7th European Conference of National Ethics Committees

7ème Conférence Européenne des Comités Nationaux d'Ethique

COMETH

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

[cometh/7è/doc/opinions.CNE] COMETH/INF (2003) 1 multilingue

New Ethical Challenges
Bioethics education and Biobanks

———————————

Nouveaux Défis Ethiques
Education à la bioéthique et biobanques

1-2 December 2003 / 1-2 décembre 2003
Strasbourg

List of Opinions and reports prepared by the National Ethics Committees

———————————

Liste des avis et rapports préparés par les Comités Nationaux d'Ethique

Table of contents / Sommaire

BELGIQUE

Comité Consultatif de Bioéthique de Belgique

www.health.fgov.be

Liste des avis

avis n°14	relatif aux "Règles éthiques face aux personnes atteintes de démence", 10 décembre 2001
avis n°15	concernant les questions éthiques relatives à l'impact du « résumé clinique minimum » (RCM) sur le nombre de journées d'hospitalisation des patients, 18 février 2002
avis n°16	relatif au refus de transfusion sanguine par les Témoins de Jéhovah, 23 mars 2002
avis n°17	relatif aux "aspects éthiques des autotests de dépistage du virus de l'immunodéficience humaine (VIH)", 10 juin 2002
avis n°18	relatif à la recherche sur l'embryon humain *in vitro*, 16 septembre 2002
avis n°19	relatif à la destination des embryons congelés, 14 octobre 2002
avis n°20	relatif aux tests génétiques prédictifs et tests HIV dans le cadre des relations de travail, 18 novembre 2002
avis n°21	relatif au "Traitement forcé en cas d'hospitalisation sous contrainte", 10 mars 2003

FINLAND

National Advisory Board on Health Care Ethics

www.etene.org

- Opinion of the national advisory board on health care ethics on the memorandum of the working group assigned to define the use of drug tests, June 10, 2002
- Opinion on new amendments against terrorism on penal code and the coercive measures act on August 8, 2002
- Opinion to the Parliamentary ombudsman concerning not performing resuscitation on November 9, 2002
- Opinion to the Ministry of Trade and Industry on the proposal of the European Commission on the human embryonal stem cell research on August 29, 2003
- Opinion on the amendments of the Act on the status and Rights of Patients on Sept 17, 2003

(The latest two are still in Finnish but will be translated into English by the COMETH Meeting.)

- Reports of the Sub-Committee on Medical Research Ethics :
  - Report on DNA Samples in Epidemiological Research (will be sent later, the translation is in preparation
  - Perspectives on medical research conducted in children (will be sent later, the translation is in preparation

OPINION OF THE NATIONAL ADVISORY BOARD ON HEALTH CARE ETHICS ON THE MEMORANDUM OF THE WORKING GROUP ASSIGNED TO DEFINE THE USE OF DRUG TESTS

The proposal deals with a very important and topical theme. Use of drugs and other intoxicants is increasing in Finland and this is linked with considerable health, psychological and economic harms and security risks. Detecting drug use by valid tests and elimination of related risks, as well as creating appropriate treatment options for substance abusers are important and urgent issues from the ethical point of view.

The request for opinion addressed to ETENE is dated 25 May although the memorandum of the Working Group was completed much earlier. Since the Advisory Board is broad-based forum including various expertise, a thorough processing of issues takes a long time. Due to the short period of preparation the Advisory Board has not been able to discuss the memorandum taking account of all possible considerations. In case a more detailed statement is desired, the Advisory Board should be given much more time for preparing it.

For the time being the Advisory Board has viewed the matter above all from the perspective of health care and wishes to stress in particular the following:

The aspiration to reduce and prevent drug use and to treat abusers is ethically important for, i.e., the following reasons:

- drug use causes considerable problems for the users themselves, the people close to them, their unborn children, the immediate community and society and, moreover, it is a serious security risk to society and the general public;
- in working life drug use is a safety issue, in some jobs in a very critical way, e.g. in traffic and health care professions;
- drug use is linked with many serious social problems, such as crime and prostitution;
- it has to be kept in mind that in quantitative terms the biggest and economically the most considerable substance abuse problem is still alcohol abuse.

From the ethical point of view the most important aspect in the matter is that the tests must be carried out within the framework of health care services. The tests should be made as competently and correctly as possible. All essential ethical principles must be observed in the testing, including expertise, reliability, confidentiality, security, and protection of the client's human dignity and interests in terms of care.

It is important that the screenings are targeted, i.e. based on defined criteria, which are listed in the law. From the point of view of health care it is important to emphasise that when carrying out the tests substance abusers should at the same time be offered care options. It is a good thing that the employer arranging drugs tests is obligated to prepare an anti-drug action plan. Particular attention should be paid to vulnerable and dependent groups, such as young trainees and job applicants. Faulty test results and possibilities of misleading should be eliminated to as great an extent as possible.

ETENE appreciates the idea included in Professor Helena Taskinen's supplementing opinion that the preparation of anti-drug action plans and the performing of tests presupposes in practice a considerable investment in high-quality training for occupational health service staffs, in the context of which ethical issues must be given a great deal of attention.

Helsinki, 10 June 2002
National Advisory Board on Health Care Ethics

Martti Lindqvist	Ritva Halila
Chairman	General Secretary

Subject **PROPOSAL FOR A GOVERNMENT BILL ON INCORPORATING PROVISIONS CONCERNING TERRORISM INTO THE PENAL CODE AND THE COERCIVE MEASURES ACT: Views on the bill from the point of view of the National Advisory Board on Health Care Ethics**

The Ministry of Social Affairs and Health has asked the National Advisory Board on Health Care Ethics (ETENE) to issue an opinion on the above-mentioned proposal for a Government bill. The Advisory Board has not convened since receiving the request for comments, and so this opinion has been prepared by its chairman and the general secretary.

The proposal deals with a very important and topical theme. Societies have undoubtedly a legitimate right to protect themselves against the threat of terrorism. This concerns local, national and international communities. The more terrorism is internationalized the more international co-operation and instruments are needed to tackle the issue.

One difficulty in dealing with the issue is that it is not necessarily clear, at least not in practical situations, what is regarded as terrorism and what is regarded as legitimate self-defence or fight for freedom. In an aggravated situation there is a danger that the tolerance for difference is reduced and human dignity and human rights are put at risk. Therefore it is important that the planned legislation must not in any way jeopardise the human rights laid down in the Constitution. Attention should be paid, in particular, to those considerations that have been put forward in the statement of reasons for section 6 (on pages 43-48). The legislation now being prepared may not restrict e.g. the traditional right to strike and demonstration.

The area dealt with in the report does not very specifically concern the sphere of authority of the National Advisory Board on Health Care Ethics. Mainly, the issues concerning health-related crimes and privacy protection, and taking, storing and utilisation of DNA samples are an integral part of health care and thus of vital interest to the Advisory Board. It is both understandable and ethically acceptable to create new provisions concerning the acquisition, production, storing and use of biological weapons in connection with terrorism. The former definition of health-related crime evidently does not cover this area.

As stated in the report, the provisions of the Finnish Penal Code apply at present, almost without exception, to the terrorist crimes referred to in the framework decision. Thus it would not appear to change or threaten the already established penal basis.

Referring to the right of a community to protect itself against terrorism it is in our opinion justified also to prescribe about the duty to notify a crime in the way proposed in the report.

In our opinion, extending the electronic listening, electronic supervision and technical monitoring to issues related to terrorism does not in the proposed form change the policy line chosen before, and thus it does not constitute an essential threat from the point of view of human rights issues.

The issue that is most closely associated with the sphere of authority of the Advisory Board is the definition and recording of DNA identifiers. It is stated in the proposed bill that the change would be temporary until the bill 52/2002 enters into force, since it enables bodily search in case the most severe punishment for the crime in question is at least six months' imprisonment. On the other hand, if such an amendment to the Coercive Measures Act is already under consideration at Parliament, is this addition at all necessary? There does not seem to be any ethical contradiction in the content of the proposal as such.

As regards the amendment of the Coercive Measures Act it is essential that the extension of the group in whose privacy it would be allowed to interfere is fairly small and sufficiently exactly defined in the present proposal.

It can be concluded from the above that from the point of view of the National Advisory Board on Health Care Ethics there is no obstacle to implementing the said proposal.

