



**European Commission
Research Directorate-General**

**Survey on opinions from National
Ethics Committees or similar bodies,
public debate and national legislation
in relation to human biobanks**

**Directorate E
Biotechnology, Agriculture and
Food**

**Edited by Line Matthiessen and Kimmo Pitkänen
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Directorate E - Biotechnology, agriculture and food
The Director

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INTRODUCTION

The recent developments in biomedical research and biotechnology have increased the interest for the use of human biological material and the information contained in biobanks. At the same time it has led to new ethical dilemmas which among others are under discussion in ethics committees at national and international levels. New specific legislations regarding biobanks have been implemented in a few countries (Denmark, Norway, Iceland, Estonia and Sweden) and other countries are discussing legislative proposals or the need for specific regulation.

In order to feed the debate, the European Commission, DG Research, has now updated the survey concerning the opinions from national ethics committees and national legislations in relation to biobanks.

National Ethics Committees or Ministries of Health in the EU Member States, candidate countries, Georgia, Iceland, Israel, Norway, Switzerland as well as Canada and the United States have contributed. The current update is based on the information received until October 2004.

I would like to thank the contact persons in each country for providing this information.

The survey will continue to be updated on a regular basis. We would therefore like to invite you to provide any comments or new information you may have to Dr. Line Matthiessen (e-mail: line-gertrud.matthiessen-guyader@cec.eu.int) or Dr. Kimmo Pitkänen (kimmo.pitkanen@cec.eu.int or fax for both +32.2.299.18.60), who have been responsible for collecting the information.

Christian PATERMANN

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EU COUNTRIES

Survey on Human Biobanks

AUSTRIA

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

<http://www.bundeskanzleramt.at/DesktopDefault.aspx?TabID=3455&Alias=BKA>

Contact:

Dr Robert Gmeiner

Head of the Secretariat of the Bioethics Commission, Federal Chancellery

Hohenstaufengasse 3, A-1010 Vienna

Tel.: ++43/1/53115-4319

Fax: ++43/1/53115-4307

<mailto:robert.gmeiner@bka.gv.at>

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

For human biobanks general regulations concerning medical purposes are valid. The processing of medicines is regulated in the Austrian Pharmaceuticals Act (AMG) and the regulations on blood safety.

Contact person: Dr. Hans Kurz, Federal Ministry of Social Security and Generations, Department VIII/D/21, Radetzkystr.2, A-1031 Vienna, Phone: +43 1 71100 4643

If human biologic material is used for genetic testing the regulations of the Austrian Gene Technology Act provide special conditions that have to be considered: purpose of testing, handling of samples, institution, equipment, qualification of staff, protection of data and genetic counselling are regulated.

Contact:

Dr. Michel Haas

Federal Ministry of Social Security and Generations, Department XI/9

Radetzkystr.2, A-1031 Vienna, Tel: +43 1 71100 4845

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

Survey on Human Biobanks

BELGIUM

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Il faut toutefois savoir que certains avis font allusion à cette problématique; ainsi l'avis n° 25 faisant état de délai de conservation de fiches de sang ; de même l'avis n°24 en matière de cellules souches et clonage thérapeutique (recommandations : point 6 notamment) ; l'avis n°11 sur le don d'organes. Ces avis peuvent être consultés sur le site du comité : www.health.fgov.be

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

Arrêté Royal 15/04/1988 relatif aux banques de tissus et du prélèvement, de la conservation, de la préparation, de l'importation, du transport, de la distribution et de la délivrance de tissus (Moniteur Belge, 29/04/1988).

Arrêté royal du 23/12/2002 remplaçant l'AR du 15/04/1998 susdit ; il a été suspendu par le Conseil d'Etat ; conséquence : c'est l'AR 15/04/88 qui continue à s'appliquer.
Personne contact : Mr BONTEZ 00.32.2.210.47.69 du service public fédéral de la Santé publique

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

Revision AR 23/12/2002 susdit.

Survey on Human Biobanks

THE REPUBLIC OF CYPRUS

1. **Has your National Ethics Committee or similar body provided an opinion on human biobanks?**

yes

no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

2. **Will (~~or has~~) a public debate take (~~n~~) place on human biobanks?**

yes

no

If yes, how ~~was~~ / will it be organised, what were the conclusions, who is the contact person?

It will be within the future activities of the Cyprus National Bioethics Committee.

3. **Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person?**

There is no specific legislation regarding biobanks. The Law on the protection of personal data (L. 28(III)/2001) applies where the issue of such a protection arises as far as it regards human biomedical materials and the persons involved.

4. **Could you please indicate if any new legal and / or regulatory framework for human biobanks is under preparation?**

The Cyprus National Bioethics Committee has recently sent a letter to the Minister of Health with a view to get information regarding the biomedical materials collected during the IVF. The Committee will use these informations in order to provide its opinion / advice regarding the necessary legal or regulatory framework for human biobanks as far as it regards the biological materials collected to be used in IVF procedures.

The contact person, as far as legal situation is concerned, is Dr. Štěpán Hůlka from the Ministry of Health of the Czech Republic and, as far as practical medical questions are concerned, Dr. Radka Řízková from the same Ministry.

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

Except above mentioned decrees there is not foreseen any new regulations.

Survey on Human Biobanks

DENMARK

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

X yes

If yes, could you please summarize the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The work is available on: www.forsk.dk, click English version, click the button "SSVF", click "publications" but please note that new recommendations have been prepared by a working group chaired by the Danish Ministry of Interior and Health who is examining the area of human information banks in Denmark also with a view to incorporating the EU-directive on Personal Data protection.

The old work is from 1996, "Health Science Information Banks - Biobanks. 1996". This situation has been acknowledged previously by, amongst others, the Danish Council of Ethics (DCE), the Danish Medical Research Council (DMRC) and the Danish Central Scientific Ethical Committee (CSC).

Consequently, the three bodies established a cooperation in 1994 with a view to considering the new issues in a joint report. During the extensive work involved, it soon became clear to the authors group that, rather than a common debate outline or a customary report, what was needed was a publication that not only had the flavour of a report but could also double as a handbook proper for administrators, politicians, researchers and scientists.

The committee members were in agreement that biobanks are of immense importance to prevention, diagnosis, treatment and care within the health service and in evaluating the quality of these services. The use of biobanks by the research community plays a central role here, as is documented by a number of examples.

The collection of material for biobanks does not require consent for the storage of material extracted in, say, a diagnostic context and its subsequent use for some other purpose. Conversely, if a register is created, the Danish regulation does stipulate a number of regulations, including that of reporting it to the Data Surveillance Authority. If material or information from the biobank is used in a research project, the additional approval of the research ethical committee system is required, though not necessarily the consent of the person from whom that material or information originates.

2. Will (or has) a public debate take(n) place on human biobanks?

X yes

no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

Please contact The Danish Ethics Council: www.etiskraad.dk for further information.

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person.

Currently, in Denmark biobanks are not regulated by a specific legislation. The regulation of biobanks can be found in the following regulations:

Act on Processing Personal Data (Act no 429 of May 31 2000 as revised by Act no 280 of 27 April 2001 (Lov om behandling af personoplysninger))

Act on Legal Rights of Patients (Act no 482 of 1. July 1998 (Lov om patienters retsstilling)) with the amendments issuing from Act no 312 of 5. May 2004

Act on a Scientific Ethical Committee System (Act No. 402 of 28. May 2003 on a Scientific Ethical Committee System and the Handling of Biomedical Research Projects (Lov om et videnskabetisk komitéssystem og behandling af biomedicinske forskningsprojekter))

Act on the central management of the public health service (Act no 215 of 9. April 1999 as revised by act no 258 of 12 April 2000 and act no 141 of 5 March 2001 (Lov om Sundhedsvæsenets Centralstyrelse))

Please contact the Danish Ministry of Health Head of Section Bent Rasmussen for a description of the current legal situation: bra@im.dk

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

A task group of representatives of the Ministry of Interior and Health, the Ministry of Science, Technology and Innovation and the Ministry of Justice have been assigned to make an analysis of the requirement of further legislative regulation of the biobanks in Denmark. The task group issued a report in May 2002 (Betaenkning no 1414 by The Ministry of Interior and Health, May 2002).

It is stated in the English summary of the report, that the objectives of the task group has been examining the possibilities of securing the protection of the integrity of the tissue donors, and, if need be, to make recommendations for new legislation. The essential balance between the interests of the individual and society is the foundation on which the task group was to base its considerations and recommendations.

The task group has defined a biobank as follows: *“A biobank is defined as a structured collection of human biological material which is accessible under certain criteria, and where information contained in the biological material can be traced back to individuals.”*

The task group states the following in the English summary:

“It has been an important guiding principle for the considerations of the task group that under Danish legislation a biobank can be regarded as a so-called ”manual register” (non-electronic register), which is subject to the act on personal data processing (the personal data act). The act is based on the EU directive on the protection of physical persons in connection with personal data processing, etc., and it is therefore an expression of the legal principles applying within the entire EU area.

The EU directive has created or will create uniform rules for personal data in many of the countries with which Denmark co-operates and for personal data exchanged between these countries.

The task group has assessed that the personal data act in interaction with the relevant legislation within health and research (act on the legal status of patients, act on a science-ethical committee system and treatment of bio-medical research projects, act on central management of the public health service, etc., and other acts) does sufficiently regulate the majority of aspects of the biobanks.

It is therefore the assessment of the task group – in general for all biobanks within public health service and medical science – that the rules of the respective existing acts with regard to setting up, closure, control and supervision of biobanks and the rules on the rights of tissue donors are found to be sufficient to secure the consideration of patients' self-determination and integrity, balanced against the consideration of research and society.

However, the task group does find that there is a need for new legislation in two areas:

1) Self-determination of biological material donated in connection with examination or treatment should be separately regulated by including new rules in the act on the legal status of patients. This will provide the patient with the opportunity to ”back out” in relation to a central register; ”The Register for Application of Tissue” with regard to non-treatment related application of donated biological material at the same time as the patient is given a right to destruction and a conditioned right to surrender of donated biological material.

2) It must be ensured that all research projects - also including register research projects - that incorporate biological material are notified to and approved by a science ethical committee. This will require an amendment of the act on a science-ethical committee system and treatment of bio-medical research projects.

