 20th century
- Increasingly considered to be inseparable



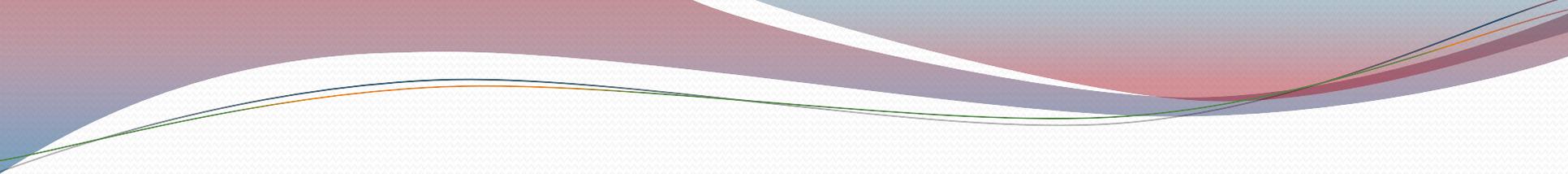
Some key resources

- Journal of Medical Ethics
- Bioethics
- Cambridge Quarterly of Healthcare Ethics
- Hastings Center Report
- American Journal of Bioethics
- Journal of Agricultural and Environmental Ethics
- Environmental Politics
- Ethics and the Environment
- Journal of Public Health Ethics (new in 2008)
- Journal of Animal Ethics (new in 2008)



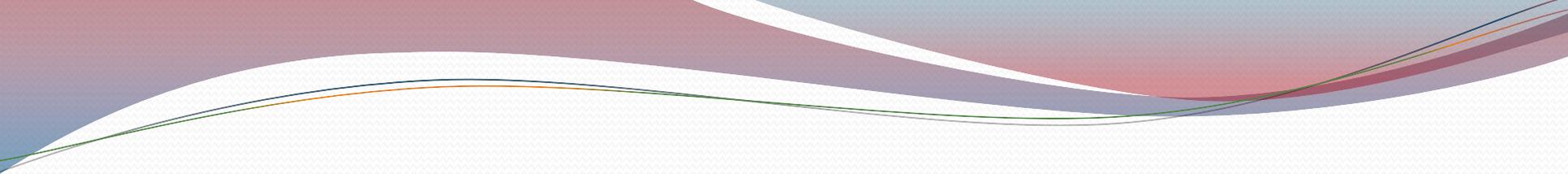
Two dimensions

- law and professional guidelines
- reflection



How does it work?

- Establishing knowledge of the relevant legal and professional guidelines
- Exercise your ability to reflect: How?

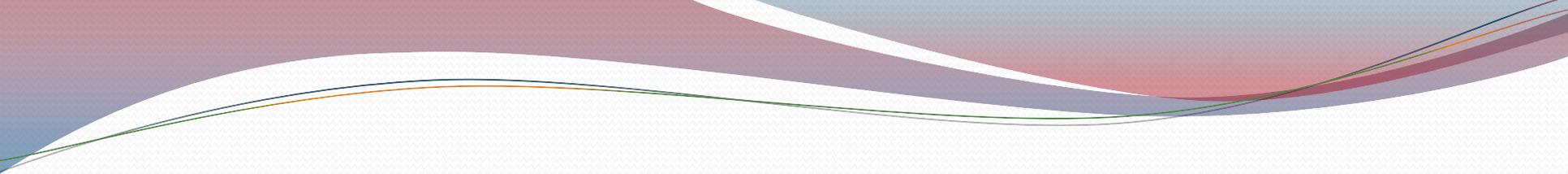


A range of tools

- Principle of non-contradiction
- Analogies
- Thought experiments

Principle of non-contradiction

- A researcher who carries out research on patients with advanced dementia says the following:
 - I believe that researchers who want to carry out research on patients should only proceed if patients give their voluntary, informed consent to research participation.

