

## **The use of human biobanks – public law aspects**

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### **Introduction**

The public law part of the Biobank Project is primarily focused on issues concerning the legal protection of human rights concerning e.g. privacy, personal integrity, self-determination and non-discrimination. The study thus deals inter alia with the obligations of society, with regard to the provision of judicial protection for patients and research subjects from whom biological samples are obtained. A similar need for protection can also be perceived with regard to the genetic relatives of such donors, sometimes even to persons belonging to a group of people with a genetic make-up related to that of the donor. There are, however, other interests to consider as well, such as the interest of society in furthering good research and making effective use of valuable resources. The measures taken by public agencies in order to monitor, limit and control various activities concerning the use of human biobanks must always be governed by basic public law principles such as proportionality, legality and equality before the law. The recommendations that may be inferred from the study will thus be aimed at facilitating efficient management of Swedish biobanks, while also offering appropriate protection for the rights of individuals and groups concerned. The study involves the analysis of relevant areas of both Swedish and international public law, as well as comparative aspects regarding the internal law of certain other jurisdictions, primarily the Nordic countries.<sup>1</sup> This first report is limited to a short overview of some relevant sources of law and the legal issues that are being studied.

### **International aspects**

As a member of the European Union, Sweden is obliged to observe the developments within EU law, also when it comes to designing our internal law in many areas. In one way, EU law should be considered an integral part of Swedish law, at least to the extent that it is directly binding. In another sense, however, EU law is still a part of the international law that in different ways governs or influences our domestic legal rules. Other important influences of international law are related to our membership of international organizations such as the Council of Europe and the United Nations, and to treaties signed or ratified by Sweden. EU legal documents of relevance to the public law study include the directives on the protection of personal data,<sup>2</sup> on in vitro diagnostic devices<sup>3</sup> and the recently adopted directive on clinical trials.<sup>4</sup> None of these directives deal directly with biobanking, but they regulate matters concerning the processing of personal information, the use of human biological material and some of the prerequisites for research involving humans. The Council of Europe has produced a number of documents relevant to the handling of biobank materials. A most important one is

the Convention on Human Rights and Biomedicine (1997),<sup>5</sup> even though Sweden has not yet ratified this convention. In Article 22, it is thus prescribed that if any part of a human body has been removed in the course of an intervention, it may be stored and used for a purpose other than that for which it was removed only if this is done in conformity with appropriate information and consent procedures. An earlier recommendation specifically dealing with human tissue banks, No. R (94) 1,<sup>6</sup> proposes inter alia that such banking activities should be carried out by non-profit-making institutions. It is also recommended that the distribution of banked materials “take place in such a way as to permit optimal use of the tissues on an equitable basis in accordance with national law, rules and practice and objective selection criteria”. In other documents, the Council of Europe has voiced the idea that human tissue should be considered as a source of information and be protected in the same way as other media carrying personal information.<sup>7</sup> Other examples of international documents that must be considered in this context are the UNESCO Universal Declaration on the Human Genome and Human Rights (1997)<sup>8</sup> and the WHO Proposed international guidelines on ethical issues in medical genetics and genetic services (1997).<sup>9</sup>

### **Swedish law today**

At present, there is no comprehensive Swedish legislation specifically regulating the use of biobanks. A proposal for a new Act concerning Biobanks in Medical Care etc. was presented in a report from the National Board of Health and Welfare in May 2000,<sup>10</sup> and has been circulated for consideration. Until such an Act is passed by the Swedish Parliament – and without doubt even thereafter – certain issues related to biobanking are regulated by provisions scattered over a number other acts and statutory instruments. There are also non-binding ethical guidelines adopted by the Swedish Medical Research Council in 1999, specifically dealing with biobanks in medical research.<sup>11</sup>

To a certain extent, the duties of the state and all public institutions in their relations with the citizens are laid down already in basic laws with constitutional status. Thus it is clear from the Instrument of Government (1974:152), Chapter 1 Section 2, that public institutions shall inter alia respect the human dignity and equal value of all human beings, and protect the privacy of individuals. Under Chapter 2 Section 6, all citizens shall be protected against any physical violation in their relations with the public administration, which would seem also to include protection against coercive blood tests etc. This right may only be restricted by a statute enacted by the Swedish Parliament, and only to the extent necessary for purposes acceptable in a democratic society; see the Instrument of Government, Chapter 2, Section 12. The Freedom of the Press Act (1949:105), Chapter 2 Sections 1-2, lays down the principle of public access to official documents, but also restrictions motivated e.g. by the need for protection of the privacy of individuals. Although constitutional rights are important, however, in order to be effective the basic principles often need to be transformed into clear and enforceable rules in ordinary legislation.