Martti Lindqvist	Ritva Halila
Chairman	General Secretary

Subject **THE PARLIAMENTARY OMBUDSMAN'S REQUEST FOR OPINION**

In his letter of 16 September 2002 to the Ministry of Social Affairs and Health the Parliamentary Ombudsman asked that the Ministry obtain an opinion of the National Advisory Board on Health Care Ethics from the ethical point of view on a complaint regarding a decision to give up the resuscitation of a patient in a situation described in the request. Therefore the Ministry's Health Department has requested the Advisory Board to give such an opinion and submit it to the Department's Health Services Branch by 30 November 2002.

The Advisory Board has discussed the issue at its meetings on 8 October 2002 and 27 November 2002. Based on these discussions it would like to state first that it cannot take a stand on individual cases but only deals with issues of the said kind from the point of view of principle. The Advisory Board has not had any other material at its disposal when dealing with the complaint in question. Therefore this opinion is not a direct expression of opinion on the complaint.

The Advisory Board further states that it has in its publication "Kuolemaan liittyvät eettiset kysymykset terveydenhuollossa" - Ethical issues related to death in health care (Publication 4 of the National Advisory Board on Health Care Ethics, Helsinki 2002) extensively dealt with ethical issues related to this area from the point of view of resuscitation situations, too. The publication includes an article on this theme by MD Maaret Castrén. The publication is attached to the opinion.

A human being is in all situations entitled to good care. When the cause of asystole is unclear or it is not caused by an anticipated death as a result of a serious illness or injury, resuscitation is a part of good care. The patient's age is not as such a cause for not resuscitating the patient. A decision not to resuscitate a patient is part of the decision-making in which the care staff change over from active care to symptomatic care. As a rule, decisions not to resuscitate should not be made in acute resuscitation situations but the care decisions should be made in mutual understanding with the patient and his or her relatives. There should be, especially for long-term patients, a care plan that is followed and adjusted all the time. All too often the information of a decision not to resuscitate has not been recorded clearly enough, and thus it is not at the disposal of the health care professionals on duty. In a sudden situation it is necessary to act quickly, and then the doctor on duty has to make decisions using his or her best judgment. The information obtained from the patient records and from the relatives affects the measures to be taken.

It can hardly be stressed too much that the objectives and line of care as well as different future situations should be discussed in advance as openly as possible with the patient and relatives taking into account their wishes. The discussions with the patient and relatives in advance always facilitate both the decision-making in acute situations and the subsequent investigation of the case. When assessing the resuscitation decisions the prognosis is of primary importance, and so is the will expressed by the patient. Also the quality of life to be acquired affects the care decisions. The decisions must always respect the principle of good care and the patient's human dignity.

A careful discussion afterwards often contributes to dispelling any doubts and creating the prerequisites for a competent, humane and diversified assessment of the decisions and events.

Helsinki, 27 November 2002
For the National Advisory Board on Health Care Ethics

Martti Lindqvist	Ritva Halila
Chairman	General Secretary

APPENDIX: Kuolemaan liittyvät eettiset kysymykset terveydenhuollossa / Ethical issues related to death in health care (Publication 4 of the National Advisory Board on Health Care Ethics, Helsinki 2002)

FINLAND

The Nordic Committee on Bioethics

www.ncbio.org

A publication titled “Teaching bioethics”, 2002

FRANCE

Comité Consultatif National d'Ethique

www.ccne-ethique.fr

Liste des opinions

N°069	L'assistance médicale à la procréation chez les couples présentant un risque de transmission virale - réflexions sur les responsabilités -	2001-11-08
N°070	Consentements en faveur d'un tiers	2001-12-13
N°071	Avis sur la neurochirurgie fonctionnelle d'affections psychiatriques sévères	2002-04-25
N°072	Réflexions sur l'extension du diagnostic pré-implantatoire	2002-07-04
N°073	Les essais de phase 1 en cancérologie	2002-09-26
N°074	Les banques de sang de cordon ombilical en vue d'une utilisation autologue ou en recherche	2002-12-12
N°075	Questions éthiques soulevées par le développement de l'ICSI	2002-12-12
N°076	A propos de l'obligation d'information génétique familiale en cas de nécessité médicale	2003-04-24
N°077	Problèmes éthiques posés par les collections de matériel biologique et les données d'information associées : " biobanques ", " biothèques "	2003-03-20
N°078	Inégalités d'accès aux soins et dans la participation à la recherche à l'échelle mondiale - problèmes éthiques	2003-09-18
N°079	Transposition en droit français de la directive européenne relative aux essais cliniques de médicaments : un nouveau cadre éthique pour la recherche sur l'homme	2003-09-18

GEORGIA

NATIONAL COUNCIL ON BIOETHICS

List of opinions

29.04.2002	"Draft Recommendation on the Use of Foetal Stem Cells for Therapy"*
17.06.2002	"Recommendation on Draft Law on Biomedical Research Involving Human Subjects"
25.09.2002	"Recommendation on Position of Georgia Concerning International Ban on Cloning Human Beings"
19.03.2003	"Recommendation on the Development of Ethics Committees in Georgia"
2001-2003	Various Recommendations on Improvements in the Field of Biomedicine and Human Rights Triggered by Discussions on Specific Cases**
2001-2003	Various Recommendations on Multi-Central International Biomedical Research Projects Involving Human Subjects***

* The recommendation has not been yet finally approved by the Council;

** Council does not generally consider specific cases, however sometimes it holds discussions on such cases on the request of the Ministry of Labour, Health and Social Affairs or other bodies and offers general recommendations related to improvements in the sphere of biomedicine and human rights;

*** Although the Council avoids evaluating particular research protocols, it makes recommendations on international multi-central clinical research on the request of research team, because there is no central research ethics committee yet in Georgia.

GREECE

THE HELLENIC NATIONAL BIOETHICS COMMISSION

List of opinions

1. Recommendation on the use of stem cells in biomedicine and clinical medicine, ***21.12. 2001***

2. Recommendation on the collection and use of genetic data, ***16.09.2002***

3. Comments on the draft bill concerning medically assisted human reproduction, ***11.10.2002***

4. Recommendation on human reproductive cloning, ***28.02.2003***

****

1. RECOMMENDATION
On the use of stem cells in biomedicine and clinical medicine

The National Bioethics Commission, on the invitation of its President, held meetings on June 8th, July 2nd, October 5th, November 23rd and December 21st 2001 in order to examine the ethical and social issues falling within its competence which arise from the use of stem cells in biomedicine and clinical medicine and to formulate a proposal on the matter in accordance with article 10 of the Law 2667/1998. The Commission:

A) Taking into consideration the ever growing interest of the international scientific community for the use of human stem cells to face incurable up to date diseases, an interest that is explained by the discovery of their important therapeutic potential.

B) Reckoning though that this use of human stem cells raises ethical problems and dilemmas, since the main source of stem cells is either human embryos deriving from in vitro fertilisation procedures or embryonic tissue following abortions.

C) Considering that there is a need to clarify that cloning is a technique for in vitro induction of embryo development and therefore a possible way for stem cell isolation.

D) Finally taking into account the urgent quest for an adequate legislative framework observable today in many national legal orders as well as at the level of European Union

has arrived at the following propositions, that could guide the Greek legislator to face this issue as thoroughly as possible.

Part A

Stem cells and developmental stages of the organism

The term *stem cells* refers to undifferentiated cells characterised by a) the capability of self multiplication and b) the potential to differentiate in cells of various tissues and organs of the organism. Stem cells are found in all stages of embryonic development. The earlier the developmental stage the higher the potential to differentiate towards various cell types.

In humans, the stem cells during the first three to four days post-fertilisation are called totipotent, since they can produce all cell types including the membranes and tissues that will support embryo development (e.g., the placenta).

Following these first days, the cells that will give rise to the supporting tissues of the embryo separate from the cells that will give rise to the embryo itself. Embryonic stem cells from this stage onwards are termed pluripotent, since they have lost their ability to differentiate to all cell types needed for a complete embryo development but they retain their potential to differentiate to any other cell type up to day 14th post-fertilisation.
During the third week of embryonic development the evolving organism consists of three different cell layers. Each cell layer is "programmed" to give rise to defined (particular) tissues and organs. Depending on the layer on which the stem cells reside, they differentiate to the predefined cell types.
As embryonic development proceeds, stem cells lose gradually part of their pluripotency. Finally in adults the stem cells that remain, and serve for the renewal of destroyed cells in the tissues, can only differentiate to cell types of the tissues where they reside.