The basic aim of the proposals / bills is that the biological material must not be used for purposes other than those about which the patient / experiment person has been informed and which have expressly or tacitly been approved, or in the event of register research in which biological material is incorporated by having the

committee system in certain research projects that do not cause any liability on the experiment person attend to his or her interests without obtaining any consent. The central element in a re-arrangement is the opportunity of the patient to "back out" in relation to the Register for Application of Tissue with regard to non-treatment related application of donated biological material. Thus a patient may decide that biological material donated by that patient or which the patient has donated in connection with examination or treatment shall be applied only for examination or treatment of the person concerned and for purposes in immediate connection herewith. Such a decision must be recorded in the Register for Application of Tissue. Hereby the patient is safeguarded against the application of donated biological material, for instance, for research or commercial purposes, as the health person responsible for storing the biological material will have to search for information in the register if a non-treatment related application of the biological material is contemplated.

This right to "back out" in relation to the Register for Application of Tissue is supplemented with a right of destruction and a conditioned right to surrender of donated biological material. If a patient wishes that the donated biological material be destroyed, such wish shall – practically always – be fulfilled. If a patient wishes the donated biological material to be surrendered to him or her, the patient shall be able to show a special interest in this in order for the material to be surrendered.

Otherwise, the tissue donors have all the rights under the personal data act, e.g. the right to insight in information being processed and the right to be notified that information is being collected. In addition, the donor persons have all the rights and complaint opportunities under the act on the legal status of patients, act on central management of the public health service, etc., the act on patients' insurance, and the act on compensation for medicinal injuries. Thus the patient may complain to the Patients' Complaints Board of the National Health Service of the professional activities of health persons and raise issues on compensation for physical injury inflicted at a public hospital, etc., or compensation for medicinal injuries before the Patients' Insurance.

The new rules are proposed to apply solely to biological material donated after the enactment of the bill, although the rules of the personal data act on processing of personal data should incorporate all established biobanks, i.e. also biobanks that were set up prior to the enactment of the new rules."

Act no 312 of 5. May 2004, which amends the Act on Legal Rights of Patients concerning autonomy over biological material delivered in connection with medical treatment, implements the above mentioned proposals into law.



In the volume 2, ANNEXES, you can find the following documents:

- Act n°312 of 5 May 2004

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

The EGP biobank of blood samples, related phenotype and genealogical data regulated by the Human Genes Research Act. Additionally, the Convention of Human Rights and Biomedicine was ratified by Estonian Parliament on 8 February 2002 and entered into force on 1 June 2002. The human biobanks are regulated to some extent also by Law of Organ and Tissues Transplantation, which was adopted on 30 January 2002 and entered into force on 1 June 2002. The Additional Protocol to the Convention concerning transplantation of organs and tissues of human origin was signed by Estonia on 21 January 2002 **and ratified by Parliament (Riigikogu) on January 17, 2003**

At the Tartu University there are two other additional biobanks

1) Biobank of bones and other tissues at the Dept.of Traumatology and Orthopaedics of Tartu University Clinics. This bank was founded 1961 and is registered at the European Tissue Banks Association.
Contact person Prof. Tiit Haviko, MD, PhD, Head of the Dept.of Traumatology and Orthopaedics, University of Tartu.
Puusepa Street 8, Tartu 51014, Estonia
Phone +372 7 318 202
Fax +372 7 318 106
e-mail Tiit.Haviko@kliinikum.ee

2) Tissue Bank for Research, mainly histological materials. The principles of activity and constitution of this bank are approved by the Ethics Committee of Human Research of Tartu University. The activity of Tissue Bank is in conformity with the Estonian legislative system.
Contact person Andres Kulla, MD , Head of the Dept. of Pathology and Neuropathology of the Tartu University Clinics.
Ravila Street 19, Tartu 50411, Estonia
Phone +372 7 374 270
Fax +372 7 374 272
e-mail Andres.Kulla@kliinikum.ee

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

In this moment there are no other documents under preparation.

Survey on Human Biobanks

FINLAND

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The Sub-Committee on Medical Research Ethics has recently finalised an memorandum on DNA in epidemiological studies. This memorandum has been sent also to the Ministry of Social Affairs and Health. There the Sub-Committee says that our legislation does not cover research where there are thousands of samples that are intended to use to other purposes than originally intended. According to our Act on Medical Research or Act on medical use of organs and tissues it is not possible to give an open or wide consent that is needed for samples in biobanks. There seems to be a consensus about the need for separate legislation (or some amendments to the present legislation).

N.B. There is the report of the Nordic Committee on Bioethics on "Human Biobanks"(Nord 1997:9, Nordic Council of Ministers), available also in web: www.ncbio.org.

2. Will (or has) a public debate take(n) place on human biobanks?

yes, some

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

Some biobanks have been established in Finland. There is a need for a regulatory network on biobanks that is not covered by our legislation. The Act on Medical Use on Human Organs and tissues does not cover specific issues on biobanks (open/less open consent, further use of samples, genetic information etc.)

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

The Act on Medical Use of Human Organs and Tissues (no. 101/2001) was given 2 February 2001 and came into force in September 1st, 2001. This covers also the storage of tissue taken from donors or diseased persons and the necessary specific requirements. However, there are no specific regulations concerning biobanks.

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks

There has been some discussion about the specific need of legislation on biobanks on genetic information. As previously indicated, we will most probably either make amendments to the Act on Medical Use of Human Organs and Tissues or issue a separate act on Biobanks during the next years.

Survey on Human Biobanks

FRANCE

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

see opinion N° 77 available in English and in French version.

A specific n° of the Journal “Les Cahiers du CCNE” has appeared in 2004, N° 38 where this opinion + the annexes and various comments are available. An issue will be sent to you by surface mail.

A main characteristic has been a common “preamble” with the German National Ethics Committee (Ethikrat) that has worked on the same subject and has issued its opinion in March 2004.

The main rapporteur who can be contacted is Mme Nicole Questiaux, who you can contact through the CCNE or Anne Cambon-Thomsen (cambon@cict.fr)

<http://www.ccne-ethique.fr/>

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

La loi n° 2004-800 du 6 août 2004 relative à la bioéthique a été promulguée le 6 août 2004, elle a été publiée au Journal officiel du 7 août 2004.

Loi n° 2004-800 du 6 août 2004 relative à la bioéthique
Legifrance

<http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0100053L>

La loi relative à la politique de santé publique a été promulguée le 9 août 2004 et publiée dans le Journal officiel du 11 août 2004.

Loi n° 2004-804 du 9 août 2004 relative à la politique de santé publique
Legifrance

<http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0300055L>

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

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In the volume 2, ANNEXES, you can find the following documents:

- National Consultative Ethics Committee for Health and Life Sciences: Opinion no 77. Ethical issues raised by collections of biological material and associated information data: "biobanks", "biolibraries"

Survey on Human Biobanks

GERMANY

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

The National Ethics Council began debating this issue in May 2002. A joint debate with the French National Consultative Ethics Committee (Comité Consultatif National d'Éthique) began in late June 2002 in Berlin and led to a common declaration on the subject in October 2003. An opinion on human biobanks was published by the German National Ethics Council in March 2004.

From the perspective of biomedical research, biobanks are instrumental in the acquisition of important knowledge that enables the dedicated, continued development of therapeutic and diagnostic methods and applications. The economic potential of biobanks is substantial and as such of great interest to the pharmaceuticals industry, for instance.

In this context, the role of patients and donors and their rights of personality and right to information must be given due consideration.

The ethical and legal implications of biobanks become particularly apparent e.g. when considering the possible reuse of collected bodily materials for other purposes. In this respect, it is still unclear to what extent the patients and donors, or their families, must be informed in order to gain their consent.

http://www.nationalerethikrat.de/themen/pdf/Stellungnahme_Biobanken_04-03-17.pdf

The Central Ethics Commission of the Federal Chamber of Medical Doctors (Bundesaerztekammer) published its opinion on the (further) use of human body materials for the purpose of medical research. This opinion refers to the systematic storage of biological materials. It can be found at:

<http://www.zentrale-ethikkommission.de/10/30Koerpermat.html>

-The <<**Working Group of the Medical Ethics Committees***>> has discussed ethical and legal issues of the use and storage of human biomaterials during its 21st annual meeting on November 22, 2003. The discussion focused mainly on to what extent patients and other donors including their respective families must be informed in order to gain their consent. No definite agreement among the members of the Working Group could be reached on a document entitled <<Manual for informed consent on the scientific use of blood and tissue samples and the personal data involved>>.

The dissenting views mainly remained on:

a) whether informed consent can be asked for concerning measures and procedures (involving the storage and future use of non-anonymized biomaterials and data) the future personal and legal consequences of which are yet completely unknown to the patient or donor.

b) whether there should be a time limit to the validity of the informed consent given (e.g. 20 years) and thus to the storage of the biomaterials donated.

The controversial arguments are listed in the foreword of <<Anhang 3>>(attachment 3) (p.32/33) of the <<Protocol of the 21st annual meeting of the Working Group of the Medical Ethics Committees in the Federal Republic of Germany>>

The protocol itself can be found under the link <<Protokolle>> on the official homepage of the Working Group. The URL of the homepage is:
<http://www.ak-med-ethik-komm.de>

The Working Group decided to discuss the document in 2 years again and then have the plenary make a final decision (see TOP 6 section 2 <<Formale Vereinheitlichung>> of the document , p.17/18)

-- The **Enquete Commission Ethics and Law in modern medicine of the German Parliament** (Enquete-Kommission Ethik und Recht der modernen Medizin des Deutschen Bundestages) has issued a statement at its 8th session on November 11, 2003 concerning the

adoption of a Directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (Interinstitutional Dossier 2002/0128). Within this statement, under paragraph III. 1 c) and d) , p.10/11 the Enquete Commission deals with ethical questions concerning access and benefit sharing which it recommends for commercial biobanks. Ethical questions concerning informed consent are also dealt with (p.11)

The document can be found under the URL:

http://www.bundestag.de/parlament/kommissionen/ethik_med/berichte_stellg/03_11_03_Stellg_Gewebe.pdf

- On March 27, 2003 the Senate Commission on Genetic Research of the **Deutsche Forschungsgemeinschaft (DFG, German Research Organisation)** has formulated a new statement on predictive genetic diagnostics. It takes the place of the statement "Humangenomforschung und prädiktive genetische Diagnostik: Möglichkeiten - Grenzen - Konsequenzen", issued in 1999, and reaches beyond the latter's content.