With regard to the taking of biological materials from humans, there are relevant provisions to be found in the Health and Medical Services Act (1982:763) and the Act (1998:531) on Professional Activity in Health and Medical Services, when the removal of the material is part of a medical treatment of the person concerned. If the material is removed for other medical purposes, the provisions of the Transplant Act (1995:831) or the Autopsy Act (1995:832) will normally apply, complemented by statutory instruments and general recommendations issued by the National Board of Health and Welfare.<sup>12</sup> For certain measures there is additional, specific regulation. When samples are taken as part of a clinical drug trial, the procedure will also fall under the requirements laid down in Sections 13-14 of the Medicinal Products Act (1992:859) and the Medical Products Agency’s provisions and

guidelines on the clinical trials of medicinal products.<sup>13</sup> With very few exceptions, the provisions regulating the taking of human materials for different medical purposes require the free and informed consent of the individual concerned. This goes well with the constitutional protection offered in the Swedish Instrument of Government, Chapter 2, Section 6, for the bodily integrity of all citizens. When the person concerned is incompetent to give legally valid consent, however, the law is less clear, particularly regarding incompetent adults. Also, the legal rules mentioned above do not explicitly deal with issues concerning the further use of the biological material, once it has been removed from the human body. A somewhat broader perspective can be seen in some provisions, e.g. the regulation on in-vitro diagnostic medical devices, where the National Board of Health and Welfare prescribes that certain measures concerning the taking, collection and use of human tissue, cells and substances must be in keeping with the European Convention on Human Rights and Biomedicine.<sup>14</sup>

Measures concerning the collection and storage of biological materials from humans are less regulated by Acts of Parliament than is the actual removal of such materials. Apart from the odd provision in the Act (1991:115) concerning Measures for Purposes of Research or Treatment Using Fertilized Human Ova. and the Insemination Act (1984:1140), there are also statutory instruments and general recommendations by the National Board of Health and Welfare, on matters such as the use of biological waste materials, storage of blood for transfusion purposes, storage of sperm for insemination, and routines for the preservation of samples at departments of pathology.<sup>15</sup> At this stage, the provisions are mainly focused on issues of quality and safe preservation. The interests of the donors are not given nearly as much attention, but there are still some references made to the wishes of the persons concerned.

When it comes to provisions regulating the actual use of biological materials from humans, Swedish law is very sparse indeed, with the exception of the areas of assisted procreation and research on fertilised human ova. There is also an Act (1991:114) concerning the Use of Certain Genetic Technology in Medical Screening, specifically regulating DNA and RNA analyses, but the scope of this act is rather limited and it has never been applied so far. The transfer of human biological materials is regulated mainly with regard to the prohibition of financial gains; see section 15 of the Transplants Act (1995:831). In addition to this, there is also a provision in Section 6 of the Insemination Act (1984:1140), prohibiting import of frozen sperm without the authorisation of the National Board of Health and Welfare.

Out of the different issues related to biobanking, the handling of information concerning or derived from human materials would seem to be the area most thoroughly regulated, especially when the information can be related to identifiable individuals. The rather strict legal requirements for professional confidentiality and secrecy concerning health related information are thus laid down mainly in Chapter 7, Section 1 of the Secrecy Act (1980:100) and – with regard to the private health care sector – in Chapter 2, Section 8 of the Act (1998:531) on Professional Activity in Health and Medical Services. There are also relevant provisions in the Medical Records Act (1986:203). Should a private health care provider for any reason discontinue his or her business, the medical records will be taken care of in accordance with specific requirements in Sections 11-14 of this Act. Statutory provisions regarding the processing of personal information in databases or registers can be found in the Personal Data Act (1998:204), the Health Data Registers Act (1998:543) and the Medical Care Registers Act (1998:544). When sensitive personal information is processed for research purposes, whether in the private or the public sector, the consent of the individual concerned will normally be required. However, this requirement can be waived in certain cases where the interest of society in the research project “is manifestly greater than the risk of improper violation of the personal integrity of the individual”.<sup>16</sup> Automated processing of personal data regarding hereditary disposition derived from genetic investigation is subject to

a particular requirement of mandatory prior notification to the Data Inspection Board, under Section 9 of the Personal Data Ordinance (1998:1191). There are also special provisions regulating DNA registers for criminal investigations, in the Police Data Act (1998:622).