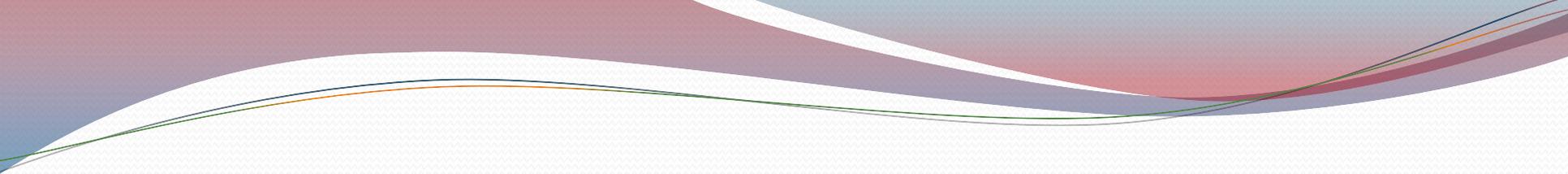


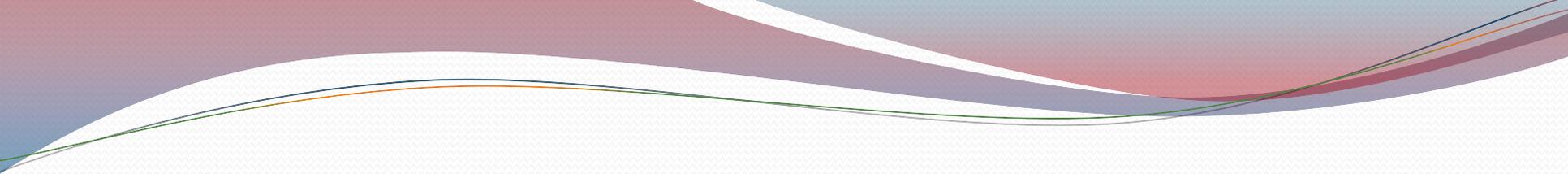
Analogies

- When a research project is likely to kill human research subjects, research should not proceed.
- When a research project is likely to kill nonhuman research subjects, research should not proceed.
 - Is this a valid analogy? Why/why not?

Thought experiments

- Imagine the explosion of a nuclear reactor, leaving your one year old child exposed to nuclear fall out. Numerous children develop leukaemia, including your own. Bone marrow can now be generated most successfully by reprogramming brain cells, which are more resistant to radiation damage than bone marrow. Unfortunately, a whole brain must be destroyed. The extracted stem cells could be reprogrammed to treat ten children.

- 
- Since a one in eleven chance of certain death seems preferable to a one hundred percent chance of imminent death, the question is: would you enter your child into a lottery and risk a 1/11 chance of your child being sacrificed (by being killed to treat others) or refrain from entering your child into such a lottery (which would mean certain death for your child)? (Savulescu J. The Embryonic Stem Cell Lottery and the Cannibalization of Human Beings. *Bioethics* 2002;**16**:508-529.)



Some ethical theories

- Consequentialism
- Deontology
- Virtue theory
- Principlism

Consequentialism

- Good: what is likely to produce more good than bad consequences.
- Bad: what is likely to produce more bad than good consequences.
 - E.g.: utilitarianism: good is what produces the greatest utility (usually understood in terms of ‘happiness’) for the greatest number.
 - Often used for resource allocation issues: how can we promote the largest amount of happiness with limited resources?
 - Example: Savulescu’s thought experiment

Consequentialism

- Problems:
 - Can we know the likely consequences of our actions? What if there is great uncertainty?
 - Impartial moral theory \leftrightarrow Some would say that we have a duty to be partial.
 - Certain rules may be ignored (yet some forms of consequentialism take some deontological principles into consideration)