Regarding genetic samples and data banks, the DFG recommends under paragraph 5 (p.34 -54) that procuring, storing and processing samples and data has to go hand in hand with a reliable protection of the respective donors from any abusive use. In addition, the donor has to give his self-determined consent to the use of his samples and data. Under these conditions, the DFG also holds that a donation of samples or data with a right of usufruct formulated in broad terms and without being tied to any concrete research projects is ethically and legally justified. The emphasis has to be on striking an appropriate balance between the legal protection of the donor's personality and the protection of confidence for the researcher.

In the field of labour and insurance law, the DFG suggests that predictive genetic tests only be carried out in connection with an employment relationship if the tests serve the protection of the employee and a predictable emergence of a genetic disease is at issue that is immediately related to the employment relationship. Furthermore, it should be possible to conduct these tests if the consequences of such a genetically conditioned disease probably occurring would put other people at a considerable risk.

The DFG holds the opinion that predictive genetic tests should not be made a general condition for effecting insurances.

The document can be found under the URL:

http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2003/download/paediktive_genetische_diagnostik.pdf

There is also an English version available under the URL:

http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2003/download/predictive_genetic_diagnosis.pdf

* The “Working Group of the medical ethics committees in Germany” (“Arbeitskreis medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland”) is constituted by the ethics committees of the chambers of medical authorities (“Landesaerztekammern”) of each state of the Federal Republic of Germany and the ethics committees of medical faculties of German universities.

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

The German National Ethics Council held a public conference on the issue on 24 October, 2002. The conference papers and discussion received considerable attention in the general media as well as more specialised publications. The opinion on human biobanks published in March 2004 has also drawn considerable attention from the media and other interested parties.

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

There is up to now no explicit law or regulatory framework referring exclusively to human biobanks. The Federal Data Protection Law (“Bundesdatenschutzgesetz”) is, of course, relevant here.

A statement by the German government given before parliament on Feb 18, 2002 regarding the use of human tumour tissue summarizes the current situation. The statement can be found on the internet at:

<http://dip.bundestag.de/btd/14/082/1408256.pdf>

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

The German Government (German Ministry of Health and Social Security) has announced to finally bring a first draft of the long planned law on genetic testing/diagnosis before parliament in June 2004. All relevant ethical issues concerning informed consent, the storage and further use of biomaterials and personal data linked to it shall be dealt with according to a spokesman of the Ministry of Health and Social Security.

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In the volume 2, ANNEXES, you can find the following documents:

- Predictive genetic diagnosis: Scientific background, practical and social implementation
 Memorandum by the Senate Commission on Genetic Research
- 21. Jahresversammlung/Mitgliederversammlung des Arbeitskreises Medizinischer Ethikkommissionen in der Bundesrepublik Deutschland am 22. November 2003 in Munster (the minutes of the meeting)
- Gutachtliche Stellungnahme der Enquete-Kommission Ethik und Recht der modernen Medizin des Deutschen Bundestages vom 03.11.2003 (8. Sitzung) zum *Erlass einer Richtlinie des Europäischen Parlaments und des Rates zur Festlegung von Qualitäts- und Sicherheitsstandards für die Spende, Beschaffung, Testung, Verarbeitung, Lagerung und Verteilung von menschlichen Geweben und Zellen (Interinstitutionelles Dossier 2002/0128)*
- Zusammenfassung - Regelungsvorschläge des Nationalen Ethikrates

Survey on Human Biobanks

GREECE

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarize the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

<http://www.bioethics.org.gr/>

<http://www.bioethics.gr/>

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

Human biobanks are only covered in regard to human tissues for transplantation. Law 2737/99 on transplantations of human tissues and organs, in article 6 provides for the establishment of Tissue Banks. Such biobanks can be kept either in public hospitals or in the Research Institute “Demokritos” and are under the supervision of one of the following Ministries: Health, Education, Defence or Development. The National Transplant Organization (EOM) is the main advisory body of the Government in regard to the functioning of each biobank to be established. Contact person Mme Yiota Makrodimitri at EOM, eom@otenet.gr

The law 2928/2001, on the organized crime, provides in principle the destruction of biological material which has been examined in criminal procedure. However, it provides also the storage of such material, only in exceptional cases of further crimes’ investigation, just for a limited time period, on the basis of a special judicial decision.

The recent law 3089/2002, on medically assisted human reproduction, provides, in general, the possibility of storage of gametes or surplus embryos in cases of IVF treatment. In this respect, the concerned persons must decide, in written form, whether the stored material should be a) donated to other persons for reproductive purposes, b) used for therapeutic or research purposes, or c) destroyed. The maximum storage period is 5 years.

After this period the stored material should be either destroyed or used for therapeutic or research purposes. Furthermore the law provides that the identity and/or medical data of donors and recipients of gametes or embryos must be kept confidential. Access to such personal data is permitted only for medical reasons of the child.

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

All relevant activities in Greece have to be carried out under the conditions provided in Law 2472/97 regarding Data Protection.

Greece will have to harmonise its legislation with Directive 2004/23/EU on standards of safety and quality regarding donation, storage etc of human tissues and cells, by 7 April 2006.

An ad hoc legislative committee of the Ministry of Health elaborates a draft bill, concerning issues of licensing and function of IVF centers.

In the Bill, reference is made to biobanks, but only as far as medically assisted reproduction is concerned. Namely the Bill provides for the licencing and functioning of Cryopreservation Banks regarding human gametes, tissue and fertilized ova in the context of assisted reproduction only.

The Umbilical Cord Blood Bank in Greece (situated in the Foundation for Biomedical Research of the Athens Academy) is technically ready but it has not yet been officially established as the relevant legislative framework is under preparation. Tthe basic legislative framework is provided by the Law on Transplantations, but the detailed one has to be worked upon. The latter will be based on the Netcord - FACHT standards as well as on the European Directive regarding standards of quality and safety for the donation, procurement, testing, processing, preservation etc of human tissues and cells. It will be the first official bank of its kind in Greece.

Survey on Human Biobanks

HUNGARY

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

National Ethics Committee has already discussed one proposal on Hungarian biobanking. Contact person:

Dr. Andras Falus, PhD, CMA
Professor and Chairman
Department of Genetics, Cell- and Immunobiology, Semmelweis Medical University
4 Nagyvarad ter, H-1089 Budapest Hungary
tel: 36-1-210-2929, fax: 36-1-303-6968
faland@dgci.sote.hu

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

There is a proposal for Hungarian legislation on a law on Human genetics and biobanking, it is discussed publically

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

It is not yet established, the debate on the law is just in progress (see 2.)

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

See. 2., 3.

Survey on Human Biobanks

IRELAND

- 1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?**

yes no.

The Irish Council for Bioethics established in May 2002 currently has a working group on human biological material that may deal with this issue in its forthcoming report. The Council's website is <http://www.bioethics.ie/>

- 2. Will (or has) a public debate take(n) place on human biobanks?**

yes X

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

- 3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person**

None.

- 4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation**

Survey on Human Biobanks

ITALY

- 1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?**

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

<http://www.palazzochigi.it/bioetica/>

- 2. Will (or has) a public debate take(n) place on human biobanks?**

yes no

- 3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person**

Regarding the treatment of personal data for biomedical research, a regulation is provided by the law n.675 on data protection, and by the decree n.281 on the treatment of personal data for scientific research, or statistical and historical purposes. (july 30, 1999). The law and the successive implementation decrees are available in the website www.garanteprivacy.it. This regulation concerns only data that permit personal identification and it excludes the anonymous data (decree 281/99 see art.10). The law n.675/96 does not require the consent to treatment of anonymous data in case of scientific research. About the biobanks it can be observed that the only regulation that could be considered connected with this issue is the law n.91 (april 1, 1991) on the organs and tissues transplantation. In fact, the fifteen article of the law provides for the creation of scientific structures for the conservation of human tissues assigned to therapeutic transplantation, in any Italian district.

Please note: all these informations refer to research on human biological material and cannot be considered related to experimentation on human subjects (the clinical experimentation and the role of the Ethics Committee -IRB- are regulated by a specific rule).

- 4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation**
-

Survey on Human Biobanks

LATVIA

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

YES

Latvian Human Genes Research Act –approved by Saeima in 03.07,2002, into force from 01.01. 2004.

Objectives:

1. to regulate creation and function of the Genome Database and genetic research connected with the database;
2. to ensure the voluntary nature of gene donation and the confidentiality of the identity of gene donors;
3. to protect gene donors from misuse of their data and from discrimination based on interpretation of their DNA.
- 4.

Central Medical Ethics Committee of Latvia provided an opinion on draft law, sent it to the Government and the media for publishing.

Central Medical Ethics Committee of Latvia is providing an opinion and is participating in working group on Law on Protection of Dead Human Being and use of Human Organs and Tissues (15.12.10992, modification on 21.09.1995 and 06.12.2001 into force since 01.01.1993) and Act of storage, accumulation and Use of Human Organs and Tissues (Cabinet of Ministers, Rules No 398, July 15, 2003)

2. Will (or has) a public debate take(n) place on human biobanks?

YES

The public debate has been induced by draft Human Genes Research Act and is widespread now. The reaction in the media have been quite different.

3. Could you please describe the current legal and/or regulatory framework for human biobanks in your country and indicate a contact person

Law on Protection of Dead Human Being and use of Human Organs and Tissues (15.12.1992, modification on 21.09.1995 and 06.12.2001 into force since 01.01.1993) The object of the regulations is to protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to transplantation of organs and tissues of human origin.

Act of Use of Human Organs and Tissues- Cabinet of Ministers, rules nr.398, 19.07.2003. This act covers the relevant professional obligations and standards in accordance with which all interventions in the transplant and storage process must be performed.

There are two Regulations of Cabinet of Ministers: 1) on State Genoma Register and 2) Regulation on Transfer abroad of Tissue Samples or Copies of Written Health Status of Patient. Accepted in 2004.