When it comes to the monitoring or supervision of biobank activities, there are several public agencies with different responsibilities. The National Board of Health and Welfare thus monitors the areas of health care and clinical research in connection with the treatment of patients.<sup>17</sup> The Board also monitors clinical trials regarding medical devices, whereas the Medical Products Agency monitors all clinical drug trials.<sup>18</sup> The processing of personal data is monitored by the Swedish Data Inspection Board, which presented its first report on biobanks in the year 2000.<sup>19</sup> All three of these agencies cover both the public and the private sector. Regarding biobank research that is not related to clinical trials or the treatment of patients, public universities and research institutions can be considered subject to some kind of monitoring on the part of the National Agency for Higher Education,<sup>20</sup> at least in theory. Sweden has no general legislation on research involving humans, a shortcoming that has repeatedly been pointed out.<sup>21</sup> Some types of biomedical research that is conducted e.g. by private companies thus would seem to avoid any real monitoring, apart from personal data processing.

This short overview of Swedish law applicable to biobank activities shows that while we do have rules regulating the interventions required to remove samples of human material from a person or a body, and the processing of personal information related to such samples, the rules concerning collection, storage, use and transfer of the biological material itself are sparse. Quite obviously, there are gaps in the legal safety net aimed at protecting the autonomy, privacy and personal integrity of individuals. With regard to personal information in a more traditional form, individuals are offered protection against infringements of their privacy and integrity, and are also guaranteed almost unlimited access to the information available about their health, e.g. in their medical records.<sup>22</sup> There are no similar rules concerning a person's access to biological materials removed from his or her body,<sup>23</sup> nor are there any clear rules on the right to decide about further use of such materials. Whereas the interests of society, with regard to the preservation of information in official documents and recordings, are protected by statutory rules, e.g. in the Archives Act (1990:782), the preservation of biological materials is mainly provided for by non-binding recommendations. The present legal situation does not only involve risks related to the rights of individuals, but can also constitute an actual impediment to the effective and justifiable use of valuable resources. The lack of appropriate regulation concerning the preservation, access and distribution of human materials may thus lead to unnecessary waste of such resources.

## **Developments in the Nordic countries**

In all of the Nordic countries, the need for regulation concerning biobank activities has been given increased attention during the past few years. Iceland was the first to adopt an Act on Biobanks (110/2000),<sup>24</sup> which entered into force on 1 January 2001. In Finland, a new Act (101/2001) on the Use of Human Organs and Tissue for Medical Purposes was recently passed. The Finnish Act, which includes certain provisions on the taking, collection and further use of human tissue, will enter into force 1 September 2001. Although the legal issues related to biobanking were observed and debated in Denmark already in the mid-nineties,<sup>25</sup> no specific legislation regulating biobank activities has been adopted so far. Structured biobanks with samples from identifiable individuals do however fall under the Danish legislation on data registers,<sup>26</sup> and an inter-ministerial group is at present investigating the possible need for comprehensive legislation.<sup>27</sup> In Norway, a commission is preparing a report on the same subject.<sup>28</sup>

The legislation suggested by the Swedish National Board of Health and Welfare is at present being considered and processed by the Ministry of Health and Social Affairs,<sup>29</sup> after having been circulated for comment. One prominent feature of the proposal, which is clearly influenced by the European Convention on Human Rights and Biomedicine, is the rather strict consent requirements with regard to measures involving biological material from living donors. It is also suggested that the establishment of biobanks for research purposes, as well as the use of biobank materials in research, should be subject to mandatory review by a research ethics committee. The National Board of Health and Welfare will monitor biobank activities and keep a register of the new and existing banks. One important limitation, however, is that the proposed legislation only applies to biobanks containing samples that originate from the health care sector. Certain biobanks that are independently set up by e.g. biotechnology companies or research institutions thus would not seem to be covered by the proposed Act concerning Biobanks in Medical Care etc.

The Icelandic biobank legislation does not require samples to originate from the health care sector, but on the other hand excludes banks that are only for temporary use and that will be destroyed within a period of five years. The new Finnish Act would seem to cover a broader scope of biobanks compared to the Icelandic and proposed Swedish legislation, but then it does not contain the same type of requirements concerning notification, authorisation and registration of biobank activities, nor any provisions on coding or depersonalisation of samples.

