



The Swedish Life Science Industry Organization
swedenBIO

Biobanks

Issues and Recommendations

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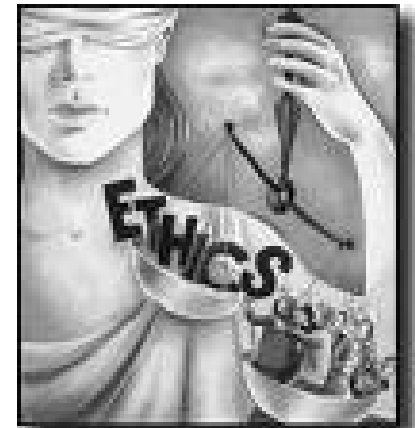
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What can be done with parts of the human body?

- What are the answers to ethical questions regarding Biobanks?
- Europe today:
 - lack of a common definition for Biobanks
 - confusion between law and ethics



There is a need to discuss recommendations in order to establish a common ground regarding Biobanks issues and hence to ensure continuous progress in research.



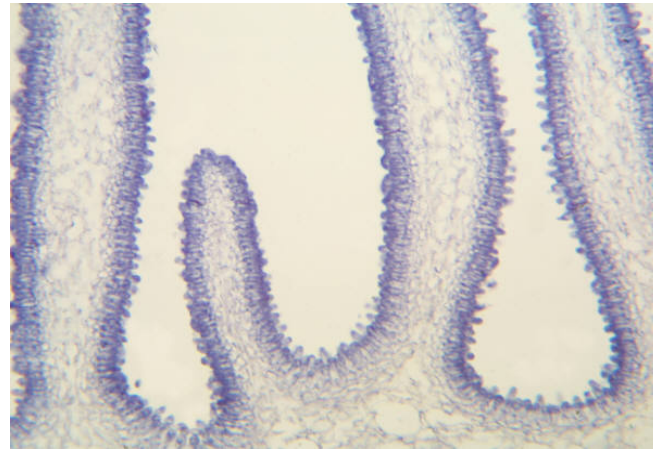
Bioethical Guidelines & Recommendations

Biobanks-related issues:

- They come from questions and concerns raised by the life science industry that were presented at the Conference 1, Dec 2007
- Recommendations were discussed within the consortium and resulted in DRAFT 4
- Today's task will be to discuss each issue and the corresponding recommendations

Why are Biobanks important?

- Identify causes of disease in individuals or in a group
- Develop diagnostic tools
- Apply therapeutic and preventive methods
- Study pharmacogenetics and pharmacogenomics



Issue 1: Lack of Regulation and/or different Applications of the Regulation in different parts of Europe and Internationally

Recommendations:

- All biobanks are sovereign in their decision to transfer samples.
- When samples are transferred to another location, all information useful for the considered use and responsibilities can be transferred except the identifying key.

Q: What if the individual can be identified accurately without the key?

Q: What about information on a minority group?

- There should be a consensus for the application forms to Research Ethics Committees and subsequent evaluations. More interactions and discussions between Biobanks, REC and researchers across Europe are needed. For further information on present initiatives at European level see the following websites: *European Network of Research Ethics Committees – EUREC* and *European Clinical Research Infrastructures Network – ECRIN*.

Issue 2: When different Laws are applicable, which Law takes priority over Biobanks issues?

Recommendations:

- The basis is the **Oviedo Convention** that demands respect for each person's integrity and the **Declaration of Helsinki** that clearly states that the will of the individual precedes the greater good of the group.
- Following the **Recommendation of the Council of Europe (2006)** is strongly advised.

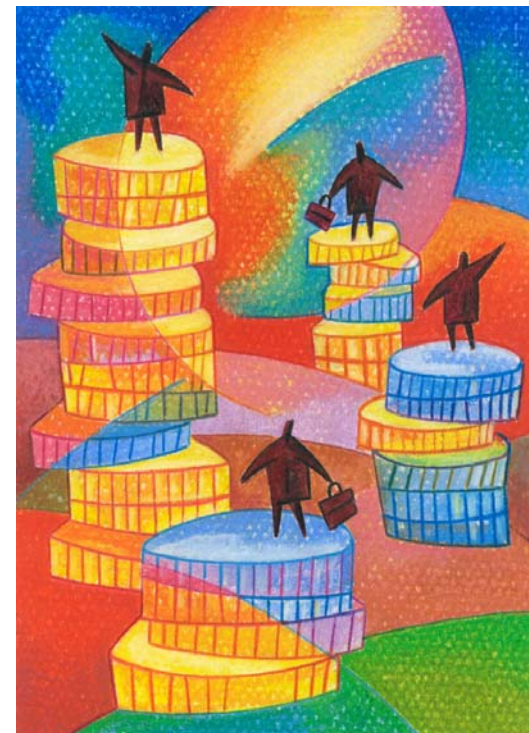


Issue 3: Reimbursement or compensation to patients participating in a study?

Recommendations:

- Healthy individuals can be compensated for the time spent and for expenses such as travel costs if they are linked to their participation in studies.
- Patients should be reimbursed for costs related to travels and lost income due to the study.
- Patients and healthy individuals should **not** be paid for participating in a biobanks study, as it could be viewed as unduly persuasion.
- The ethical issues surrounding compensation should be precisely described in the protocol submitted to the REC. Industry organizations should ensure that this point is clear for the patient.

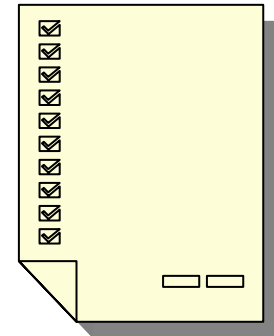
Q: Difference between compensation and reimbursement?



Issue 4: Consent – broad or specific?

Recommendations:

- The man in the street has difficulties understanding the meaning of “broad consent”. This might lead to fear “Frankenstein-type research” and to a negative attitude towards research.
- A kind of broad consent is to consent for all research as long as it applies to the patient’s disease area.
- The consent form should include a box where NO can be ticked.
- A possibility would be to have two questions on the form:
 - one for consent for the particular study and one for future studies.



Q: Differences between countries which have great confidence in research and others which are skeptical – broad consent could be an option in the first case, but not in the latter.