Deontology

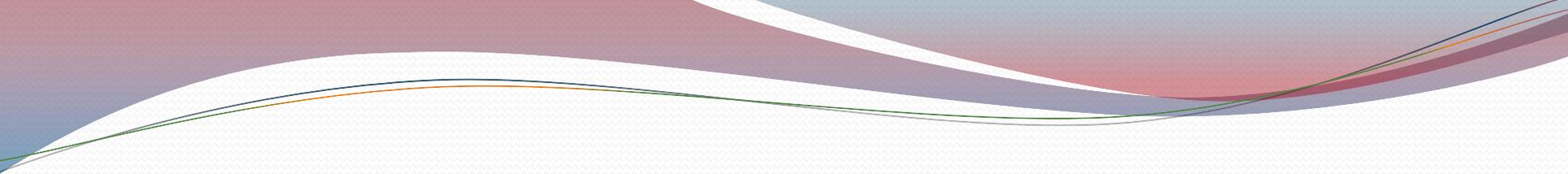
- From the Greek word for ‘duty’
- rules, which express our duties
 - E.g. killing someone to give their organs to someone else may ignore our duty to respect that person’s right to life.

Deontology

- Problems:
 - Always following rules of conduct can lead to negative consequences
 - e.g. allowing a massive bomb to explode by refusing to torture someone
 - e.g. not fabricating a research result might mean admitting that your study found nothing that is interesting.

Virtue theory

- focus on the agent of action, rather than on rules or consequences
- Role-model
- Problems:
 - It may fail to guide our actions, as there are no clear, golden rules that can be applied.
 - What is ‘virtue’? Might ‘virtue’ be ‘vice’?



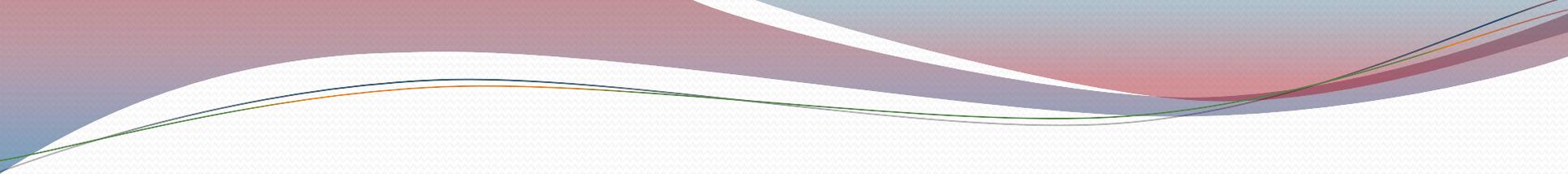
Principlism

- ‘The four principles’ approach
 - The most widely used approach in Western bioethics
 - Incorporates elements from both consequentialist and deontological theories

What are these 4 principles

- Autonomy
 - Right of self-determination
 - Related to ‘informed consent’
 - In order to give consent:
autonomy/competency/capacity must be possessed.
- Beneficence – to do well, to promote well-being
- Non-maleficence – to do no harm, to avoid doing harm
- Justice – treat like alike

(T. Beauchamp and J. Childress, Principles of Biomedical Ethics, 5th edition, New York/Oxford: Oxford University Press, 2001.)

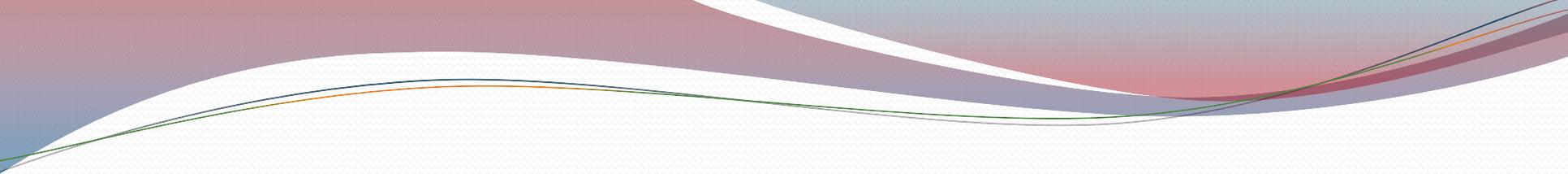


Theories in environmental ethics

- Strong anthropocentrism (speciesism)
- Weak anthropocentrism
- Pathocentrism
- Biocentrism
- Ecocentrism