Regulation of Ministry of Welfare of Latvia on blood safety nr.260, September 20,1995.

These regulations covers blood and the products derived from blood for use in transfusion medicine, preparation, use and quality assurance of blood components
Law on Reproductive and Sexual Health (approved 31.01.2002, in force on 01.07.2002)

Act on Human Reproductive and Sexual Health covers the relevant professional obligations and standards in accordance with sexual and reproductive health including the human medical assisted reproduction, storage of reproductive tissue and protection of Embryo.

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation.

Survey on Human Biobanks

LITHUANIA

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Lithuanian Bioethics Committee has not discussed an issue on human biobanks explicitly, however, the question of banking human gametes was included in the discussion of the Law on Artificial Fertilization.

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

Two draft Laws on Artificial Fertilization have been discussed in the Parliament this summer. One of them, proposed by the Ministry of Health, envisages storage procedures for human reproductive cells and embryos. An alternative draft prepared by the group of parliamentarians does not allow: (1) the donation of human gametes, (2) banking of sperm and ovum as well as human embryos.

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

Regulations, related to this issue are:

The Law on Human Tissue and Organ Donation and Transplantation, 1996, amended on 25-03-2004. According to the article 2 paragraph 8 of this law, Tissue bank is defined as a public health care institution responsible for the procurement, preservation, storage and distribution of tissues and/ or cells as well as for other functions defined by law.

Article 4 of the law states that the tissue banks can be established only by the tertiary level public health care institutions and/or medical universities.

This regulation does not cover reproductive cells (eggs, sperm), embryos and embryonic stem cells, foetal tissues, and blood components (except transplantation of haematopoietic cells taken from adults, placenta, or the umbilical-cord blood).

The use of blood and its components is regulated by the Blood Donation Law, 1996 (amended on 09-10-2003).

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

Lithuanian competent institutions are working on the harmonisation of national laws with the EU instruments, such as Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

Following the Ministry of Health decree to set “Procedural and Financial Guidelines for Transplantation of Human Organs and Tissues”, the guidelines related to biobanking of Bone tissue, cornea, heart valves are to be drafted in the future.

Contact addresses:

Lithuanian Bioethics Committee

Tel./Fax: 3702 224565

National Organ Transplantation Office

Tel. + 370 5 279 60 96

Fax. + 370 5 279 66 91

Survey on Human Biobanks

LUXEMBOURG

(up-date of 15.10.2001)

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

This subject was raised during the elaboration of our opinion on medical assisted procreation; this opinion will be published soon.

Contact:

Jean-Paul Harpes

Co-ordinator of CNE

20, montée de la Pétrusse Tel.: 352.478.66.28

L – 29 12 Luxembourg Fax: 352.2921.86

2. Will (or has) a public debate take(n) place on human biobanks?

yes not yet

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

A copy of the opinion will be sent to you.

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

This framework does not exist yet.

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation.

This problem will be raised when a Medical Centre for Medical Assisted Procreation will be created.

Survey on Human Biobanks

THE NETHERLANDS

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

The Health Council of the Netherlands (Gezondheidsraad) has issued several reports relevant to biobanks (but none specifically on that issue):

- Health Council of the Netherlands. *Proper Use of Human Tissue*. The Hague: Health Council of the Netherlands, 1994. Publication number: 1994/01. An English translation of the report is available from the secretariat of the Health Council (tel +31 70 3407520; fax +31 70 3407523; order@gr.nl).
- Health Council of the Netherlands. *Stem cells for tissue repair*. The Hague: Health Council of the Netherlands, 2002. Publication nr 2002/09. English version available on website: www.healthcouncil.nl Contact Person at the Health Council: dr PA Bolhuis: pa.bolhuis@gr.nl
- Health Council of the Netherlands. *Hematopoietic stem cells*. The Hague: Health Council of the Netherlands, 2003. publication no. 2003/17. Report in Dutch; English translation of the executive summary on www.healthcouncil.nl Contact Person at the Health Council: dr PA Bolhuis: pa.bolhuis@gr.nl

The Royal Dutch Academy of Sciences (KNAW) is currently preparing a report on multifactorial diseases that will also include discussion of whether a national biobank should be set up in the Netherlands. In view of this, an invited workshop on biobanks was held at the KNAW on 24 September 2004. Information on this project: KNAW@bureau.knaw.nl

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

Safety and Quality of Human Tissue Act (in force since 1 July 2004). Aim of this law is to achieve a quality regime for the donation, manipulation and implantation of human bodily tissue. The core of the legal system is the requirement that human tissue aimed for medical purposes (with certain exceptions, eg certain bodily material falling under the Organ Donation Act) must be offered to an organ bank.

Decree concerning Requirements for the handling of Human Tissue (in force since 1 July 2004). Specifies requirements for Organ Centers (under the Organ Donation Act) and Organ banks (under the Safety and Quality of Human Tissue Act).

Contact person at the Ministry of Health for this legislation: mrs ir.GJ Huisman: gj.huisman@minvws.nl With regard to biobanks: dr GJ Olthof: gj.olthof@minvws.nl

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

Relevant legislation under preparation:

Bill on the right of determination concerning human tissue

Survey on Human Biobanks

POLAND

- 1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?**

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

<http://www.bioetyka.am.wroc.pl/>

- 2. Will (or has) a public debate take(n) place on human biobanks?**

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

- 3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person**

- 4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation**

Survey on Human Biobanks

PORTUGAL

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The National Council of Ethics for Life Sciences has deliberated to prepare an opinion on Human Biobanks that shall be ready during 2005.

<http://www.cnecv.gov.pt/CNECV/SiteEntry/>

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

Public debate is expected as soon as the National Council of Ethics for Life Sciences begins its discussion for the opinion.

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

There is no legal and/or regulatory framework for human biobanks in Portugal.

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation.

Apart from the opinion mentioned in nº 1 no legal or/and regulatory framework for human biobanks is under preparation.

Survey on Human Biobanks

SLOVAK REPUBLIC

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

No specific legislation so far, to my knowledge.

I think, there are some guidelines produced by the Ministry of Health, or responsible medical officers – specialists of the Ministry for the tissue and blood banks.
I shall search for more specific information shortly.

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

Not to my knowledge.

Survey on Human Biobanks

SLOVENIA

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

* yes

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The recommendation was formulated by the National Medical Ethics Committee but has not been published. It is given to researchers submitting projects for ethical review where research is done on archived biological materials of human origin not collected prospectively for those particular studies. The main points are the following: arrangements must be made to protect privacy and confidentiality of personal medical data;

- prior approval by a research ethics committee must be obtained for any research use of such data or material;

in the course of a research study, early anonymisation of the material is required;

in many clinical studies biological specimens are collected and stored with a view to a possible, at that time undefined, research use. Before the biological material (or information) is used for a research purpose not foreseen and approved at the time of its collection, consent of the data subject should be sought and obtained if reasonably possible;

when this is not possible or the effort and cost would be disproportionate to the (minor or remote) possibility of damage to the interests of privacy and confidentiality, the ethics committee may absolve the researcher from the duty to seek consent;

the patient may give a blanket consent to all future uses of his/her stored specimens, or may opt to be asked for consent to any new use, or may refuse consent to further storage after the study is completed.

if a patient withdraws from a study, he or she may opt to have his/her biological samples removed and destroyed and further use of any identifiable personal information prohibited;

information to source subjects on unexpected findings relevant to their health must be provided together with appropriate counselling in a health care setting;

special rules apply in case of genetic studies in order to protect confidentiality and avoid harm of predictive tests.

Contact person: Prof. Jože Trontelj, Chair, National Medical Ethics Committee,
Zaloška 7, SI-1525 Ljubljana, Slovenia. E-mail:
joze.trontelj@kclj.si

2. Will (or has) a public debate take(n) place on human biobanks?

no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

There is a law on police which regulates their biobank.

There are plans to prepare legal regulations for biobanks in the medical setting.

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

In Slovenia we are waiting for the guideline currently in preparation by the CDBI (Council of Europe).

Survey on Human Biobanks

SPAIN

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

no

The Spanish Advisory Committee on Ethics of Scientific and Technological Research (Comité Asesor de Ética en la Investigación Científica y Técnica) is preparing an Opinion for the Spanish Government, in which some relevant considerations on biobanks and human samples will be included.

Contact person: Prof. Dr. Cesar Nombela (Chairman): rosa.capeans@fecyt.es

http://www.fecyt.es/default.cfm?id_seccion=3851&id_sec=1585&nivel=1

2. Will (or has) a public debate take(n) place on human biobanks?

yes

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

IX Meeting on Law and the Human Genome, 2002, Bilbao.

The main conclusion was that there is no specific regulation under Spanish Law concerning the storing, the use and research with human samples and that a legal framework is urgently needed.

Contact person: Prof. Dr. iur. Dr. med. Dr. h.c. CM Romeo-Casabona, Director, Inter-University Chair in Law and the Human Genome, University of Deusto (e-mail : cromeo@genomelaw.deusto.es)

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

* The Act 45/2003, 21th November, which modifies Act 35/1988, on Human Assisted Reproduction, has previewed the creation of the National Centre for Transplants and Regenerative Medicine. At this Centre a National Bank of Cell Lines will be created. The main tasks of this Bank will be the obtaining, banking, keeping and management of line cells according to rules and standards stipulated by national and international laws. There is also previewed a multidisciplinary Commission for the Monitoring and Control of the Donation and Use of Human Cells and Tissues.

The Statute of the National Centre for Transplants and Regenerative Medicine has been approved by Royal Decree 176/2004, 30th January. Two Reference Centres for banking and research with human embryonic stem cells (from surplus frozen embryos) have been approved: Andalusia and Catalonia. The multidisciplinary Commission will begin its tasks in September 2004. Andalusia has its own Act (Act 7/2003, 23th October, on the research in Andalusia with non-viable for human reproduction pre-embryos), but no rules concerning biobanks has been established. Contact person: Dr. Rafael Matesanz, Director of National Centre for Transplants and Regenerative Medicine: rafmatesanz@yahoo.es

- * There is a national specific regulation on the use of human tissues (Royal Decree 411/1996, 1st March), which includes the definition and functions of tissue banks for therapeutic purposes exclusively (tissue transplants).
In this regulation there is a lack of provisions in relation to the use of human biological samples and tissues for research, but it has been by the new rules as it has been explained before. The ONT is depending from and coordinated by the National Centre for Transplants and Regenerative Medicine, as it has been stipulated by Act 45/2003.
Contact person: Dr. Eduardo Fernandez Zincke: ONT email: ezincke@msc.es.