Stem cells in research

In the field of basic research, the identification of factors that determine the process of cell differentiation during embryonic development is critical for a better understanding of the diseases that are due either to cell differentiation and cell multiplication abnormalities or to disruption of the mechanism responsible for cell renewal and replacement.
In the field of pharmacology, essays on activated pluripotent stem cells can provide a safe way for testing new drugs in a variety of cell types, substituting in many cases direct experimentation with laboratory animals or clinical trials in humans.
In the field of transplantation and replacement of destroyed cells (e.g., Parkinson, Alzheimer) the possibility of a renewable source of cells, tissues and organs derived from pluripotent stem cells, that could be used as grafts, is promising to cover the growing need of organ donation and to treat many incurable to date diseases and disabilities.

Part B

The following recommendations aim to contribute to the formation of a reliable thesis (from a scientific and deontological point of view) and to assist policy-making on the matter of stem cell use. Currently these recommendations could be proved useful for an active participation of Greek representatives in decision-making meetings that take or will take place on the international level. In the future these recommendations could be used in the case of elaboration of specialized relative legislation.

The following points concern the three possible sources for stem cell derivation: points 1 to 3 refer to stem cell removal from embryonic tissue following elective abortion, points 4 to 7 refer to removal from embryos produced in vitro, points 8 and 9 refer to removal from an adult person. The last two points deal with stem cell use in general (10) and the funding of relevant research projects (11).

Stem cell removal and abortion

The Commission points out the connection that exists between stem cell removal and the approval of abortion. In both cases the question is whether the worth of the embryo is equivalent to that of a "person". Most members of the Commission recognize that, although abortion naturally raises certain ethical considerations, it is entrenched in the framework of contemporary law. Consequently, to the degree that removal of stem cells following abortion does not raise ethical dilemmas of a different nature, there is no reason to be prohibited in advance.
From the point of view though of a member of the Commission (D. Roupakias), the worth of "person" (as unity of body and soul) exists from the moment of fertilization. Therefore, not only stem cell removal cannot be accepted but also abortion itself is morally questionable. According to this view the only probable acceptable source are somatic stem cells derived from an adult or a minor (if there are intended for his own therapy), in condition that there is firm prohibition for their use in reproductive cloning or embryogenesis (embryo induction for therapeutic purposes) and after setting the technical specifications for approved research laboratories and the terms for conducting such research.

Removal from embryonic tissue

In accordance with the above mentioned, most members of the Commission consider that stem cell removal from embryonic tissue after abortion is legitimate, ?n condition that the donors of the gametes have given their consent following appropriate information about the specific use.

Prohibition of agreements

The Commission considers that antecedent or posterior to conception agreements resorting to abortion and stem cell derivation should be prohibited since they might conceal embryo commercialization and women exploitation that offend her human worth. The relevant penalties should be more severe in cases where such agreements comprise financial compensations.

Research on embryos in vitro

Most members of the Commission agree with the general principal of article 18, of the Convention on Human Rights and Biomedicine by the Council of Europe, that generally allows research under specified conditions on embryos in vitro. They consider though that further clarification is needed concerning the conditions for embryo research and stem cells derivation.

Conditions for stem cell removal from embryo in vitro

Most members of the Commission consider that authentic and informed consent from the donors of the gametes is required in order to derive stem cells from an embryo in vitro. Furthermore the donors of the gametes should be given certified assurance that refusal of consent will not affect any future medical assistance to them.
In order to protect the donors from exploitation by third parties, the possibility of agreements, which comprise financial compensation for stem cell removal, should be precluded.

Agreements which comprise financial compensation

Many members of the Commission consider that financial agreements for stem cell derivation from embryos in vitro should be precluded in order to prevent donors' exploitation from third parties. However, other members of the Commission consider that absolute prohibition of such agreements does not guarantee lack of exploitation, since it incites to illegal trade, and functions as an impediment to research progress. According to this point of view, financial agreements could be allowed in the form of either gamete sale or participation of donors to future economic benefits coming from research applications.

Embryo production for therapeutic purposes (therapeutic cloning)

Most members of Commission consider that embryo production for therapeutic purposes via cloning and derivation of stem cells from such embryos should not be precluded, in condition that there is no alternative cure.
It is noted that article 18 of the Convention on Human Rights and Biomedicine of the Council of Europe prohibits generally embryo production for research purposes. However, since therapeutic intervention cannot be applied –even on an experimental phase- without research being carried out previously, it seems that article 18 prohibits embryo production for therapeutic purposes as well.
It is however stressed in the Additional Protocol to this Convention (where explicitly it is prohibited embryo production via cloning for reproduction purposes) that "some cloning techniques themselves may contribute to scientific knowledge and its medical application". Based on this, the Commission (by majority) reckons that therapeutic cloning is exempted from the general prohibition of article 18.

Removal from a person

The Commission holds the view that removal of somatic stem cells from an adult presupposes his/her authentic consent, under the same guarantees as previously mentioned. It should be appropriate to preclude removal of somatic stem cells from a minor for research purposes but it could be allowed for his/her own therapy, given that similar to transplants principles for minors' protection personhood are adhered.

Anonymity of the donor

In order to avoid unfair reliance and to protect the personhood of the donor and the recipient of the stem cells, it should be apt to observe the rule of donor anonymity, as is the case for transplant donation, in the exception of therapeutic use on him/herself.

Use of stem cells on humans

The recipient of stem cells – or tissue and graft that might be derived in the future from stem cells- should be protected against the odds of becoming a research "means". The Commission notes that the Convention on Human Rights and Biomedicine includes the fundamental principles that guarantee the protection of a person from such a threat.

Funding research projects

The Commission, given the great importance of research on this field, reckons that the State should elaborate a funding policy of research projects based, among others, on the above-mentioned deontological principles. In order to facilitate the observation of such principles it is recommended that all research projects should be accompanied by a report of ethical adequacy. Research ethics committees that would function in the frame of the funding and research institutions should assess the project based on the report. According to a member of the Commission (D. Roupakias) funding according to the above-mentioned conditions should be restricted exclusively to research on somatic stem cells derived from an adult person.

****

2. RECOMMENDATION
On the collection and use of genetic data

The National Bioethics Commission met upon invitation by the President thereof on January 25th, February 8th, March 8th, April 5th, May 17th, June 10th and September 16th 2002 in order to consider the ethical and social issues within its jurisdiction which arise from the collection and use of genetic data and to formulate a proposal on the matter pursuant to article 10 of Act 2667/1998.

The Commission:

Having already issued an expert opinion on the use of genetic data in criminal proceedings,

Considering the constantly expanding use of genetic data in healthcare for diagnostic, preventive and therapeutic purposes,

Recognizing the fundamental importance of genetic research for the comprehension of genome function and evolution,

Taking into consideration the international interest incited by the announcement of human genome sequencing and its forthcoming practical applications,

Having in mind that the current technological capacity for rapid collection and extensive diffusion of genetic data may lead to undesirable social consequences, especially discrimination based on a person's genetic makeup,

Acknowledging that genetic data should be protected insofar as they characterize identifiable persons,

Sharing the concerns expressed on international level by organizations, governments and bioethics committees about the lack of relevant legislation to keep in pace with the progress of events,

has drawn up the following proposals to determine the basic rules on this issue.

Consent

General Principle

Respect for the value of human beings requires the free and informed consent of the person whose biological sample is collected for the purpose of genetic testing. In order to ensure genuine conditions of free will, the information should be provided, if possible, in advance of seeking the consent.

Content of information prior to consent

a) The purpose of the test should be adequately explained in comprehensible language,
b) It should be clarified whether the genetic data will be destroyed or stored after the test; in case they are stored, whether they will be anonymous or confidential as well as whether they are destined to commercial exploitation,
c) It should be clarified whether the biological sample will be destroyed or stored after the test; in case it is stored, whether it will be linked to the resulting genetic data or not.