A selection of prominent issues

- Should scientists consider the possibility that their research might encourage bioterrorism?
- Should regulations underpinning good research be the same everywhere?
 - E.g. research on Aids/HIV
- Why are health resources scarce (in some countries) and how should resources be allocated?
 - E.g. malaria tablets, HIV/Aids drugs
- When is withholding/withdrawing treatment appropriate?
- Should euthanasia be legalised in the UK?

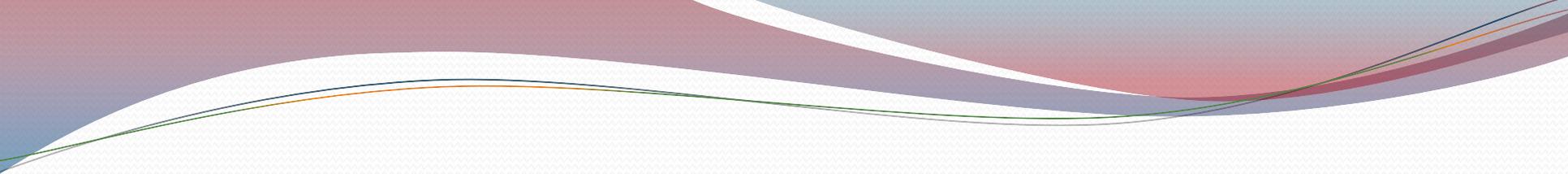


A selection of prominent issues

- Is research on those who cannot give consent permissible?
 - E.g. children, adults who lack capacity, nonhuman animals
- How should we assess capacity/competence?
- Should human embryos be used for research?
- Should abortion legislation be changed?
- Should nonhuman animals be used for research?
- Is genetic modification acceptable?

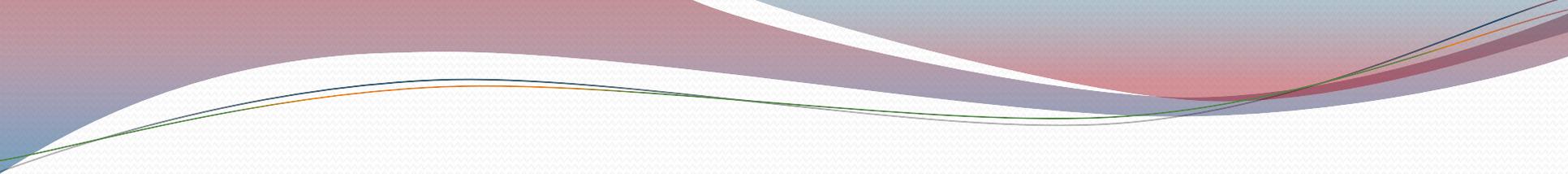
A selection of prominent issues

- Should people who suffer from ‘self-inflicted diseases’ be treated in the same way as people who suffer from diseases not caused by their own lifestyles?
 - E.g. alcohol, smoking, obesity, ...
- Should people be encouraged to take their health (more) seriously? Why?
- Which measures to promote public health are acceptable?
 - E.g. compulsory vaccination?
- What are the purposes of pre-implantation genetic diagnosis and pre-natal diagnosis? Can these purposes be justified? Which means are acceptable?
- Should treatments which are not recommended by NICE be available on the NHS anyway?