## **The public law study**

As mentioned above, the study deals with public law issues related to the taking and gathering of human material for biobanking, the preservation, use and transfer of such material, as well as the processing of information related to it. Previous research in this area, with regard to Swedish law, has been very limited.<sup>30</sup> When analysing the national sources of law and the requirements laid down in international law, one important aspect concerns the degree of judicial protection that is offered individual autonomy, privacy and integrity in different contexts. Other aspects are related to the legal guarantees for the preservation of and access to information of considerable value to society.

One relevant question is thus to what extent the rules governing confidentiality and the processing of personal information vary, depending on the medium carrying the information (e.g. paper, audio/video tape, automated data base or human tissue), and whether the differences are justified. What do the different laws have to say, for example, about consent requirements, withdrawal of consent, anonymity and encoding of information? Important questions concern the very concept of personal data with regard to information obtainable from human material by genetic testing. On the one hand, it could be argued that even anonymous biological material can be traced back to the individual by means of genetic analysis, making complete anonymity virtually impossible in this context. On the other hand, one of the characteristics of genetic information is that it rarely concerns only the person from whom the sample is taken. How are the interests of relatives and other identifiable groups of people being taken into account? We also need to consider the particular vulnerability of minors and incompetent adults, for example.

The interests of individual donors and associated groups must be a primary consideration, but as mentioned above, valuable research should not be unnecessarily hindered. Furthermore, the need for protection of different parties may vary depending on how the biological material is used, e.g. as a source of information for different types of studies or as raw material for a product.<sup>31</sup> Somewhat varying solutions to the biobank issues

are being presented or contemplated in different legal sources and jurisdictions. These examples bring both inspiration and complexity to the study.

## References:

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- <sup>1</sup> For a comparative report (in Swedish) on Nordic law regarding the use of gene technology on humans, see Rynning, *Genteknikens användning på människa – rättsliga aspekter med särskild inriktning på Sverige och övriga Norden*. Appendix 5 to the final report of the Biotechnology Commission (SOU 2000:103), pp. 405-468.
- <sup>2</sup> Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. OJL 281, 23/11/1995 pp. 0031 – 0050.
- <sup>3</sup> Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. OJL 331, 07/12/1998 pp. 0001 – 0037.
- <sup>4</sup> See Common Position (EC) No 44/2000 of 20 July 2000 adopted by the Council, OJL 300, 20/10/2000 p. 32; and the European Parliament legislative Resolution of 12 December 2000 (information note 14041/00), regarding the Commission's amended proposal for a European Parliament and Council Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use /COM/99/0193 final – COD 97/0197/. OJL 161, 08/06/1999 p. 0005.
- <sup>5</sup> Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine (1997, ETS No. 164). The convention entered into force 1 December 1999. See also the Explanatory Report, CM (96) 175 final, and Rynning, *Mänskliga rättigheter och biomedicin – om Europarådets konvention och svensk rätt*. De lege. Juridiska fakulteten i Uppsala årsbok, årgång 7, Iustus Förlag 1997 pp. 311–350.
- <sup>6</sup> Recommendation No. R (94) 1 of the Committee of Ministers, on human tissue banks.
- <sup>7</sup> The Committee of Ministers' Recommendation No. R (92) 1 on the use of analysis of deoxyribonucleic acid (DNA) within the framework of the criminal justice system and Recommendation No. R (92) 3 on genetic testing and screening for health care purposes. See also Hondius, *Protecting Medical and Genetic Data*, *European Journal of Health Law* 4:361–388, 1997, at pp. 377–378.
- <sup>8</sup> At <http://www.unesco.org/ibc/uk/genome/projet/index.html>. (010201)
- <sup>9</sup> At <http://www.who.int/ncd/hgn/hgnethic.htm> (010201).
- <sup>10</sup> *Biobanker i hälso- och sjukvården m.m.*, Socialstyrelsen 2000, at <http://www.sos.se/FULLTEXT/0077-011/0077-011.htm> (010201). For a summary in English, go to <http://www.sos.se/sos/publ/refereng/0077011e.htm> (010201).
- <sup>11</sup> Research ethics guidelines for using biobanks, especially projects involving genome research. Adopted by the Swedish Medical Research Council (MFR) in June 1999, (Dnr 1999-570). English version at <http://194.52.62.221/SinglePage/SinglePage.asp?ItemID=670> (010201).
- <sup>12</sup> Socialstyrelsens föreskrifter och allmänna råd (SOSFS 1997:4) *Organ- och vävnadstagning för transplantation eller för annat medicinskt ändamål* and Socialstyrelsens föreskrifter och allmänna råd (SOSFS 1996:28) *om kliniska obduktioner m.m.* It should be observed that general recommendations (allmänna råd) issued by Swedish public agencies are not formally binding in same way as statutory instruments in the form of regulations etc (föreskrifter).
- <sup>13</sup> Läkemedelsverkets föreskrifter och allmänna råd (LVFS 1996:17) *om klinisk läkemedelsprövning*.
- <sup>14</sup> Socialstyrelsens föreskrifter (SOSFS 1999:24) *om medicintekniska produkter för in vitro-diagnostik*.
- <sup>15</sup> Socialstyrelsens föreskrifter och allmänna råd (SOSFS 1997:4) *Organ- och vävnadstagning för transplantation eller för annat medicinskt ändamål*; Socialstyrelsens föreskrifter (SOSFS 1989:38) *om blodgivning, blodtransfusion m.m.*; Socialstyrelsens föreskrifter och allmänna råd (SOSFS 1987:6) om