Warrants for the protection of confidentiality or anonymity

The information should include specific warrants ensuring the protection of confidentiality or anonymity of biological samples or genetic data. It should be pointed out - and the person concerned should be thus advised - that for certain genetic conditions associated with visible phenotypes, anonymity cannot be ensured.

Form of Consent

The consent must be written, specific and revocable at any time before the onset of sample or data processing.

Future research on anonymous samples or genetic data

Renewal of consent is not required for future uses of anonymous samples or genetic data since privacy is ensured by anonymity.

Future research on confidential samples or genetic data

The use of confidential samples or genetic data in future similar research is covered by the initial consent provided the person concerned was informed accordingly. This information is essential for the purpose of personal data protection since the identity of the person concerned can be determined at any time.
Any use of confidential samples or genetic data in future research unrelated to the object for which the initial consent was given, requires a new consent following *ad hoc* information provided the person concerned explicitly stated so in the initial consent.

Research on population groups

The use of genetic data resulting from population genetic research also requires the prior informed consent of each member individually.
In order to facilitate the planning of such research projects, a collective consent may be sought; however, every member reserves the right not to participate.

Prohibition of hierarchical orders to conduct research in specific cases

Any hierarchical orders or pressures whatsoever by supervising authorities to carry out population genetic research in facilities associated with mandatory attendance or confinement where special power relations prevail – such as army camps, schools, prisons, etc. – should be ruled out.

B. Disclosure

1. The right to know and the right not-to-know

Everyone, in the context of self-determination, have the right to know the results of any medical, diagnostic or preventive genetic tests they were subject to. However, the right not to know is also acknowledged upon explicit request by the person concerned.
In case the results of genetic tests involve the health of third persons:
a) any person exercising their right to know must also assume responsibility for informing any third persons involved;
b) in case people exercise their right not to know, the physician may inform third persons, if absolutely necessary, in the context of the general medical obligation to care for human life (Code of Medical Ethics, article 9).
Exceptionally, the right to know the results of genetic tests cannot be exercised in the context of research projects when the interpretation of results is uncertain.

2. Disclosure of genetic data to third parties: general principle

Everyone has the right to determine whether their genetic information is to be disclosed or not to third parties as well as the content of such information and the time of disclosure.

3. Disclosure of genetic data in the context of labour relations

The Commission believes that disclosure of genetic information to employers is unacceptable even with the consent of employees or applicants. This solution is justified by the usually unequal position of employees vis-à-vis employers.

The Commission recognizes the following two exceptions from the above general rule: a) in case specific working conditions may trigger the development of genetic disease, employers may be allowed access to related genetic information with the consent of employees or applicants provided there are no alternative protective measures, and, b) in case a given occupation puts the safety of third persons at risk, employers may ask the performance of genetic tests and the communication of their results in order to guarantee the safety of the third persons involved.

The Commission recommends the adoption of specific legislation on disclosure of genetic information in the context of labour relations establishing the principle of prohibition and specifying possible exceptions.

4. Disclosure of genetic information in the context of insurance

The Commission considers that disclosure of genetic information to public social security funds is unacceptable even with the consent of the insured or prospective insured. This solution is justified by the nature of social security as public good which should be made available to all without discrimination.

As far as private insurance is concerned, disclosure of genetic information remains unacceptable when the insured or prospective insured is not covered by public social security. This solution is justified by the unequal position of the insured vis-à-vis the insurer.

However, when private insurance is complementary to social security, disclosure of genetic information is allowed provided the insured or prospective insured consents in accordance with the principle of freedom of contract.

C. Specific matters

1. Genetic tests on embryos

The Commission considers that the value of human life is independent from genetic makeup. Therefore, the Commission believes that genetic tests conducted on embryos either *in vitro* or *in vivo* should be allowed only in exceptional cases, i.e. when it is highly probable that the embryo is affected by a severe genetic disorder which will be manifested immediately after birth or in the early years of life and for which there is no adequate treatment.

The Commission stresses that the acceptance of embryo genetic testing by future parent/s is independent from their decision on the future of the embryo.

The Commission endorses the principle of equal treatment of embryos with different genetic makeup provided it does not lead to manifestation of the disease for which genetic testing was performed.

2. Genetic tests on population groups

The Commission considers that, in order to protect freedom of research and avoid social discrimination, genetic tests on population groups should be conducted in accordance with research protocols approved by a responsible bioethics committee specifically established to that purpose.

3. Storage of biological samples and genetic information

With respect to storage of biological samples, the Commission believes that storage must be governed by clear operation rules ensuring in particular that only authorized persons may access the stored samples and specifying the time of preservation of identifiable samples.
The Commission underlines that storage of records with identifiable genetic information should be covered by a licence granted by the Personal Data Protection Authority in compliance with the relevant laws on treatment of sensitive personal data.

****

3. COMMENTS ON THE DRAFT BILL CONCERNING MEDICALLY ASSISTED HUMAN REPRODUCTION

The National Bioethics Commission, following the request of the Speaker of the Parliament (ref. No 3154/07.10.2002), held a meeting on October 11th 2002 in order to examine the ethical and social issues, falling within its competence in accordance with article 10 of the Law 2667/1998, raised by the draft bill on "Medically Assisted Human Reproduction". The draft bill, prepared by a special legislative committee at the Ministry of Justice, has been submitted to the Parliament. Its discussion at the plenary session is expected shortly.
The Commission
appreciating the critical issues regulated by the bill in respect to the protection of the value of human beings and their fundamental rights and
being aware of the strong public interest in relation to medically assisted reproduction
has arrived to the following comments in regard to the first article of the draft bill (new articles of the Civil Code 1455-1460).

General comments

The need of legislation regulating assisted reproduction

The widespread use of assisted reproduction methods reflects a reality that is beyond any doubt. Irrespectively of whether the lawmaker intervenes or not in order to regulate the relative matters, the use of assisted reproduction meet an obvious social interest, namely facilitates the creation of family overcoming the physical inability to have children.
However, the lawmaker's intervention is considered necessary to the degree that it guarantees certainty of law in an area of complex social relationships. Therefore, the National Bioethics Commission welcomes this legislative initiative.

Greece/English

The content of the draft bill

The regulations introduced by the draft bill are, first of all, based on the acceptability of medically assisted reproduction. The Commission considers that, in principle, the bill is consistent with the social and ethical views in our days, given that is supportive of a technology that enables and advances the enjoyment of fundamental rights, and more precisely the enjoyment of the right to reproduction and the right to family. In addition, the Commission stresses that the bill is in accordance with the Convention on Human Rights and Biomedicine of the Council of Europe, a binding text for the greek legislator on the matters of biomedicine (Law 2619/1998, article 28 para 1 of the Constitution).
Furthermore, this document introduces two types of regulations and restrictions in regard to medically assisted reproduction: a) permits recourse to the methods of assisted reproduction only for medical reasons, either to cure infertile persons or to avoid transmission of severe genetic disorders to the child and b) defines a specific and strict framework into which the complex relations that arise are to be interpreted in order to avoid legal complications.
The Commission stresses that, from a legal and ethical point of view, the right to reproduction and the right to found a family allow of limits, because of their connection with the rights of a third person and the interests of the child to be born. In addition, restrictions appear necessary in the case of assisted reproduction because of the important physical and psychological charge of the participants.
Taking into consideration these general comments, the particular provisions of the draft law are examined further.

Comment on the terminology used

The term “reproductive material” is used in articles 1456, 1459 and 1460. The Commission stresses that the term is accurately used only in article 1460 of the draft bill, where it refers to gametes (sperm and ova). In articles 1456 and 1459 the term is unidiomatic since it refers both to gametes and the early stages of embryonic development.
The term “fertilized ovum” used in the draft bill (articles 1458 and 1459) refers exactly to these early stages of embryonic development (6-8 cells) and so could be used in articles 1456 and 1459. Despite the fact that the term “fertilized ovum” is not scientifically precise, since in reality wants to refer to fertilized ova and their division products, it could be accepted because it does facilitate the comprehension of the matter by the non-experts as well. However, Prof. Roupakias expressed his reservation and proposed the term “embryo” as more appropriate.

Comments on the articles

Article 1455

“*Medically assisted human reproduction (artificial fertilization) is permitted only in order to treat the incapacity to have children by natural way or to avoid the transmission of a severe genetic disease to the child. Such medical assistance is permissible up to the reproductive age of the assisted person. Human reproduction with the methods of cloning is prohibited.*
Sex selection of the child to be born is prohibited, unless a severe hereditary sex-linked disease is to be avoided.”