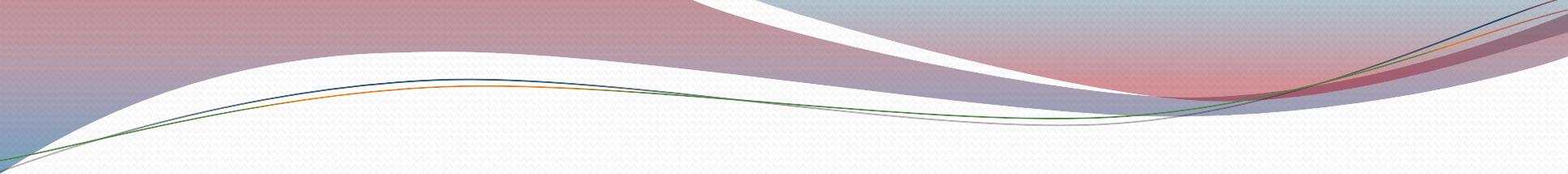
Does my research need ethical approval?

- Two possibilities: My research involves:
 - A: NHS staff or patients
 - B: others



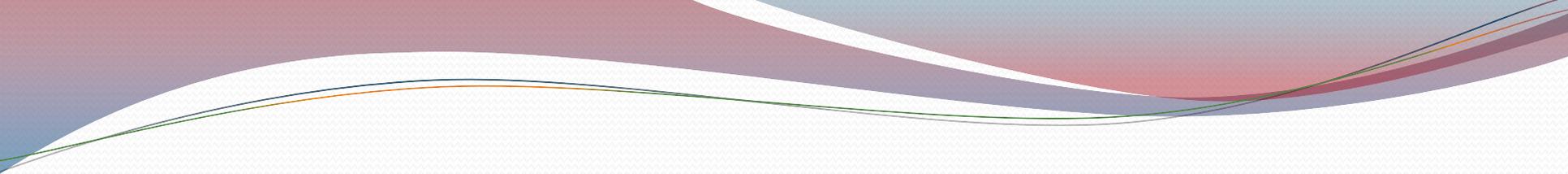
If A

- research needs to be approved by a LREC (Local Research Ethics Committee)



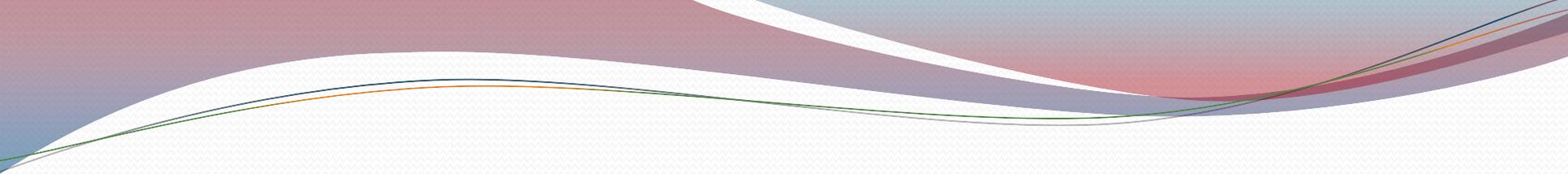
National Research Ethics Service

- a directorate within the National Patient Safety Agency, replaced COREC
- co-ordinates activities of the Research Ethics Committees in England



If B

- Many research councils and other funders have their own research ethics committees.
- Universities (and some Faculties/schools) have research ethics committees.



Some questions to ask in relation to personal research projects

- What is the aim of my research?
- Whose interests will be served by my research?
- What are the risks?
- What are the opportunity costs?

Prominent ethical codes

- Oath of Hippocrates (4th c BC)
- Nuremberg Code (1947): issue of human experimentation
- Declaration of Helsinki (1964) (WMA): issue of human experimentation
 - First serious attempt of medical community to regulate itself
- Declaration of Geneva (1948)
 - Issued as a development on the Oath of Hippocrates
- CIOMS Guidelines (1993)
 - ‘International Ethical Guidelines for Biomedical Research Involving Human Subjects’
(CIOMS: the Council for International Organizations of Medical Sciences)
- Universal Declaration on Bioethics and Human Rights (UNESCO; United Nations Educational, Scientific, and Cultural Organisation) (2005)