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Biobank perspectives

current issues in biobank ethics and law

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BBMRI.se
BioBanking and Molecular Resource Infrastructure of Sweden

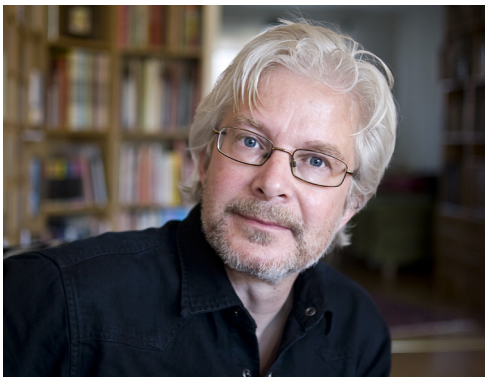
Stem cells: a new type of biobank material?

Stem cells are perhaps not what first springs to mind as biobank material. Yet, even stem cells can be biobank material and there are biobanks that focus on stem cells. The use of this biobank material, however, has some unique features.

Stem cell researchers process not only data from human material. The material itself is "processed" and sometimes transplanted to research participants. Commercializing stem cell research moreover implies that cells derived from donated human tissue appear in products on a market. A new project investigates ethical and legal issues in the development of stem cell treatments for type 1 diabetes.

Today, diabetes is treated with daily insulin injections or with insulin pump. An alternative treatment is to transplant new insulin-producing cells derived from human embryonic stem cells. The devices with transplanted cells detects blood sugar levels and regulates the secretion of insulin. Making such treatment available for diabetes patients (not only for research participants) presupposes commercialization. However, does law allow for patenting cell lines derived from human donated material? Is buying and selling such material lawful? The project is led by Mats G. Hansson, professor of biomedical ethics.
The project is a collaboration between several researchers at Uppsala University: Olle Korsgren, professor of transplantation immunology, Anna-Sara Lind, associate professor of public law, Bengt Domeij, professor of private law, Jessica Nihlén Fahlquist, deputy senior lecturer in medical ethics and Pär Segerdahl, associate professor of philosophy.

One issue concerns research participants' right to withdraw their consent at any time. Does that right imply that transplanted cells must be removed from research participants if the embryo donor withdraws consent? Moreover, assuming that researchers share stem cell lines with companies, are these companies willing to invest in the development of stem cell products if embryo donors may withdraw their consent at any time?



Pär Segerdahl, photo: Gunilla Segerdahl

Another difficulty is the purpose to which embryo donors are asked to consent. According to Swedish law, human embryos can be donated only for research purposes (or to other IVF patients). Yet, medical research loses its meaning if results cannot be commercialized. It is important to inform donors about this broader context of embryo donation. Does that imply that the consent becomes broader than has support in the law? Or is there support since the embryos are not used in product development, only derived material?

The answers to these questions probably depend on whether one can distinguish between donated embryos and cell material derived from embryos. This raises also more philosophical questions about how to view embryos, stem cell lines, matured cells, and human tissue.

B3Africa: first 18 months

In its first 18 months, B3Africa has taken two essential steps: the development of a technical solution for biobank research, and the design of a culture sensitive ethical and legal framework to ensure the rights of the sample donors are safeguarded.

B3Africa
BRIDGING BIOBANKING AND BIOMEDICAL RESEARCH ACROSS EUROPE AND AFRICA

B3Africa is coordinated by Erik Bongcam-Rudloff at the Swedish University of Agricultural Sciences. It is carried out in parallel with the H3Africa Initiative and Ciara Staunton from the H3Africa ELSI team recently visited Uppsala to present and discuss a Framework for Best Practice for Genomics and Biobanking Research in Africa. The framework has been developed to both safeguard African values and promote biobank research, in close collaboration with African stakeholders and the B3Africa ELSI expert Jane Reichel.

Jane Reichel, Erik Bongcam-Rudloff, Santa Slokenberga & Ciara Staunton

The B3Africa ELSI team is coordinated by Jane Reichel and Santa Slokenberga. They now move on to examine issues related to biobank research on animal samples, and to develop tools to ensure the exchange of samples and data between Europe and Africa.

Editors: Anna-Sara Lind & Josepine Fernow

Read more: www.crb.uu.se or BBMRI.se

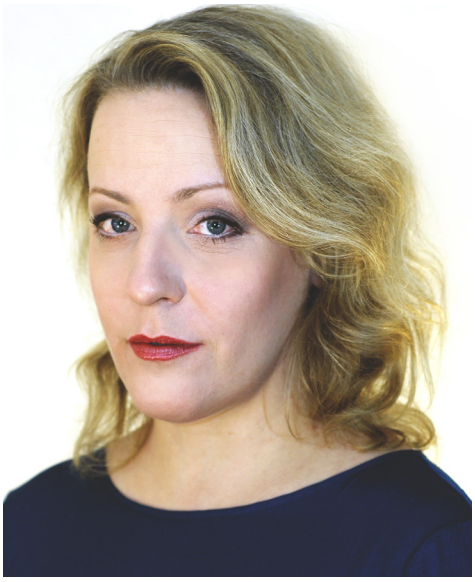
A new Swedish legal framework for handling alleged misconduct

Recently, a Swedish Government Inquiry proposed a new legal framework for handling and investigating research misconduct. A new act is suggested to enter into force on 1st of January 2019. Here, Anna-Sara Lind presents the main novelties in the proposal.

The Inquiry (SOU 2017:10) defines the term good scientific practice as the collective ethical standard for how good research should be conducted. Even so, there are major differences between disciplines and traditions. Accordingly, a rather broad legal definition of research misconduct is suggested: "Serious breaches of good scientific practice in the form of fabrication, falsification or plagiarism that are committed intentionally or with gross negligence in the planning, performance or reporting of research."

The inquiry suggests that a new agency, Research Misconduct Board (RMB), is established under the realm of the Swedish research council, in order to guarantee that possible cases are investigates objectively. This means nationally recognised decisions that could have a mainstreaming effect on how misconduct is perceived. Research performed in the public sphere is included, i.e. all research conducted by authorities, municipalities and counties.

The RMB will, according to the suggestion, rule on the misconduct, but there are no sanctions that follow the ruling. The decision can be appealed to court.



Anna-Sara Lind, photo: Eva Holst

The higher education institutions should report all cases of breaches of good scientific practice and how good practice is promoted in order to prevent research misconduct. Spreading information and knowledge is at the very heart of the proposal as it is suggested that every institution should report these activities annually. The Inquiry suggests that the act will apply retroactively 10 years from the entry into force.

The proposed act still leaves questions unanswered. One is how to handle cases not being classified as fabrication, falsification or plagiarism, another is co-writers' responsibility. But it is a start for a new way of approaching misconduct.

New Swedish legal officer in the BBMRI-ERIC ELSI helpdesk

From February 1 2017, LL.D. Santa Slokenberga is taking over Moa Kindström Dahlin's obligations at the BBMRI-ERIC ELSI Common Service.

Santa Slokenberga will continue the work to set up an ELSI helpdesk. She will be working closely with other BBMRI-ERIC ELSI Common Service team members to ensure that those in need receive the necessary support on ethical, legal and societal issues related to biobanking activities.

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Want to read more about ethics? visit www.ethicsblog.crb.uu.se

Questions?

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Recent publications from CRB

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