The Commission considers that the right to reproduction is an expression of the fundamental right to the free development of personality and a crucial precondition for the enjoyment of the right to found a family.
From a legal point of view, the right to personality development is subject to the general restrictions foreseen by the Constitution (article 5 para 1), which is the respect of the Constitution, of other person’s rights and of public morals. The Commission considers that the particular restrictions to the right to reproduction, using methods of assisted reproduction, which provides this article, are exactly those that serve best the constitutional demand.

From a bioethical point of view the interest is focused on the fact that recourse to assisted reproduction methods is not permitted for every reason but only for the treatment of pathological conditions. This restriction is legitimate, since the meaning of a person's option to exercise his/her rights (in this case, the right to reproduction and the right to family) in case of involuntary deprivation could not lead to the "liberalism" of favoring technical processes over the natural ones. The ban of reproductive cloning and the prohibition of sex selection (unless there is to be avoided a sever sex linked genetic disorder) are considered legitimate as well, since they reflect commonly accepted socio-ethical views of contemporary civilization that are incorporated in international texts (Universal Declaration of UNESCO for the Human Genome and Human Rights, the Convention on Human Rights and Biomedicine of the Council of Europe, the First Additional Protocol of the Convention on the Prohibition of Cloning).
According to the Commission, the general stance of the article restricts sufficiently the recourse to methods of assisted reproduction, defining also the requirements for their application.
In regard to these requirements Prof. Roupakias expressed certain reservations since he considers that the value of a human being, (which represents a unity of body and soul), exists from the moment of fertilization. According to Prof. Roupakias, the fertilization of more than one ovum per cycle of infertility treatment (a common practice adopted in order to increase the probability of the method's success) is unacceptable, since it leads to the creation of "supernumerary" fertilized ova. Furthermore, Prof. Roupakias expressed his concern in regard to the wording of the provision prohibiting sex selection, maintaining that it does not preclude interpretations that could permit selection for other characteristics.

Article 1456

"Medical acts that intend to assist human reproduction, pursuant to the stipulations of the previous article, are undertaken with the written consent of the persons who wish to have children. In the case of unmarried or single women, her consent or the consent of her partner –if such exists- are furnished by a notary document.
Consent can be withdrawn with the same way till the moment of transfer of reproductive material to the female body. Subject to the provisions of article 1457, the consent is considered to be withdrawn if one of the persons, who had already consented, died before the transfer."

The Commission considers that the provisions in regard to the procedure of consent obtaining are necessary in order to ensure the sincere will of the persons that recourse to the methods of assisted reproduction. The Commission believes that it is rightful the application of these methods to unmarried persons, since the right to reproduction and the right to found a family are fundamental and thus enjoyed by everyone.
Reservation has been expressed by Prof. Maniatis, who considers that the law should not explicitly encourage the recourse to assisted reproduction for those persons that deny the socially established conventional obligation of marriage in order to have children.
A different reservation expressed by Prof. Roupakias; according to him law should explicitly prohibit recourse to the methods of assisted reproduction for single or unmarried persons.

Article 1457

"Assisted reproduction after the death of the spouse or the partner is allowed by court authorization and only if both of the following requirements are met:
The spouse or the partner suffered from a disease that either could affect fertility performance or endangered his life.
The spouse or the partner had consented via a notary document for post- mortem fertilization.
Assisted reproduction is carried out not before six months and not after two years from the death of the spouse or partner."

The Commission considers that the right to reproduction and the right to found a family include the possibility of post mortem fertilization, in case of death of one of the donors, as the draft bill anticipates it.
Prof. Roupakias expressed his reservation in regard to these provisions.
In relation to the time lapse between the death of the donor and the post mortem fertilization, Prof. Krimbas expressed reservations, regarding as extremely restrictive the maximum (2 years) and minimum (6 months) time provisions.

Greece/English

Article 1458

"The transfer of fertilized ova to another woman and pregnancy by her is allowed by a court authorization issued before the transfer, given that there is a written and, without any financial benefit, agreement between the involved parties, meaning the persons wishing to have a child and the surrogate mother and in case that the latter is married of her spouse, as well. The court authorization is issued following an application of the woman who wants to have a child, provided that evidence is adduced not only in regard with the fact that she is medically unable to conceive but also with the fact that the surrogate mother is in good health condition and able to conceive."

The provisions in regard to the recognition of surrogate motherhood divided the Commission. In favor of the option of surrogate motherhood, given the restrictions and the requirements of the relative provisions, has expressed the Chairman of the Commission Prof. Koumantos and the Professors Agouridis, Krimbas and Manoledakis.
Reservations were expressed by Professors Maniatis, Roupakias and Vlahoyiannis who consider that introduction of such an option is precocious, given the current socio-ethical views and the psychological and biological cost of pregnancy.
Prof. Tsoukalas expressed a different reservation in regard to surrogate motherhood, considering that such regulations do not protect our societies from the undesirable eventuality of both embryos and surrogate mothers being subject to commercialization. Prof. Roupakias agreed with this as well.
Prof. Dragona-Monachou abstained from voting, pointing to a lack of evidence-based survey regarding the pragmatic social need of surrogate motherhood in Greece.

Article 1459

"Persons resorting to assisted reproduction should decide in common, declare their will in a written form and address it to the doctor or the responsible of the fertility clinic before starting the relevant treatment, whether any cryo-preserved reproductive material that is not going to be used for their own treatment (surplus):
should be donated for fertility treatment of other persons that the doctor or the fertility clinic will decide
should be used for research or therapeutic purposes
should be destroyed
In case there is no common declaration of the persons concerned, cryo-preservation can last up to five years. After this period of storing, cryo-preserved material can either be used for research and therapeutic purposes or be destroyed.
Non cryo-preserved fertilized ova are destroyed after the completion of 14 days post-fertilization. Any intermediate cryo-preservation period is neglected."

The Commission considers legitimate the provisions in regard to the possible use of supernumerary fertilized ova. Especially, in regard to the use of supernumerary fertilized ova for research purposes, the draft law is in accordance with the Commission's Recommendation dating back to December 21st 2001 concerning the «use of stem cells in biomedical research and clinical medicine», where it is stressed the prerequisite of free and informed consent of the donors. Prof. Roupakias maintains his objections stated on that earlier recommendation.

Article 1460

"The identity of the donor of reproductive material is not disclosed to the persons wishing to have a child. Medical information concerning the donor is kept confidential with no identification. Access to this information is permissible only to the child and only for medical reasons related to the child's health.
The identity of the child and its parents is not disclosed to the donor."

The Commission considers necessary the provisions demanding confidentiality of personal information regarding the donors, the children to be born and their parents, in order to safeguard the privacy of all implicated parties.

****

4. RECOMMENDATION
On human reproductive cloning

The National Bioethics Commission met upon invitation by the President thereof on January 17th and February 28th 2003 in order to consider the ethical and social issues within its jurisdiction with regard to human reproductive cloning and to draft a related proposal pursuant to article 10, Act 2667/1998. Taking into account that:

Whereas the question of human reproductive cloning is currently at the center of international attention due to swiftly and emphatically spreading rumors of human beings already born or about to be born by the use of this method,
Whereas several national as we
ll as international jurisdictions are urgently seeking the appropriate legislative solutions to deal with the question,
Whereas the initiative, also advocated by Greece, for adopting an international convention in the framework of the United Nations concerning the prohibition of human reproductive cloning was interrupted before the above rumors began to spread,
Whereas the biomedical community but also large part of society focus their interest on the use of the nuclear transfer method which does not involve implantation of the cloned somatic cell in a female uterus for the purpose of developing treatments for currently incurable diseases,
Whereas, in its 21.12.2001 report on "the use of stem cells in biomedical research and clinical medicine" the Committee argued in favor of the use of the nuclear transfer method for therapeutical purposes with Prof. Roupakias disagreeing,

the Committee has concluded the following:

Biological parameters

Reproductive cloning is based on the technique of nuclear transfer, i.e. the replacement of the egg's nucleus by the nucleus of an adult somatic cell. Chemical or electric stimulation is then applied and sometimes this new egg starts dividing like a normally fertilized egg. If the successive divisions continue, embryonic development may reach the stage preceding implantation (blastocyst). If transferred, at this stage, into a female uterus, it may be implanted, embryonic development may continue and perhaps lead to birth of a new organism (clone).
Therefore, the technique of nuclear transfer may be seen as an attempt of reproductive cloning only if the egg-recipient of the somatic cell's genetic material is implanted in the uterus that will gestate it.
It must be stressed, however, that all mammals born to this day by the method of reproductive cloning present serious or unpredictable health disorders.
Bearing that in mind, any attempt to use this method on human beings would mean that women and any children/clones born in this way are made into guinea pigs. At the present stage, therefore, the international community considers the use of reproductive cloning on human beings as extremely unsafe on biomedical grounds.
In addition, the method in question would entail an unjustified waste of resources as it would require experimenting with hundreds of eggs with a high biological cost for the female organism in view of the required hormone treatment the long-term consequences of which are yet unknown.