See Annex for:

- * Act 45/2003
- * Royal Decree 176/2004
- * Royal Decree 411/1996

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

- * Spanish Government has communicated its intention to review deeply the current rules of Acts 35/1988 and 45/2003, on Human Assisted Reproduction. As it was explained before, these Acts have the rules for research with human embryos. The previous task for the preparation of a Draft has been committed to the National Assisted Reproduction Commission. It is foreseeable that some aspects related to biobanks will be changed.

CM R-C

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In the volume 2, ANNEXES, you can find the following documents:

- LEY 45/2003, DE 21 DE NOVIEMBRE, POR LA QUE SE MODIFICA LA LEY 35/1988, DE 22 DE NOVIEMBRE, SOBRE TÉCNICAS DE REPRODUCCIÓN ASISTIDA
- MINISTERIO DE LA PRESIDENCIA : 1849. REAL DECRETO 176/2004, de 30 enero, por el que se aprueba el Estatuto del Centroo Nacional de Transplantes y Medicina Regenerativa.
- REAL DECRETO 411/1996, de 1 de marzo, por el que se regulan las actividades relativas a la utilización de tejidos humanos

Survey on Human Biobanks

SWEDEN

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

The Swedish Medical Research Council (MRC) (www.vr.se)

The Swedish National Council on Medical Ethics (www.smer.se)

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

There has been a relatively lively media debate about the biobank legislation that came into effect on January 1, 2003 .

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

The Swedish Act (2002 :297) on Biobanks in Health Care came into effect on January 1, 2003. (The Governmental Bill 2001/02:04 as well as the Act is available in Swedish on the Riksdag website www.rixlex.se). The National Board on Health and Welfare has issued additional regulations and recommendations. The legislation applies to biobanks in the private sector as well as those in the public sector, and to old banks as well as new ones. Under certain conditions, samples of human biological material may thus be stored and used for health care purposes or other related purposes, such as biomedical research, production of medicinal products etc. An important limitation to the scope of the Act on Biobanks is, however, that it only applies to samples that originate from the health care sector. Samples collected by e.g. pharmaceutical companies, biotech companies or research institutions, without any connection to health care activities, are not covered by the legislation. Routine samples taken solely for diagnosis or treatment of the donor, are only covered if they are preserved for more than two months. Samples that cannot be traced to an identifiable individual do not fall under the Act.

The Act on Biobanks in Health Care regulates a number of issues, such as the setting up, registration and monitoring of biobanks.

Requirements concerning information and donor consent are prescribed, as well as further prerequisites for the use and transfer of biobank samples, such as coding or de-personalisation. There is an explicit prohibition against any transferring of or granting access to biobank samples with the purpose of financial gain. If the bank as such is to be transferred or discontinued, the authorization of the National Board on Health and Welfare will normally be required. Biobank materials must be stored in such a way that they are protected from being spoiled, or accessed by unauthorised persons.

The Act on Biobanks also contains certain provisions on the role of the Boards for Ethics Review, with regard to research involving biobank samples. As of January 1, 2004, there is a new Act (2003:460) on Ethics Review of Research Involving Humans. This Act makes ethics approval a mandatory prerequisite for any research involving the use of biological samples taken from a human being, provided the samples can still be traced to the donor. Ethics approval, based on certain consent requirements and other safeguards, is thus required for research on biological samples regardless of whether or not the material is covered by the Act on Biobanks.

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

A Government Bill on stem cell research (Regeringens proposition 2003/04:148) has been presented in June 2004. Certain changes are proposed in the Act (1991:114) Concerning Measures for Research or Treatment Involving Fertilized Human Ova, making it clear that embryos may be created for research also by somatic cell nuclear transfer, under the same restrictions that apply to research on fertilized ova (e.g. ethics approval, 14-day limit, no implantation).

Survey on Human Biobanks

UNITED KINGDOM

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The Nuffield Council on Bioethics in 1995 published a report called ‘Human Tissue; ethical and legal issues’. The report was not primarily concerned with biobanks but did make some relevant recommendations. The conclusions and recommendations can be found at <http://www.nuffieldfoundation.org/bioethics/publication/index.html>

In May 2002 the Human Genetics Commission published a report called ‘Inside Information: balancing interests in the use of personal genetic data’.

A copy of the report, summary and supporting evidence is at www.hgc.gov.uk/business_publications.htm#insideinformation.

The HGC concluded that medically-based research was essential to benefit from advances in genetic knowledge. It recommended that it give further consideration to the establishment of large genetic databases to consider questions such as consent, privacy, access and ownership. It also recommended an independent oversight mechanism for all large genetic research databases. The HGC has held fruitful and informative discussions with the funders of the large population cohort.

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

There has been considerable media and public debate about human tissue storage in the UK. The Human Genetics Commission has consulted widely on the protection of genetic information, including human biobanks. The results of the public consultations are on the HGC website www.hgc.gov.uk.

The Department of Health’s consultative report, ‘*Human Bodies, Human Choices*’, was published in July 2002 following the Department’s review of the law on human

organs and tissues. The report set out the current position regarding the removal, retention and use of human tissue and organs from the living and the dead, whether for therapeutic, research or other purposes. Proposals for new legislation were published in September 2003, followed by introduction of the Human Tissue Bill into Parliament in December 2003. For further information see the Department of Health website at: www.doh.gov.uk/tissue, and the UK Parliament website www.parliament.uk

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

Much of the current legal framework for dealing with human tissue is covered in the Department of Health's consultative report '*Human Bodies, Human Choices*', published in July 2002 (see Q2 above). Further, '*The use of human organs and tissue : An interim statement*' published in April 2003, provides interim guidance on the removal, retention and use of human tissue.

A non-statutory accreditation scheme and Code of Practice was put in place in April 2002 for the regulation, within the public health sector, of human tissue banking for therapeutic purposes.

Contact: Hugh Whittall, Human Tissue Branch, Department of Health, Skipton House, 80 London Road SE1 6LH. E-mail: hugh.whittall@doh.gsi.gov.uk

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

A consultative document, '*Human Bodies, Human Choice*' was published in July 2002. The consultation closed in October 2002 and proposals for new legislation on human tissue, including a comprehensive regulatory framework, were developed following this consultation, leading to the introduction of the Human Tissue Bill in the UK Parliament. (See question No.2).

The UK, in common with other member states, is required to implement Directive 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells.

NON-EU COUNTRIES

Survey on Biobanks

CANADA

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

no

(no specific opinion on human biobanks, but the Tri-Council policy statement has a chapter on biobanks. This statement provides ethical guidance that researchers funded by the three organizations need to follow when undertaking research involving human subjects.

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Medical Research Council of Canada, Natural Science and Engineering Research Council of Canada, Social Science and Humanities Research Council of Canada (1998), Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans, Canada, August 1998 (with 2000 and 2002 updates), Official site of the Tri-Council, http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf (date accessed: April 19, 2004)

Chapter 8 on Genetic research (impact on biobanks through the back door) (consent issues, access by third parties dependant upon individual consent, family information to be coded, access to genetic counseling when appropriate))

Contact person: Derek J. Jones, Executive Director, Interagency Advisory Panel on Research Ethics, 350 Albert Street, Ottawa, Canada, K1A 1H5, Tel +001 (613) 996 0072

<http://www.ethique.gouv.qc.ca/>

<http://www.ncehr-cnerh.org/>

2. Will (or has) a public debate take(n) place on human biobanks?

no

(But the abovementioned organizations are contemplating the updating of their statement, and will possibly address the issue of human biobanks)

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

→ Currently, there is no specific federal or provincial legal framework specific to human biobanks. However a number of legal instruments and regulations either on privacy protection of personal information or research, or tissues that are relevant to biobanks

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks

→ No new legal regulatory framework for human biobanks.

Survey on Human Biobanks

CROATIA

- 1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?**

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

- 2. Will (or has) a public debate take(n) place on human biobanks?**

yes not yet

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

- 3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person**

There is no framework, but cord-blood bank exists.

- 4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation**

No

Survey on Human Biobanks

GEORGIA

(Updated, 21 May 2004)

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person¹

There is only one type of human biobanks established by Law in Georgia. In particular, the Law on Human Organ Transplantation² sets up the basis for the establishment of transplantation banks. Below is given general statements from the above-mentioned law related to Transplantation Banks.

Any independent medical institution or a part of a medical institution licensed according to the Legislation of Georgia can serve as the Transplantation Bank.

Transplantation Bank is managed by the physician or biologist possessing a relevant license.

Transplantation Bank:

performs testing and selection of the deceased and/or alive donors,
ensures that only appropriately selected and tested organs are taken,
ensures that organs are adequately typed, transported and stored with the aim of its subsequent transplantation.

¹ The law has been drafted by the health legislation group (now Department of Health Legislation and Bioethics) at the National Institute of Health. The Department is headed by Professor Guram Kiknadze. I (Givi Javashvili) am an expert of the above group from the day of its establishment.

² The Law of Georgia on Human Organ Transplantation was adopted on February 23 2000. The following articles concern the issues related to transplantation banks: 25, 27, 30, 32, 34, 35, 36, 37, 38, 41, 44, 45, 46, 57.

*Transplantation Bank shall keep detailed records reflecting data about donor testing, organ taking, typing, transportation, processing and storage.
Export of the human organs from Georgia is allowed only under the permission of the Ministry of Labour, Health and Social Affairs via Transplantation Bank.
The Ministry of Labour, Health and Social Affairs is in charge of monitoring the compliance of the operations performed by transplantation banks with the established standards.*

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

There are no new legal or regulatory instruments for human biobanks under preparation.

CONTACT PERSON:

Givi Javashvili, M.D., Ph.D.,

Expert, Health Law and Bioethics Department, National Institute of Health;

Vice-Chairman, National Council on Bioethics;

Chairman, Georgian Health Law and Bioethics Society;

National Expert and Bureau Member of the Council of Europe Steering Committee on Bioethics.

