Topic 7
Bioethics: Questions and issues

- This lecture presents selected issues of biosafety, ethics, cells and tissues
- The emphasis is on the safe use of these materials and the aim is to introduce some key issues
- The presenter of these lectures does not represent any legal, religious or other authority, and the opinions and views presented are based on publicly availble facts and in line with good scientific conduct
- The aim is to present views and issues for the participants to dicuss and to reflect on

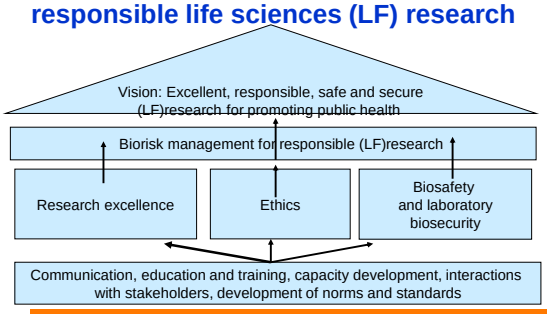
Topics for today

- Stem cells, tissue engineering – risk vs. benefit
  - To use or not to use – who is to decide ?
- Origin of cells, iPS cells – ethical dilemmas and new technologies
  - New technologies offer solutions to ethical issues – or do they ?
- Biobanks
  - What's the big deal ? Or is there a deal ?

The three pillars for biosafety

1. Research excellence
   - Quality for development of new treatment and therapies, strengthtening health research systems and promoting public health surveillance and response
2. Ethics (we will continue with this pillar)
   - Responsible and good research practices, discuss, analyse and resolve openly potential dilemmas in research, including possibility of accidents or misuse
3. Biosafety and biosecurity
   - Minimize the risk of worker exposure to biological agents, pathogens, protect, control and account for valuable biological materials in laboratories, reduce risk of accidents and misuse.

Biorisk management framework for responsible life sciences (LF) research



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Pillar 2: Ethics

- **Key ethical questions for consideration**
- How to weigh the potential benefits of research against the risks for misuse? On which criteria should this assessment be based?
- How to weigh the individual interests of researchers against the common good of public health? Who should make these decisions? How can tensions between individual researcher and institutions/society best be managed?
- How to best manage the risks associated with research without hindering its beneficial application to public health?
- What are the responsibilities of individual researchers and of the scientific community as a whole to society?

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Views and opinions – what is right and what is wrong, good or bad ?

- Some consider scientific knowledge to be inherently good
- Others believe that it is not scientific knowledge per se that is good or bad but rather the way that knowledge is used
- the need to place limits on the application of that knowledge in certain defined circumstances is broadly accepted.
- There are, however, differing views on the question of whether scientists should be held responsible for the misapplications of their research by others, whether foreseeable or not

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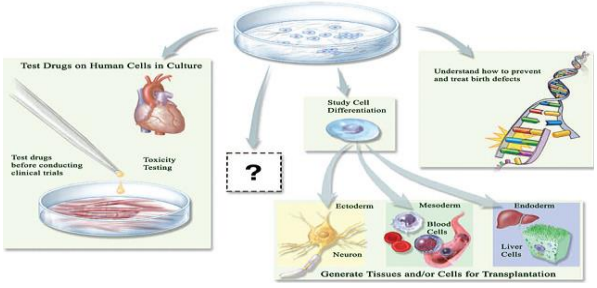
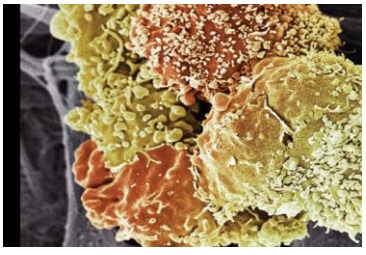
The Promise of Stem Cell Research*



*http://stemcells.nih.gov/info/media/promise.htm

hES[1] are "probably the most complex human therapeutic imaginable "



Vigilance for chromosomal abnormalities will be high as [1] human embryonic stem cells move into the clinic. FOX, L (2008) FDA scrutinizes human stem cell therapies, *Nature Biotechnol.* 26 (6) 598.

Embryonic stem cells

- Obtained from the embryos left over after fertility treatment (these are embryos that would never develop into a fetus; they are left over)
- These cells are undifferentiated stem cells and have unlimited scope for division under cell culture conditions
- In principle they can differentiate into any cell or tissue type, but they cannot create an embryo nor a human being
- Must have permission to use from parent and ethical permission from review board
- The collection of stem cells of both fetal and embryonic origins involves destruction of the "donor" – (embryo) – and is still ethically problematic

http://www.etene.fi/c/document_library/get_file?folderId=18388&name=DLFE-670.pdf

Fetal stem cells

- Fetal stem cells can be obtained (depending on consent) from eg. amniotic fluid, placenta and umbilical cord after birth

http://www.etene.fi/c/document_library/get_file?folderId=18388&name=DLFE-670.pdf

Ethical issues concerning the use of stem cells

- Many previous ethical issues have been averted by new technologies such as iPS cells = Induced Pluripotent Stem Cells, which are “taylor-made” stem cells with the unlimited potential of embryonic and fetal stems cell
- iPSc cells also offer an ample supply of cells, which in the past has been a problem, as the recovery rate of stem cells is usually low
- Fetal stem cell lines have previously been established from cells isolated from aborted fetuses – some of these cell lines are available for research, but regulation is very strict; and new technologies have largely offered more ethical approaches

Critical questions for hES

- Lot production
- Purity and other control measures
- Appropriate animal models (preclinical trials)
- Safeguards in testing and using stem cells
- Particularly hES recipients should be followed on a long-term basis for signs on cancer and other abnormalities

Biobanks – what's the big DEAL $??

- A **biobank*** is a type of biorepository that stores biological samples (usually human) for use in research
- Since the late 1990s biobanks have become a key resource, supporting many types of contemporary research like genomics and personalized medicine
- Biobanks give researchers access to data representing larger numbers of individual people than could be analyzed in previously used systems
- samples in biobanks and the data derived from those samples can often be used by multiple researchers for multiple purposes.

Moore v. Regents of the University of California (1990)
- the issue of property rights in one's own body parts
- John Moore underwent treatment for hairy cell leukemia at the Moore's cancer - later the cells were used to develop a cell line that was commercialized
- The California Supreme Court ruled that Moore had no right to any share of the profits realized from the commercialization of anything developed from his discarded body parts

- **Greenberg v. Miami Children's Hospital Research Institute** (2003)
- decision which ruled that individuals do not own their tissue samples when researchers take them for testing
- The plaintiffs in this case were a group of parents of children who had Canavan disease and three non-profit organizations who developed a confidential Canavan disease registry and database.
- The parents provided their children's tissue for research on the disease and the non-profit groups aided in the identification of other affected families
- The defendant was NN, who received these tissue samples and used them to isolate and patent the Canavan gene sequence. He subsequently developed a genetic screening test for it and began claiming royalties whenever the test was used.

Biobanks vs. property rights

- Biobanks provide researchers with extremely valuable data for the development of treatments for severe illnesess/congenital defects as well as for prevention and detection of illnesess
- Since thte 1990' – 2000' experiences, the legislation has developed and the activities are well coordinated
- Consent is allways required
- Possible commercialization of biobank materials is still a difficult issue and involves strick legal agreements between donor and biobanks