Legal parameters

Human reproductive cloning is explicitly prohibited at the level of international law but also within the Greek legal system.
Pursuant to article 11 of the 11.11.1997 Universal Declaration on the Human Genome and Human Rights by UNESCO, "Practices which are contrary to human dignity such as reproductive cloning of human beings shall not be permitted".
In addition, in accordance with the 18.02.1998 First Additional Protocol to the 4.4.1997 Convention on Human Rights and Biomedicine by the Council of Europe, "Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited".

Besides, article 3 (2) of the 7.12.2000 Charter of Fundamental Rights of the European Union explicitly prohibits the reproductive cloning of human beings.
Finally, by the recent Act 3089/2002 on “medically assisted human reproduction” Greek law explicitly prohibits reproductive cloning (new art. 1455 of the Civil Code).
It should be noted that all these provisions are not accompanied by sanctions in case of infringement. Yet they do reflect a clear trend in contemporary law.

Positions

Insufficient state-of-the-art technology

In consideration of all the above parameters, the Commission believes that on the basis of our current knowledge and the corresponding state-of-the-art technology the use of reproductive cloning on human beings constitutes totally impermissible experimentation. This in itself suffices to justify the current prohibition.

Disrupting social structures

Aside from any technical problems, the use of the method gives rise to serious misgivings and reservations as to its moral and social acceptability. At the social level, in particular, an eventually widespread use of the method could visibly lead to radical disruption of fundamental social structures such as the family.

Promoting an international Convention

The Commission takes the view that an international convention should be adopted on the prohibition of reproductive cloning stating in clear terms that the transfer of a human egg the nucleus of which was replaced by the nucleus of a human somatic cell into a female uterus is not allowed. The Greek State should insist in promoting such an instrument by taking a specific initiative to that effect.

ICELAND

NATIONAL BIOETHICS COMMITTEE (NBC)

www.visindasidanefnd.is

Opinions

1. Attention should be brought to the Icelandic legislation concerning biobanks. In Iceland two types of biobanks are defined: those based on the gathering for storage in a biobank for scientific purposes and biological samples gathered for clinical tests. All studies conducted on any biological samples stored in biobanks are subject to the approval of the Data Protection Authority and the National Bioethics Committee. Samples collected for clinical studies benefiting the patient her/himself are collected under assumed consent for storage, but may not be used in scientific research without the approval of said authorities. Generally, approval is conditioned on the specific, informed consent of the donor of the clinical sample. This also generally applies to samples collected under a general informed consent of storage for scientific purposes. Exceptions may be made when research is of an epidemiological nature, or when samples are used for purposes of comparison, without any attached identifiers. Donors of samples for clinical purposes shall be informed of the storage of the sample and given an opportunity to refuse the utilisation of their sample for research purposes.

2. Recently, the NBC has established the following procedure for the handling of biological samples sent from researchers to companies specialising in specific diagnostics:

a) The NBC shall be kept informed of the general activities of the company, as well as the technique and the procedures applied within the company.
b) A clause shall be included in all contracts made on behalf of the company, stating that the client has obtained the approval of a pertinent NBC or IRB ("Institutional Review Board") and that verification of this will accompany the samples and that the biological samples involved have been obtained and handled in an internationally approved, ethical fashion.
c) The NBC will be sent a standardised letter for every diagnostic contract made. A copy of IRB approval shall accompany the letter.

ITALIE

COMITÉ DE BIOÉTHIQUE D'ITALIE (CNB)

www.governo.it/bioetica

Liste des avis

56
Avis du CNB sur les recherches utilisant des embryons humains et des cellules souches (cell stem) 11 avril 2003

55
Avis du CNB sur le tabagisme (nicotine addiction) 21 mars 2003

54
Avis du CNB sur le projet de protocole sur la génétique humaine (6 mars 2002)

53
Buts, risques et limites de la médecine (14 décembre 2001)

52
Considération éthique et juridique sur l'usage des biotechnologies (30 novembre 2001)

51
Bioéthique et science vétérinaire: bien être de l'animal et santé humaine (30 novembre 2001)

The Italian National Bioethics Committee

The Italian National Bioethics Committee approved an **Advisory Opinion on nicotine addiction on 21st March 2003**.
The conclusions are outlined below:

Nicotine addiction, like all other drug addictions, is combated principally by preventative measures and, when these do not suffice, by measures intending to limit its spread and harm. This difficult, complex operation must involve the whole of civil society and in particular doctors, pharmacists and health workers in general.
Prevention consists primarily in providing information at all levels, which must also be addressed to children. Besides being intrinsically correct, such prevention must take into account the characteristics specific to this phenomenon. These are principally the obstacles to a clear perception of the real dimensions of the dangers of nicotine addiction. This information, which is educational, must concern young people in an active manner, not only because they can influence the attitudes of adults, but also because they are potential victims of nicotine addiction.
Education must be accompanied by restrictive measures intended to limit the use of tobacco as well as the harm caused to smokers and to those who are passively exposed to tobacco smoke. On this point, particular attention should be paid to new-borns and to children. It should be emphasised that the ease with which tobacco can be purchased constitutes in itself a factor liable to increase nicotine addiction. In respect of individual liberty, it is necessary to take measures of incentive, by means of taxation or otherwise, to limit the use of tobacco and to enable the prevention of its sale in order to discourage its use amongst young people. The reduction of harms must not only concern treatment of the maladies of nicotine addiction, but it should also relieve dependence on tobacco insofar as this limits individual liberty and constitutes the largest obstacle in the fight against nicotine addiction.
The fact that the measures undertaken by different governments with the assistance of both national and international organisations (UN, WHO, EU) have not yielded the expected results must not be a basis for despondency. In the industrialised countries which have been leading the way in information campaigns, in education and in assistance to smokers, smoking-related diseases, especially lung cancer, have been reduced (to which the example of Finland testifies). In Italy, the National Health Plan (2001-2003) is preparing amongst other things, an institutional information campaign concerning healthy lifestyles. This promising initiative must be vigorously pursued, in particular its prevention of the use of tobacco and other drugs.
The problem of nicotine addiction is complex because of its implications, which are not only ethical, social and health-related but also have consequences for the economy and employment. Therefore, tobacco cultivation should be converted to other forms of agriculture (which would ensure an adequate income to those employed in the sector) and such moves should be realised alongside other therapeutic measures which address the essence of nicotine addiction.

The President of the Italian National Bioethics Committee is Francesco D'AGOSTINO, Professor of philosophy of law at the University of Rome 'Tor Vergata'.

ITALIAN NATIONAL BIOETHICS COMMITTEE

Via Veneto, 56
00817 Rome,
Italy

Chairman: Prof. Francesco d'AGOSTINO, Prof. of philosophy of law at 'Tor Vergata' University in Rome

Contact: Dr S. BAUZON, Scientific expert

Tel. 0039-06-48161490
Fax. 0039-06-48161493
E-mail : cnbioetica@palazziochigi.it
URL : www.governo.it/bioetica

LATVIA

CENTRAL MEDICAL ETHICS COMMITTEE

List of opinions

1. Opinion on Human Genoma Act 2002 (in latvian)
2. Opinion on store and use of human tissue and organs 2002 (in latvian)
3. Report on Directive 95/46/EC implementation into the national legislation regarding the medical research 2002 (please find attached)
4. National Regulations on Ethics and Research in Latvia 2002 (please find attached)
5. L. Rudze “Conflict of interest in medicine and science: a Latvian view” A special issue of ”Science and Engineering Ethics” (2002) 8, 343-348.