51 Javakhishvili Street,

Tbilisi, 0102,

Georgia

Tel/Fax: +995 32 940 160

E-mail: G.Javashvili@curatio.com

Survey on Human Biobanks

ICELAND

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The Bill on Biobanks was first proposed in the Parliament in 1998 and The National Bioethics Committee (NBC) provided a written opinion in December 1998 to the Parliament's Committee on Health and Social Security. Many of the recommendations of the NBC were taken into account when the Bill was revised before it was proposed again to the Parliament in year 2000. The Ethical Council of the Directorate of Health (preceeded the National Bioethics Committee) was instrumental in legislation on biobanks and drafted the first Bill on Biobanks that was proposed in the Parliament in 1998. Both the Ethical Council and The National Bioethics Committee (NBC, established in July 1997) provided written opinions to the Parliament's Committee on Health and Social Security. Many of their recommendations were taken into account when the Bill was revised before it was proposed again to the Parliament in year 2000.

In March 2000 The Centre for Ethics of the University of Iceland organized a workshop on Genetic Research and the use of Health Information, where the Bill of Biobanks was presented and discussed. The chairman of the NBC gave a presentation on informed consent and the use of biobanks for genetic research.

In May 2000 the NBC provided a written opinion on the revised Bill on Biobanks and NBC's chairman presented the committee's views and participated in discussion at a meeting with the Committee on Health and Social Security. The recommendation of the NBC were in principle all adopted in the final version of the Bill that was passed by the parliament as the Act on Biobanks no.110/2000 13. May 2000.

The chairman of the NBC assisted the Ministry of Health and Social Security in writing Regulations on the keeping and utilisation of biological samples in biobanks no. 134/2001, and the regulations were approved by the NBC before they were issued.

The written opinions of the NBC are unfortunately only available in Icelandic.

According to the legislation the Minister of Health has to obtain the opinion of the NBC before issuing an operation licence for a biobank. By the end of 2002 the following biobanks have obtained operation licence: The Biobank of DeCODE, The Tissuebank of the National University Hospital (Department of Pathology), The Biobank of the Icelandic Genomics Corporation. Furthermore the NBC has given its opinion on applications for operation licence of the following biobanks:

The Biobank of the Laboratory of Molecular and Cellular Biology at the Icelandic Cancer Society, The Biobank of Cell Research Laboratory (screening / diagnostics), at the Icelandic Cancer Society, and the Biobank of Greinir (a private tissue diagnostic laboratory).

Contact: Dr. Bjorn Gudbjornsson, chairman, National Bioethics Committee, Laugavegur 103, 105 Reykjavik, Iceland. E-mail: bjorngu@landspitali.is, visindasidanefnd@vsn.stjr.is,
Homepage: <http://www.visindasidanefnd.is>

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

There has not been an organized public debate on human biobanks but when the Bill on Biobanks proposed to the Parliament it was discussed among interest groups and professional organizations, many of which provided opinions and recommendations to the Parliament in 1998. Little public discussions took place when the Bill was proposed again in year 2000 and in general the opinions provided to the Parliament by interested parties were positive. A conference on Biobanks was organized by the Association on Cancer Research in 2002.

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

An Act on Biobanks no.110/2000 was passed by the Icelandic Parliament 13. May 2000 and took force on 1. of January 2001. Regulations on the keeping and utilisation of biological samples in biobanks no. 134/2001 were issued on 6. February 2001 by Ministry of Health and Social Security on authority in arts. 9 and 16 of the Biobanks Act no. 110/2000, and took force immediately.

The Act on Biobanks no. 110/2000

The main provisions regarding biobanks for clinical testing and diagnosis and for scientific research are summarised below:

Definitions:

Biobank: a collection of biological samples which are permanently preserved (more than 5 years)

Biological sample: organic material from a human being, alive or deceased, which may provide biological information about him/her

Objectives are defined in Art. 1:

The objective of the Act is to authorise the collection, keeping, handling and utilisation of biological samples from human beings, in such a way that confidentiality is ensured, the interests of donors of biological samples is safeguarded and that the utilisation of the biological samples serves the purposes of science and medicine, and is conducive to the public good.

The interests of science and of the community shall never be given priority over the interests of the donor of a biological sample. It is prohibited to discriminate against a donor of a biological sample on the grounds of data derived from a biological sample.

Scope is defined in Art. 2:

This Act applies to the collection of biological samples, and their keeping, handling, utilisation and storage in biobanks. The Act does not apply to temporary keeping of biological samples taken for purposes of clinical testing, treatment, or for specific scientific study, provided such samples are destroyed when the tests, treatment or research are completed. Temporary keeping means storage for up to five years, unless the National Bioethics Committee authorises a longer period of storage. Should the long-term preservation of such samples be desired, they shall be stored in a biobank.

The Act does not apply to the storage of gametes and embryos under the provisions of the Artificial Fertilisation Act, to organs under the provisions of the Act on Organ Removal, or to bodily remains under the terms of the National Heritage Act.

Consent of donor of a biological sample and withdrawal of consent is defined in Art. 7 and access to biobank and use of biological samples is defined in Art. 9

Samples collected for storage in a biobank:

Free, informed consent of donor for collection and storage;

“Consent granted in writing of the person’s own free will, after the donor of a biological sample has been informed of the purpose of taking the biological sample, its usefulness, risks attendant upon the process, and that the biological sample will be permanently preserved in a biobank for use under the terms of art. 9.”

(Act on Biobanks, art. 3, and 7)

Withdrawal of informed consent - destoyal of sample:

The donor can at any time withdraw his/her consent and the biological sample shall then be destroyed. Material that has been produced from a biological sample by performance of a study or the results of studies already carried out shall, however, not be destroyed.

(Act on Biobanks, art. 7, paragr. 2, Regulations on biobanks, art. 7)

Biological samples collected for clinical tests:

The consent of the patient may be assumed for storage of the samples in a biobank for use in scientific research provided that information on possible storage and the right to opt out has been provided.

(Act on Biobanks, art. 7. paragr. 3)

Withdrawal of assumed consent:

The donor may at any time withdraw his/her assumed consent for his/her biological sample to be stored in a biobank for use in scientific research.

The sample shall thereafter only be used in the interests of the donor or by his/her specific permission

(Act on Biobanks art. 7, para. 4)

Access to Biological samples in a biobank for scientific studies:

Approval of the National Bioethics Committee.

Permission of the Data Protection Authority

On conditions laid down by the Bioethics Committee and the Data Protection Authority

(Act on Biobanks, art. 9, para 3)

Before access to a biobank is granted by the terms of art. 9 of the Biobanks Act no. 110/2000, a research protocol shall exist, that has been approved by the National Bioethics Committee or the ethics committee of the relevant health institution, cp. Regulations no 552/1999 on scientific studies in the health sector.

In the case of a genetic study, the informed consent of the person in question shall normally be sought if he/she is alive, and always if the data can be traced back to a certain individual, and this shall be subject to the judgement of the Bioethics Committee and the Data Protection Authority. The criteria laid down by the Data Protection Authority, under the provisions of the Act on protection of individuals with regard to the processing of personal data, shall be met.

(Regulations on biological samples in biobanks no 134/2001, art. 11)

Protection of personal data:

Evaluation of security, and security measures shall be consistent with the rules laid down by the Data Protection Authority on security of personal data in biobanks.

Obligation of staff to preserve confidentiality (art. 11)

“The Data Protection Authority shall monitor the security of personal data in biobanks.” (art. 12)

The Act on Biobanks no. 110/2000 and the Regulations on the keeping and utilisation of biological samples in biobanks no. 134/2001 in English translation can be found on the homepage of the Ministry of Health and Social Security <http://brunnur.stjr.is/interpro/htr/htr.nsf/pages/lawsandregs>

Contact: Gudridur Thorsteinsdottir, Director Legal Department, Ministry of Health and Social Security, Laugavegur 116, 150 Reykjavik, Iceland.
E-mail: gudridur.thorsteinsdottir@htr.stjr.is

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks

Not expected in the near future.

Survey on Human Biobanks

ISRAEL

(up-date of July 2003)

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

Yes. In general, supports large-scale collections for medical research, with stringent control. The final version published December 2002 is available (www.academy.ac.il)

Contact : Prof. Michel Revel, Chair, Bioethics Committee, Israel Academy of Sciences and Humanities, Jerusalem, Israel.

2. Will (or has) a public debate take(n) place on human biobanks?

Yes

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

Public debates have been organised by the Ministry of Health and more will be held.

3. Could you please describe the current legal and/or regulatory framework for human biobanks in your country and indicate a contact person

The report of the National Ethics Committee asks Parliament to legislate and establish a special Authority (Human Genetics Israeli Collection – HUGIC-Authority). There is already a Genetic Information Law in Israel (2000).

4. Could you please indicate if any new legal and/or regulatory framework for human biobank is under preparation

See paragraph 3. The new authority will monitor all public and commercial genetic collections and databases which are population-based (not families) and large-scale (>/1,000 samples).

Survey on Human Biobanks

NORWAY

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

Several bodies have provided an opinion on this issue. The most recent update is provided by the Norwegian Ministry of Health.

1) The Norwegian Ministry of Health

- Contact person: Ingrid Renolen, Tel. : +47 22 24 87 63
- A specific regulatory framework has been proposed by the Government (22.03.02) (<http://odin.dep.no/hd/norsk/aktuelt/pressem/042071-990051/index-dok000-b-n-a.html>)

2) The Norwegian Biotechnology Advisory Board

- Contact person : Ole Johan Borge, the Norwegian Biotechnology Advisory Board, tel. : +47 22248791/96, Fax : + 47 22 24 27 45, E-mail : ole.borge@bion.no
- The Board Statement can be found at www.bion.no (in Norwegian)

3) The National Committee on Medical Research Ethics

- Contact person : Knut Reuter
- www.etikkom.no

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

No specific public debate has taken place. It has however been organized a few meetings open for the general public without starting a larger public debate.

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

The Norwegian Act relating to Biobanks (Act No 12 of 21. February 2003) entered into force 1. July 2003.