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inseminationer and Socialstyrelsens allmänna råd (SOSFS 1995:9) Rutiner för bevarande av provmaterial vid patologavdelningar m.m.

<sup>16</sup> Section 19 of the Personal Data Act.

<sup>17</sup> Chapter 6, section 1 of the Act (1998:531) on Professional Activity in Health and Medical Services.

<sup>18</sup> Section 11 of the Medical Devices Ordinance (1993:876) and section 23 of the Medicinal Products Act (1992:859) respectively.

<sup>19</sup> Biobankers behandling av personuppgifter. Datainspektionens rapport 2000:1 (at <http://www.datainspektionen.se/>) (010201).

<sup>20</sup> Section 3 of the Instruction Ordinance (1995:945) of the National Agency for Higher Education.

<sup>21</sup> See e.g. the two official reports on research ethics (SOU 1989:74 and SOU 1999:4), the National Board of Health and Welfare report concerning Biobanks in Medical Care etc., the government bill 2000/2001:3 p. 92, and the final report of the Biotechnology Commission (SOU 2000:103) p. 299. See also Rynning, Etisk granskning av medicinsk humanforskning - lagstiftning behövs! *Läkartidningen*, 1997:1771-1774.

<sup>22</sup> See e.g. Chapter 14, Section 4 and Chapter 15, Section 4 of the Secrecy Act (1980:100), Chapter 2, Section 12 of the Freedom of the Press Act and Section 16 of the Medical Records Act (1985:562).

<sup>23</sup> In the case RÅ 1994 note 465, the Supreme Administrative Court ruled that biological material in the form of a blood sample does not constitute a document, and is thus not covered by the right of access to official documents laid down in the Freedom of the Press Act.

<sup>24</sup> English version presented at <http://brunnur.stjr.is/interpro/htr/htr.nsf/pages/forsid-ensk> (010201).

<sup>25</sup> See Nielsen et. al., *Sundhedsvidenskabelige informationsbanker – biobanker*, Statens Sundhedsvidenskabelige Forskningsråd, Den Centrale Videnskabetiske Komité og Det Ethiske Råd 1996.

<sup>26</sup> See e.g. Blume, *Personregistrering*, 3 ed. 1996, pp. 29-34; Hartlev, *Den retlige regulering af biobanker – love og rekommandationer. Appendiks til rapporten Sundhedsvidenskabelige informationsbanker – biobanker*, Utg: Statens Sundhedsvidenskabelige Forskningsråd, Den Centrale Videnskabetiske Komité og Det Ethiske Råd 1996.

<sup>27</sup> Forskningsudvalget, Alm. del - bilag 113, at <http://www.folketinget.dk/> (010201).

<sup>28</sup> Offisielt fra statsråd 28.01.2000, at [http://odin.dep.no/smk/norsk/aktuelt/off\\_statsraad/099005-994017/index-dok000-b-n-a.html](http://odin.dep.no/smk/norsk/aktuelt/off_statsraad/099005-994017/index-dok000-b-n-a.html) (010201).

<sup>29</sup> February 2001.

<sup>30</sup> See e.g. *Human biobanks – ethical and social issues*, Nord 1997:9, The Nordic Committee on Bioethics 1997; Rynning, Biobankerna – hög tid för bankspektion? *Förvaltningsrättslig Tidskrift* 1998 pp. 303-333 and the National Board of Health and Welfare report Biobanks in Medical Care etc., 2000.

<sup>31</sup> It should be noted that property rights are dealt with solely in the private law studies of this project, whereas general matters of access, consent etc. are analysed from both private and public law aspects.