Report on Directive 95/46/EC implementation into the national legislation regarding the medical research

Introduction - Laws on data protection in the medical research

The data protection issues in medical research in Latvia are regulated by several laws, which can be subdivided in following groups:

1) General law on data protection (***Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data; Personal Data Protection Law***), which applies to the processing of all types of personal data. Personal Data Protection Law implements the Directive 95/46/EC into the national legislation;
2) General health field law (***Law on Health Protection[1], Law on Medical Treatment, Law on Sexual and Reproductive Health[2], Law on Psychiatrically Help[3], Epidemiological safety Law, Pharmacy Law.)*** – mainly applies to the public relationships in health protection field, in particular medical treatment, hospitals, physicians and other medical staff rights and duties, general principles of Medical Ethics Committees operation, epidemiological surveillance etc. Besides the health protection rules, these laws contains some specific regulations on medical research, for example, Law on Medical Treatment states general principle for using patients data in scientific research in following way "information regarding a patient may be used in scientific research if the anonymity of the patient is guaranteed or his or her consent has been received." This article applies to the scientific research generally, and does not cover all specific kinds of research, for example humane genome research, clinical trials.
3) Medical research law (***Council of Europe Convention on Humane Rights and Biomedicine[4], Humane Genome Research Law[5], Cabinet of Ministers Regulations "Procedures for Conducting Clinical Trials and Observations Regarding Use of Medicinal and Pharmaceutical Products)*** – applies directly to the medical research.

Questionnaire.

1. In accordance with the Article 2 of Personal Data Protection Law personal data is any information related to an identified or identifiable natural person. In principle it is no matter who can identify the data subject. Data could be treated as not identifiable and accordingly not as personal data only in case of they contain information that can not reasonably be used by anyone to identify individuals who donated them or to whom they relate. Personal Data Protection Law does not give direct answer to the question about its extension to the dead. However in the practice it is accepted to consider that in separate cases Personal Data Protection Law covers proceeding with dead data (for instance, genetic research or operation with the health records).

[1] Draft Law, witch has been approved by the Cabinet of Ministers and submitted to the Saeima (Parliament) on the 1.10.2002.
[2] The Saeima has adopted this Law on 31 January 2001. It comes into force only on 1 July 2002. There are several Regulations on specific fields of reproductive health, for example regarding registers on medical fertilization and data banks of gamete, which will be approved by the Cabinet of Ministers until the end of 2002.
[3] Draft Law, witch has been approved by the Cabinet of Ministers and submitted to the Saeima (Parliament) on the 1.10.2002
[4] Draft Law, which is on the second reading in the Saeima.
[5] This Law enters into the force on 1 January 2002.

2.

a) Taking into account the legal definition of personal data processing ("personal data processing is any operation carried out regarding personal data, including data collection, registration, recording, storing, transformation, utilisation, transfer, transmission and dissemination, blockage or erasure"[6]), rendering personal data anonymous shall be interpreted as personal data processing. Article 10 of Personal Data Protection Law allows personal data processing for purposes other than those originally intended only in case of it does not violate the rights of the data subject and is carried out for the needs of scientific or statistical research. In such case a system controller is obligated to provide the data subject with all information as stated by the law. So, the answer to the question depends on the content of purpose Y.

b) If the A retains the original data in personal form, there is no basis to consider that data is rendered anonymous in such a way that the data subject is no longer identifiable. So, in this case system controller shall comply with the requirements of Personal Data protection Law and provide B with information about propose of data processing, excepting a case when Y purpose can be interpreted as processing personal data for scientific, historical or statistical research and informing of the data subject requires inordinate effort or it is impossible. If the A does not retain original data in personal form, his right to render personal data anonymous for purposes other than those originally intended is precarious. Taking into account above mentioned it is necessary to consider that principal question in both cases is about personal data proceeding propose content.

3.

(i) Article 10 of Personal Data Protection Law allows the further personal data processing for purposes other than those originally intended if it does not violate the rights of the data subject and is carried out for the needs of scientific or statistical research. In such case the system controller shall act with requirements of Article 9 regarding disclosing the data to third persons and requirements of Article 10 regarding the data subject interests protection. The system controller has no obligation in case of personal data have not been obtained from the data subject, to provide the data subject with the information as stated by the law when processing personal data for scientific, historical or statistical research, the informing of the data subject requires inordinate effort or it is impossible.

(ii) Article 11 of Personal Data Protection Law allows personal data processing if it is necessary for the purposes of medical treatment and is carried out by a medical practitioner or a medical treatment institution and an adequate level of protection of personal data is ensured. According to the domestic law patients consent is compulsory requirement for any medical intervention, excepting emergency situation where such consent shall be obtained as soon as reasonably possible and situation when medical intervention is carried out on the legally incapable person where such consent shall be obtained from persons legal representative. Individual acceptance of the medical intervention in the same time accepts proceeding with his/her personal data for medical intervention purposes. Law On Medical Treatment states general principle for using patient's data in scientific research in following way: "information regarding a patient may be used in scientific research if the anonymity of the patient is guaranteed or his or her consent has been received."

(iii) Article 12 of Directive is implemented into Article 15 and 16 of Personal Data Protection Law. According to the Article 17 of Personal Data Protection Law Article 15 and 16 are not applicable if the processed data are used only for the needs of scientific and statistical research and, on the basis of such, no activities are carried out and no decisions are taken regarding the data subject. Article 13.2 of Directive is implemented into Article 9 Paragraph 2 of Personal Data Protection Law as well.

(iv) National legislation foreknows some exceptions concerning data subject's rights with design to protect the public safety or patient's interests in case of medical intervention. In accordance with the Law On Medical Treatment only medical practitioners shall provide patient information related to his/her health. According to the Article 41 of this law doctor may provide incomplete information to the patient regarding the diagnosis and prognosis of the disease if he or she considers that such information may cause deterioration of the state of health of the patient.

[6] Personal Data protection Law, Article 2

Draft Health Protection law foreknows that data subjects right to information regarding his/her health may be subject to restrictions in circumstances provided for by law in order to protect his or her health, the rights of other people, and public safety, welfare and morals. This provision corresponds to the Article 116 of the Constitution of the Republic of Latvia.

Taking into account the fact that in case of medical intervention the question about patients right to information is very closely connected to the health care quality questions, in practice sometimes it is very difficult to examine these questions separately. Thereof a patient can appeal the doctor's decision concerning information's restriction to the Quality Control Inspection for Expert Examination in Medical Care and Ability to Work and its decision to the Court.

4.

Article 7 and 8 of Directive are implemented into Article 15 and 16 of Personal Data Protection Law. That means that personal data proceeding without data subjects consent can be carried out only in circumstances provided for by law. For all that the Personal Data Protection Law does not have any references in such cases regarding obtaining the data subjects consent, some specific laws require preliminary individuals consent before his/her personal data proceeding, for instance Human Genome Research Law, Law On Medical Treatment.

5.

According to the Law on State Population Register to each Latvian inhabitant shall be given personal identity number. Several laws regulate the usage of this identification number, for instance Tax Collection laws, Administrative Procedure Law, The Commercial Law. The Personal identity number in all cases shall be treated, as information that contains particulars details regarding the private life of person and its usage requires appropriate protection according to the Personal Data Protection Law. For example, Administrative Procedure Law foreknows institutions responsibilities concerning acquiring information in following way: "if the necessary information contains particulars regarding the private life of a natural person (personal identity number, nationality, citizenship, place of residence, family status, state of health, criminal record, income, property, religious and political opinions or any other information), the institution shall explain to the person the regulatory enactments on which is based, and the purpose for the acquisition of the information wanted by the institution, as well as whether the person is required to provide the information in accordance with an external regulatory enactment, or the provision thereof is voluntary."

6.

In accordance with the Article 19 of Personal Data Protection Law a data subject has the right to object to the processing of his or her personal data if such will be used for commercial purposes. Personal Data Protection Law does not foresee any other grounds for data subject objection.

7.