The Norwegian Ministry of Health

- contact person : Ingrid Renolen, Tel. : +47 22 24 87 63
- A specific regulatory framework has recently been presented (22.03.02) (<http://odin.dep.no/hd/norsk/aktuelt/pressem/042071-990051/index-dok000-b-n-a.html>)

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks

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In the volume 2, ANNEXES, you can find the following documents:

- Act Relating to Biobanks

Survey on Biobanks

UNITED STATES OF AMERICA

1. Has your National Ethics Committee or similar body provided an opinion on human biobanks?

yes no

If yes, could you please summarise the recommendations, indicate the contact person and web address from where the extended version of the opinion is available:

The National Bioethics Advisory Commission (NBAC), the bioethics advisory body to President Clinton, issued a report entitled *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* in August 1999. The Executive Summary is attached. The full report, including Vol. II, Commissioned Papers, is currently available at <http://www.georgetown.edu/research/nrcbl/nbac/pubs.html>. It is also available from the National Technical Information Service, <http://www.ntis.gov>. In May of 2001 the U.S. Department of Health and Human Services (HHS) issued its response, available at <http://aspe.hhs.gov/sp/hbm/>.

NBAC has now been disbanded, and a new body appointed by President Bush, the President's Council on Bioethics (<http://www.bioethics.gov/>), has taken its place. If there is to be any further follow-up on the recommendations in the NBAC report, it is likely to be coordinated through the Office for Human Research Protections (formerly the Office for Protection from Research Risks) within HHS. Its website address is <http://ohrp.osophs.dhhs.gov>.

2. Will (or has) a public debate take(n) place on human biobanks?

yes no

If yes, how was / will it be organised, what were the conclusions, who is the contact person?

There has not been a large-scale public debate on human biobanks in the U.S. However, in connection with the NBAC report, a series of hearings and focus groups or "mini-hearings" were held across the United States. Participant demographics for the focus groups varied by location: in Richmond, Virginia, the target population consisted of educated baby boomers; in Honolulu and Mililani, Hawaii, members of neighborhood boards; in San Francisco, California, students and young adults; in Cleveland, Ohio, African-Americans; in Boston, Massachusetts, senior citizens; and in Miami, Florida, Jewish women.

Focus group participants were generally supportive of research, although they varied in their willingness to trade privacy for the benefits of research.

Groups were also split between those who would find a general one-time consent acceptable and those who questioned the meaning of consent in the absence of specificity about potential uses of tissue and information. Most participants were not troubled by anonymous research. Regarding sponsorship of research, most participants felt positively about research whether carried out or funded by academic medical centers, drug or biotechnology companies, or the government. Most were in favour of a requirement that all studies be approved by a committee appointed to oversee the ethics of research.

The focus groups were conducted by the Center for Health Policy Studies. A detailed description of the methodology and findings is included in the volume of commissioned papers accompanying the NBAC report. (See James A. Wells and Dana Karr, “Mini-Hearings on Issues in Human Tissue Storage.”)

Recently, discussions have been initiated about launching a large-scale cohort study in the U.S., perhaps as a public-private partnership. Dr. Francis Collins, Director of the National Human Genome Research Institute, raised the idea with the Secretary’s Advisory Committee on Genetics, Health, and Society at its March 1, 2004 meeting. (The Committee advises the Secretary of HHS.) The transcript of that discussion is available at <http://www4.od.nih.gov/oba/SACGHS/meetings/March2004/DiscussionOfIssues.pdf>.

3. Could you please describe the current legal and / or regulatory framework for human biobanks in your country and indicate a contact person

The current legal and regulatory framework in the U.S. is complex. At the federal level, the most relevant framework may be the one contained in the Policy for the Protection of Human Subjects, commonly referred to as the “Common Rule” because it has been adopted by 17 federal agencies or department. The implementing regulations of HHS (which includes the National Institutes of Health) are codified at 45 C.F.R. Part 46. The Common Rule applies to research conducted, supported, or otherwise subject to regulation by an adopting agency or department and may be extended to other research by agreement with an institution. Similar regulations of the Food and Drug Administration (FDA) can be found at 21 C.F.R. Parts 50 and 56; these apply to clinical investigations under FDA jurisdiction.

Basic protections for participants in research covered by the Common Rule or the FDA regulations include oversight by an institutional review board (IRB) and requirements in the area of informed consent. Research using human tissues may be exempt from these requirements if it involves only archived tissues and there are no accompanying patient identifiers. Regulatory guidance concerning the application of these protections to human biobanks is somewhat limited, e.g., Issues to Consider in the Research Use of Stored Data or Tissues, <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm> (1997).

Where health information is collected, another relevant framework exists under the new HHS Standards for Privacy of Individually Identifiable Information, implementing the Health Insurance Portability and Accountability Act (HIPAA).

A provision of the regulations permits covered entities (health care clearinghouses, health plans, and health care providers) to use or disclose protected health information for research purposes without patient authorization with approval from an IRB or privacy board. See 65 F.R. 82462 (December 28, 2000). Also, a limited data set that includes protected health information but excludes specified “direct identifiers” (e.g., name, social security number, medical record number) may be used or disclosed without patient authorization or IRB or privacy board approval for purposes that include research, so long as the recipient has entered into a conforming data use agreement. See 67 F.R. 53182 (August 14, 2002). In January 2004, HHS issued guidance for repositories (“Research Repositories, Databases, and the HIPAA Privacy Rule”), available at http://privacyruleandresearch.nih.gov/pdf/research_repositories_final.pdf.

At the state level, the closest thing to an act specifically targeting human biobanks created for research purposes may be a New York law that took effect January 17, 2002. The law authorizes secondary use of samples in research, but only if (a) it is conducted in accordance with applicable law and pursuant to a research protocol approved by an IRB, (b) the donors gave prior written informed consent for the use of their samples for general research purposes and did not specify time or other limits inconsistent with the planned use, and (c) either “the samples have been permanently stripped of identifying information” or “a coding system has been established to protect the identity of the individuals who provided the samples” under the oversight of an IRB. Specific standards for informed consent forms are also established. See N.Y. Civil Rights Law § 79-1 Section 9. General privacy or genetic privacy laws at the state level may also affect the operation of human biobanks, but these laws are very diverse.

4. Could you please indicate if any new legal and/or regulatory framework for human biobanks is under preparation

There is no federal legislation on the horizon that would provide a new legal or regulatory framework specifically for human biobanks. One bill introduced in the 108th Congress, the Protections for Participants in Research Act of 2003 (H.R. 3594), would strengthen the Common Rule, but the bill has not made it out of committee. Another bill pending in Congress would address genetic discrimination (S. 1053). S. 1053 passed the Senate but has not passed the House.

NATIONAL CONTACTS

EU COUNTRIES

AUSTRIA

Dr. Michel HAAS,
Federal Ministry of Social Security and Generations
Dept XI/9, Radetzkystr. 2
A - 1031 Vienna
Phone: +43.1.71100.4845
Email : michel.haas@bmsg.gv.at

Dr. Robert GMEINER
Geschäftsstelle der Bioethikkommission, Bundeskanzleramt
Hohenstaufengasse 3
A – 1010 Wien
Tel.: +43.1.53115-4319; Fax: +43.1.53115-4307
Email: robert.gmeiner@bka.gv.at

BELGIUM

Mr. E. MORBE
Coordinateur Comité Consultatif de Bioéthique
Bvd Pachéco 19, boîte 5
Quartier Vésale, 4ème étage
1010 Bruxelles
Tel.: +32.2.210.42.23
Fax: +32.2.210.42.27
Email : eric.morbe@health.fgov.be

Mrs Monique BOSSON
Tel : +32.2.210.46.25
Email : monique.bosson@health.fgov.be

Prof. Yvon ENGLERT
Fertility Clinic Dept. Ob. Gyn.
Hôpital Erasme, Free University Brussels
Phone: +32.2.555.45.70
Fax: +32.2.555.45.20
Email: yenglert@med.ulb.ac.be

CYPRUS REPUBLIC

Mrs Rena PETRIDOU
Senior Counsel of the Republic
Office of the Attorney General of the Republic of Cyprus
and the President of the Cyprus
National Bioethics Committee
1, Apellis Street
1403 Nicosia
Cyprus
tel. : 357 22889103 or 357 22899100
fax. : 357 22665080 or 357 22351994
E-mail : repetridou@law.gov.cy

CZECH REPUBLIC

Mrs. Dagmar POHUNKOVÁ, M. D.
Head of the Ethics Committee of the Ministry of Health of the Czech Republic,
Member of the Bioethics Commission of the Scientific Council of the Government,
Teacher of Social Medicine and Medical Ethics at the 1st Medical Faculty of the
Charles University at Prague.
(retired)
U Lužického semináře 24
118 00 Praha 1, Czech Republic
tel.: 420 - 257 530 738
e-mail: dagmar.pohunkova@seznam.cz; office at the Ministry: rudolf.pisch@mzcr.cz

DENMARK

Bent RASMUSSEN
Indenrigs- og Sundhedsministeriet
1. sundhedskontor
Slotsholmsgade 10-12
1216 Kobenhavn K
Tel.: 33 92 49 23
Email: bra@im.dk

ESTONIA

Prof. Arvo TIKK
Chairman of the Estonian Council on Bioethics
University of Tartu - Dept of Neurology and Neurosurgery
2 Puusepa Street
Estonia – 51014 Tartu
Email: Arvo.Tikk@kliinikum.ee

FINLAND

Mrs. Ritva HALILA
General Secretary
National Advisory Board on Health Care Ethics
Ministry of Social Affairs and Health
P.O. Box 33
FIN-00023 Government
Finland
tel. +358-9-160 73834, +358-50-370 6521 (mobile)
Fax. +358-9-160 74312
email: ritva.halila@stm.fi

FRANCE

Dr. Anne CAMBON-THOMSEN
Directrice de recherche au CNRS
Inserm U 558
Epidémiologie et analyses en santé publique : risques, maladies chroniques et handicaps
Faculté de médecine
37 allée Jules Guesde - F – 31073 Toulouse cedex
Tel. : +33.5.61.14.59.59 (secr. : 59 63 ou 59 51)
Fax : +33.5.62.26.42.40
Email : cambon@cict.fr
<http://www-toulouse.inserm.fr/srv/bmip/fdrech/unites/U558/cambon.html>

