

Introduction

Mats G. Hansson

Research Program Ethics in Biomedicine, Uppsala University

The use of human biobanks – ethical, social, economical and legal aspects. Presentation of the project.

Objectives

Human biological material – such as cells collected in research projects, biopsy specimens obtained for diagnostic purposes, and organs removed during surgery – has become vital for research in biomedicine and biotechnology. The main purpose of this project is to propose ethical and legal guidelines so that the research, diagnostic and treatment value of these biobanks may be acknowledged without violating the integrity of individual research subjects and patients. As a working definition, “biobanks” are collections of human biological material within the health care system and the medical sciences. Both privately and publicly financed biobanks are included. Within a multi-disciplinary research format, ethical, economical, social and legal problems associated with the use of human biological material are analysed. Ethical rules and guidelines and suggestions for legislation will be proposed. Open seminars are taking place on a regular basis during the project. At these seminars, representatives of the financing parties as well as the industry, public authorities and the academic community are invited to discuss the progress of the project.

The objectives of the project are:

- A. Analysis of ethical problems associated with the use of human biobanks and proposal of information and consent procedures appropriate for treatment, quality assurance and research purposes.
- B. Analysis of how different economical interests associated with the use of human biobanks (primarily those of biomedical firms) can be satisfied without coming into conflict with other important interests (e.g. , ethical and legal).
- C. Analysis of legal questions related to property and disposition claims and proposal of legislation that takes the different interests into consideration.
- D. Analysis of the relevant provisions in Swedish and international public law, and suggestions for legislation that will facilitate an efficient management of Swedish biobanks, while also offering appropriate protection to the human rights, such as privacy and integrity, of individuals and groups concerned.
- E. To stimulate a public dialogue concerning the use of human biobanks.

Project plan

September 1999 – December 1999:

Initiation of the project, fund raising, recruitment of scholars. Hearing with public authorities, scientists, and with representatives from industry and from Iceland.

January 2000-December 2000:

- A. Ethics: Ethical and philosophical analysis of the notions of “informed consent” and the ownership of bodies and body parts. Discussions of conditions for withdrawal of consent.
- B. Economics: Mapping of past, current and planned use of Swedish biobanks for industrial purposes.
- C. Private law: Inventory of existing property and disposition rights regarding till human biological material.
- D. Public law: Inventory of existing Swedish law regarding the taking, storing, use and transfer of human biological material, as well as the management of information derived therefrom.

January 2001 – December 2001

- A. Ethics: Empirical study of the public's, blood donors' and patients' preferences with regard to regulations for information and consent in the collection and utilization of biobanks. Analysis of ethical problems related to using samples that are collected without proper consent and the effect on the family of using genetic information about an individual member.
- B. Economics: Study of commercialization of public biobanks through dedicated genomics companies (such as deCode Genetics, UmanGenomics and Oxagen).
- C. Private law: Analysis of consequences regarding intellectual property law, as well as terms of access to human biological material. Legal analysis of the notion of “donation” and “gift”, as well as of EC competition law.
- D. Public law: Continued inventory of Nordic and international public law, as well as relevant EU legislation. Preliminary analysis and comparative studies.

January 2002 – December 2002

- A. Ethics: Normative analysis of intrinsic and instrumental values. Formulation of ethical guidelines, with specification of different levels of information and consent for different clinical and research purposes. Proposal for the handling of code keys.
- B. Economics: Continued study of different models for commercialization of public biobanks with respect for ethical and legal concerns.
- C. Private law: Proposal for legislation and regulations for property and disposition rights.
- D. Public law: Final analysis and comparative studies, taking into consideration the results from the other sub-studies. Suggestions for legislation and regulations in the area of public law.

The research context

The research conducted within this project is multi-disciplinary and includes collaboration by scholars at several universities. The project is hosted by the Research Program Ethics in Biomedicine at Uppsala University. Participation by scholars from other universities is based on legal contracts with each department. The research program Ethics in Biomedicine was established by the Vice-Chancellor of Uppsala University in August 1998 with the aim of initiating and coordinating research projects in biomedical ethics. Several projects are related

to ethical implications of genome and gene technology research. Of particular interest for the project on biobanks in this research environment are projects related to genetic diagnosis and treatment of hereditary cancer, the handling of genetic information, public perception of gene technology and philosophical implications of behavioral genetics. A characteristic feature of all projects is the close collaboration with natural scientists and clinicians relevant to a specific project.