Prof. Didier SICARD
Président du Comité Consultatif National d’Ethique pour les Sciences de la Vie et de
la Santé
71 rue Saint Dominique 75007 Paris
Tel.: +33.1.44.42.48.52
Fax: +33.1.44.42.48.48
Email: contact@comite-ethique.fr

GERMANY

Dr. Stephan ROESLER
Head of Division 611
Development of Biosciences; Ehtics and Law
Federal Ministry of Education and Research
Heinemanstrasse 2
D-53175 Bonn
Tel. +49-1888-573660
Fax +49-1888-5783660
Email stephan.roesler@bmbf.bund.de

Prof. Joseph SCHMUCKER VON KOCH
Institute of Philosophy
University of Regensburg
31 Universitätsstrasse
D – 93040 Regensburg
Tel. : +49 160 6008 109
Fax : +49 1212 510 380 224
Email : joseph.schmucker-von-koch@psk.uni-regensburg.de

Dr. Rudolf Teuwsen
Head of Office
German National Ethics Council
Nationaler Ethikrat
Jägerstraße 22/23
10117 Berlin
Tel. 030 / 20370-631
Fax 030 / 20370-252
E-mail: rteuwsen@ethikrat.org

GREECE

Takis VIDALIS
Scientific Assistant of the National Committee on Bioethics
T.Vidalis@primeminister.gr

Prof. George MANIATIS
Deputy Chairman of Greek National Committee on Bioethics
University of Patras Medical School
GR – 265 04 PATRAS
Email : maniatis@otenet.gr

Tina GARANI-PAPADATOS
Lawyer
National School of Public Health
Dept of Public and Administrative Health
196, Alexandra's Avenue
GR - Athens 115 21
Tel.: 00 30 210 646 5982
Fax: 00 30 210 640 0188
Email: tinagarani@hotmail.com

HUNGARY

Dr. László SZONYI
Semmelweis University
I.st. Department of Pediatrics
H- 1083 Budapest
Bókay János u.53
Tel.: 00 36 20 915 1795
Fax: 00 36 1 39 44 196
Email: szolasz@gyerl.sote.hu

IRELAND

Dr. Deirdre MADDEN
Faculty of Law
University College Cork
IRL – CORK
Tel. : +353.21.4902990
Fax : +353.21.4270690
Email : d.madden@ucc.ie

Prof. Patrick FOTTRELL
Chair
Irish Council for Bioethics
Academy House
19 Dawson Street
IRL – Dublin 2
Ph (switchboard): 00 353 1 6611901
Fax:00 353 1 6762346

Siobhan O'SULLIVAN
Scientific Director
Irish Council for Bioethics
Academy House
19 Dawson Street
IRL – Dublin 2
Phone: 00 353 1 6611901
Email : s.osullivan@bioethics.ie

ITALY

Prof. Francesco D'AGOSTINO
President of the Italian National Bioethics Committee
Via Veneto 56
IT - 00187 Roma
Tel.: +39.06.48.161.490
Fax: +39.06.48.161.493
Email: dagostino@lettere.uniroma2

Dr. Stephane BAUZON
Scientific Secretary
Italian National Bioethics Committee
Via Veneto 56
I – 00187 Roma
Email : s.bauzon@governo.it

LATVIA

Dr. Laima RUDZE
Head of Central Medical Ethics Committee of Latvia
Elektriki 3-42, Rigas raj. Kekavas pag.
LV-2111, LATVIA
TEL. 371 6377429
E-mail laima.rudze@voava.lv

LITHUANIA

Dr. Eugenijus GEFENAS
Lithuanian Bioethics Committee
LT - Vilnius 33
Tel. : +3702 224 565
Fax. : +3702 224 565
Email: lbek@sam.lt

LUXEMBOURG

Mr. Jean-Paul HARPES
Ministère de la Culture, de l'Enseignement Supérieur et de la Recherche
Commission consultative nationale d'éthique pour les sciences de la vie et de la santé
20 montée de la Pétrusse
L – 2912 Luxembourg
Tel.: +352.478.6628 - Fax: +352.29.21.86
Email : jean-luc.harpes@education.lu

MALTA

Mr. Maurice CAUCHI
Chairman of the Bioethics Consultative Committee
The Ministry of Health
Merchants St.
Valletta
Malta
Email : maurice.cauchi@um.edu.mt

Dr. Pierre MALLIA
MD MPhil, CBiol MIBiol Dip Ther (ICGP)
12 School Street
Tarxien
PLA 04
Malta
Email : pmalia@synapse.net.mt

THE NETHERLANDS

Dr. Wybo J. DONDORP
Health Council of the Netherlands
Po Box 16052
Tel.: +31.70.340.6575
Fax: +32.70.340.7523
Email: wj.dondorp@gr.nl

PORTUGAL

Mrs. Paula MARTINHO DA SILVA
Empreendimento das Amoreiras, Torre 2, 16°
PT - 1070-274 Lisboa
Tel. : +351.21.384.33.00
Fax : +351.21.3870265
Email : Pmartinho@bap.pt

SLOVAK REPUBLIC

Assoc. Prof. Jozef GLASA, M.D., PhD
Department of Clinical Pharmacology, Slovak Health University,
Institute of Medical Ethics and Bioethics Fdn.
Limbová 12, 833 03 Bratislava, Slovak Republic
tel. +421-2-59369.472, fax. +421-2-59369.506
e-mail: jozef.glasa@szu.sk

SLOVENIA

Prof. Jože TRONTELJ
Chair
National Medical Ethics Committee
Zaloška 7
SI-1525 Ljubljana
Tel. : +386.1.522.1525
+386.1.522.1500
E-mail: joze.trontelj@kclj.si

SPAIN

Prof. Carlos M. ROMEO-CASABONA
University of Deusto
Inter-University Chair in Law and in Human Genome
Po Box 1 - Avda de las Universidades, 24
ES - 48007 Bilbao
Tel.: +34.94.445.57.93
Fax.: +34.94.445.55.13
Email: cromeo@genomelaw.deusto.es
cromeoca@terra.es

SWEDEN

Dr. Elisabeth RYNNING
Uppsala University
Faculty of Law
Box 712
SE – 751 20 Uppsala
Tel. : +46.18.471 20 03
Fax : +46.18.471 76 66
Email : elisabeth.rynning@jur.uu.se

UNITED KINGDOM

Ms Nicola PERRIN
Public Liaison Officer
Nuffield Council on Bioethics
28 Bedford Square
London WC1B 3JS
Tel. : 020 7681 9627
Fax : 020 7637 1712
Email : nperrin@nuffieldfoundation.org

Mrs. Catherine PEARSON
Clinical Ethics and Human Tissue Branch
Department of Health
Tel ; +44.020.7972.3811
Email : Catherine.Pearson@doh.gsi.gov.uk
Christopher COX
Human Tissue Branch
UK department of Health
Email: Christopher.Cox@doh.gsi.gov.uk

NON EU COUNTRIES

CANADA

Denise Avar, Ph.D.
Directrice, Projet génétique et Société
Centre de recherche en droit public
Université de Montréal
C.P 6128, Succ. Centre-ville
Montréal, Qc
H3C 3J7
Tel: (514) 343-7702
Fax: (514) 343-2122
e-mail: denise.avard@umontreal.ca

Marie-Hélène REGNIER
Coordonnatrice
Projet Génétique et Société
CRDP, Université de Montréal
Montréal, Qc
H3C 3J7
Tel. : 514-343-2142
Fax : 514-343-2122
Email : marie-helene.regnier@UMontreal.CA

CROATIA

Prof. Bozidar VRHOVAC
Chairman of the Committee for Medical Ethics and Deontology
Dept of Medicine, University Hospital Rebro - Croatian Medical Chamber
Subevica 9
10000 Zagreb
Tel.: +385.1.238.8284
Fax: +385.1.2421.875
Email: vrhovac@rebro.mef.hr
bvrhovac@post.hinet.hr

GEORGIA

Givi JAVASHVILI, M.D., Ph.D.,
Expert, Health Law and Bioethics Department, National Health Management Centre
Vice-Chairman, National Council on Bioethics;
Chairman, Georgian Health Law and Bioethics Society;
National Expert of Georgia to the Steering Committee on Bioethics, Council of
Europe
51 Javakhishvili Street,
Tbilisi, 380002,
Georgia
Tel/Fax: +995 32 940 160
Email: G.Javashvili@curatio.com

ICELAND

Dr. Ingileif JONSDOTTIR
Department of Immunology
Landspítali – University Hospital
Hringbraut
101 Reykjavík
Email: ingileif@landspitali.is

ISRAEL

Prof. Michel REVEL
Chair, Bioethics Committee, Israel Academy of Sciences and Humanities.
Department of Molecular Genetics
Weizman Institute of Science
Rehovot 76100, Israel
Phone: 972-8-9342101
Fax: 972-8-9343174
Email : michel.revel@weizmann.ac.il

NORWAY

Ole JOHAN BORGE, Ph.D.
Seniorrådgiver
Bioteknologinemnda
Prinsensgt. 18
P. boks 522 - Sentrum, 0105 Oslo
Tel.: 22 24 87 96 / 97 50 05 83
Fax: 22 24 27 45
Email: ole.borge@bion.no

Ingrid RENOLEN
Adviser
Ministry of Health
Email : ingrid.renolen@hd.dep.no

SWITZERLAND

Dr. Margrit LEUTHOLD
Generalsekretärin der Schweizerischen Akademie der Medizinischen Wissenschaften
Petersplatz 13
CH - 4051 Basel
Tel.: +41.61.269.90.30
Fax: +41.61.269.90.39
Email: leuthold@samw.ch

Michel VALLOTTON
Président de la Commission Centrale d’Ethique
de l’Académie Suisse des Sciences Médicales – Division d’Endocrinologie - Hôpital
Universitaire de Genève
CH – 1211 Genève
Email: Michel.Vallotton@medicine.unige.ch

UNITED STATES OF AMERICA

Mary ANDERLIK MAJUMDER, J.D., Ph.D.
Assistant Professor
Center for medical Ethics and Health Policy
Baylor College of Medicine
One Baylor Plaza
Houston, TX 77030
Tel.: 713 798-3511
Fax: 713 798-5678
majumder@bcm.tmc.edu