Partners and collaborators

The following scholars have been employed on a full-time or part-time basis within the project.

Jacob Dahl Rendtorff, Ph.D., *Department of Philosophy, Roskilde University.*

Associate Professor Bengt Domeij, LL.D., *Industrial Economics and Management, Royal Institute of Technology, Stockholm*

Stefan Eriksson, ThD., *Research Program Ethics in Biomedicine, Uppsala University.*

Åsa Kettis-Lindblad, PhD, *Research Program Ethics in Biomedicine, Uppsala University* is collaborating with the project and is one of the authors. She is being financed with a research grant from the Swedish Council for Social Research.

Associate Professor Jens Laage-Hellman, PhD, *Institute for Management of Innovation and Technology, Chalmers University of Technology, Gothenburg.*

Lena Lundberg, Ph.D., *Research Program Ethics in Biomedicine, Uppsala University.*

Associate Professor Annina Persson, LL.D, *Department of Law , Stockholm University.*

Associate Professor Elisabeth Rynning, LL.D., *Faculty of Law, Uppsala University*

Li Westerlund, LL.D., *Department of Law, Stockholm University.*

The following scholars are working on the project within the framework of their ordinary university positions.

Associate Professor Mats G. Hansson, ThD, (Project Leader), *Research Program Ethics in Biomedicine, Uppsala University.*

Professor Marianne Levin, LL.D., *Department of Law, Stockholm University*

Associate Professor Christer Sundström, MD, PhD, *Department of Genetics and Pathology, Uppsala University.*

The following scientists are consultants to the project. They take part in seminars, write texts and review material before publishing.

Professor Maria Anvret, PhD, *AstraZeneca AB.*

Lena Jonsson, PhD, *Amersham Pharmacia Biotech*.

Professor Ulf Landegren, MD, PhD, *Department of Genetics and Pathology, Uppsala University*

Bo Lindberg, MD, Former Medical Director, *Uppsala University Hospital*

Associate Professor Kerstin Westermark, MD, PhD, *Swedish Medical Products Agency*.

Funding

Funding has been sought throughout with the aim of financing the entire three-year project. The funds are pooled, and, in accordance with agreements and contracts with the respective financing organizations, funds are requisitioned as needed. Grants have been awarded by: VINNOVA – The Swedish Agency for Innovation Systems (former NUTEK), the Swedish Foundation for Strategic Research (The ELSA-Program), the National Board of Health and Welfare and the Federation of County Councils.

Progress of the project and publications

The work is proceeding in accordance with the objectives and the timetable of the project. One hearing was held in Uppsala in September 1999. Two public hearings have been held in Göteborg during 2000. This is the report of the first phase of the project and it will be presented at a public hearing in Uppsala on 16th May 2001. Seminars are held regularly. Starting in May 2001, the project group will work together with a group of scientists at Uppsala University and representatives of Uppsala University Hospital and Uppsala County Council in order to establish a model for collecting and using human biological material for research. The individual participants of the project prepare their own manuscripts, the majority of which will be published in scientific journals during and after the final year of the project.

Publications

Domeij, B., 2001, Humanbiologiskt material och vinningssyften, *Juridisk Tidskrift* (Accepted for publication, in press)

Hansson, M.G., 2000, International Aspects: National Profiles, Scandinavia, in: Murray, T.J., & Melham, M.J., (eds.), *Encyclopedia of Ethical, Legal and Policy Issues in Biotechnology*, John Wiley & Sons, Inc., pp.731-738.

Hansson, M.G. et al, 2001, *The use of human biobanks – ethical, social, economical and legal aspects*, Reprt I, Uppsala.

Laage-Hellman, J., 2001, Kommersialisering av svenska biobanker: ett näringspolitiskt perspektiv, *IMIT- report*, Institute for Management of Innovation and Technology, (Forthcoming)

Introduction

Persson, A., Westerlund, L., 2000, *Civilrättsliga reflektioner på användningen av mänskligt biologiskt material*, Juridiska fakulteten vid Stockholms universitet Skriftserien nr 64, (70 pages).

Rynning, E., 2000, *Genteknikens användning på människa – rättsliga aspekter med särskild inriktning på Sverige och övriga Norden*. Bilaga 5 till Bioteknikkommitténs slutbetänkande *Att spränga gränser. En svensk bioteknikpolitik* (SOU 2000:103), pp. 405-468 (Partly within the finances of the project).