Personal Data Protection Law allows personal data processing for purposes other than those originally intended only in case of it does not violate the rights of the data subject and is carried out for the needs of scientific or statistical research. In such case a system controller is obligate to provide the data subject with following information: 1) the designation, or name and surname, and address of the system controller; 2) the intended purpose for the personal data processing, 3) the possible recipients of the personal data; 4) the source of the personal data, and 5) the rights of data subject to gain access to his or her personal data and the possibility of rectifying such data. The system controller is not bounded with such obligation only when processing personal data for scientific, historical or statistical research and the informing of the data subject requires inordinate effort or is impossible. In addition to the above-mentioned information according to the Article 15 of Personal Data Protection Law, a data subject has the right to obtain all information that has been collected concerning himself or herself in any system for personal data processing, unless the disclosure of such information is prohibited by law. Foregoing is related to the data, which have been obtained fro the data subject, and to the data that have not been obtained from the data subject.

8.

Personal Data Protection Law does not foresee any exceptions regarding the notification of processing to the supervisory authority. That means that every natural or legal person, who carry out or wish to commerce carrying out personal data processing, and establish systems for personal data processing, shall register such in accordance with the procedures prescribed in this Law. The persons shall submit an application for personal data system processing registration to the State Data Inspection. The same requirements concern the field of medical research.

9.

Yes, according to the Personal Data Protection Law prior to registration of a personal data processing system, the State Data Inspection shall perform an inspection of the personal data processing system. There are some specific requirements for prior checking concerning medical research. Human Genome Research Law regulates the usage of identification numbers in genetic research. In order to ensure the highest standard of data protection, Main Processor shall give each tissue sample, DNA description, health description and genealogy a unique code immediately after receipt of these data in the Genome Database. Main Processor shall replace with a code all data, which enables the reverse identification of the gene donor, including the name, personal code and residence. The code shall be indicated on the written informed consent of the gene donor. Main Processor shall appoint specific persons, who perform coding, and who issue coded tissue samples, DNA descriptions or health descriptions. The State Data Inspection shall approve the method of generating the codes.

10.

Yes, several laws regulate the order of establishment and data keeping and operation of public health registers and databases. All these regulations shall be publicised as stated by the law.

Moreover, Personal Data Protection Law foresee that the State Data Inspection maintain personal data processing systems register that shall be accessible to the society. Information concerning the registered personal data processing systems shall be published in accordance with the procedures prescribed in regulatory enactments.

11.

The general principle is that the State Data Inspection shall carry out the protection of personal data. The State Data Inspection shall take decisions and review complaints regarding the protection of personal data. However in medical research exist some additional authorities, which are responsible for lawful proceeding during research.
Central Medical Ethics Committee shall carry out the protection of ethical principles in genetic research. If the Ethic Committee has reasonable suspicions about possible violation of personal data protection, it shall inform the State Data Inspection.

The supervision on lawful clinical trials and observation regarding use of medicinal and pharmaceutical products proceeding is carried out by the Ethics Committee, State Drug Agency, State Pharmacy Inspection and the Quality Control Inspection for Expert Examination in Medical Care and Ability to Work. If these authorities have reasonable suspicions about possible violation of personal data protection, they shall inform the State Data Inspection and shall take the necessary measures for prevention of such violations.

12.

Personal Data Protection Law allows to transfer personal data to another state if that state ensures such level of data protection as corresponds to the relevant level of the data protection in effect in Latvia and written consent has been obtained from the State Data Inspection. Exemptions of above mentioned is permissible if at least one of the following conditions is complied with:
1) the data subject has given consent to the transfer of the data to another state;
2) the transfer of the data is required to fulfil an agreement between the data subject and the system controller, or the personal data are required to be transferred in accordance with contractual obligations binding upon the data subject;
3) the transfer of the data is required and requested, pursuant to prescribed procedures, in accordance with significant state or public interests, or is required for judicial proceedings;

4) the transfer of the data is necessary to protect the life and health of the data subject; or
5) the transfer of the data concerns such personal data as are public or have been accumulated in a publicly accessible register.

13.

According to the Personal Data Protection Law it is established the State Data Inspection, which carries out the protection of personal data. The State Data Inspection in the field of personal data protection has following rights:
1) in accordance with the procedures prescribed by regulatory enactments, to receive, free of charge, information from natural persons and legal persons as is necessary for the performance of functions pertaining to inspection;
2) to perform inspection of a personal data processing system prior to its registration;
3) to require that data be blocked, that incorrect or unlawfully obtained data be erased or destroyed, or to order a permanent or temporary prohibition of data processing; and
4) to bring an action in court for violations of Personal Data Protection Law.

Besides the State Data Inspection regarding medical research exist some additional authorities, which are responsible for lawful proceeding during research. Thus are: Quality Control Inspection for Expert Examination in Medical Care and Ability to Work, State Drug Agency, State Pharmacy Inspection and Medical Ethics Committees. All of them are established according to the law and they act with by- laws approved by the Cabinet of Ministers. This institutions, except the Medical Ethics Committees, has the right to take the necessary measures for medical research violations prevention, in particular they can suspend the operation of research permission, or to cancel the permit if the research activities threaten the life or the health of individual. They have rights to impose the administrative penalties to the researcher as well.

14.

The Law foresees for breaching the personal data processing the criminal, administrative and disciplinary liability.

15.

State Data Inspection can to call to justice data controller if it is proved that in consequence of his/her actions is caused any damage to the data subject or any other third person. However the State Data Inspection can decide to release from responsibility data controller if it prove that his/her is not culpable for the events giving rise to damage. In such a case data subject or third person keeps rights to appeal to the court, and solution depends on the courts decision.

16.

According to the Personal Data Protection Law consent of data subject is a freely, unmistakably expressed affirmation of the wishes of a data subject, by which the data subject allows his or her personal data to be processed. The Civil Law of Latvia states that: “the expression of intent may be express or implicit. Express intent may be expressed in words, orally or writing, or by signs which have the meaning of words. Intent is implied when if it is manifested without the direct purpose of expressing intent precisely in this meaning. For an action to be considered to be an expression of implied intent, it must be such as to allow a clear inference of the existence of such intent. Data subject’s consent can be interpreted as explicit only if it is given without mistake, fraud and duress.
If the data subject gives his/her consent in written it shall be interpreted as explicit in case of Article 1431 of the Civil Law of Latvia, which states that: “the signing of deed shall be considered to the consent of such deed, regardless of whether it applies to the signatory or to a third person, if the contents of such were known to the signatory and if he or she has a personal interest in, and the right to object to, the lawful transaction to which the deed applies.”
It should be highlighted that several laws, for example Human Genome Research Law, Pharmacy Law requires the individual consent to be expressed in written.

17.

According to the Article 18 of Personal Data Protection Law a person is not required to comply with an individual decision, which have been taken only upon the bases of data processed automatically. The person may be made subject to such aforementioned decision if it has been taken in accordance with law or contract entered into with the data subject.

Any kind of the medical research can be carried out only patient's written preliminary consent and before the patient gives his/her consent, he shall receive all information regarding research, in particular, research project purpose, tasks, terms, methods, possible risks and benefits for his/her health.

18.

According to the transition provisions of the Personal Data Protection Law chapter IV of this Law, "Registration and Protection of a Personal Data Processing System" have been entered into force on 1 January 2001. There was a transition period for persons, which have commenced operations before coming into force of this Law regarding registration into the State Data Inspection until 1 January 2002. After expiry of this term, unregistered systems shall cease operations.

19.

The Personal Data Protection law has the same regulation as Directive concerning the processing the personal data in historical research. Although Personal Data Protection Law does not define the term "historical research", at the same time this term in practice is interpreted as data, which are processed in accordance with the Law On Archive. This law regulates the operation with the archive documents (National Archive Fond and State Archive), confidentiality issues and the terms of reference of the archive staff.

20.

a) Yes, DNA samples and other biological material (hereinafter – biological materials) in a genetic research in accordance with the Law On Human Genome Research are treated as personal data. That means that the processing of biological materials in genetic research is liable under the same conditions and requirements as personal data. According to the Article 9 of Law On Human Genome Research Personal Data Protection law regulates processing of personal data, which is included into Genome database and the Gene Donor database insofar as far this law does not define otherwise. The biological material could not be treated as personal data only in a case if it contains no information that could reasonably be used by anyone to identify individuals who donated them or to whom they relate.

b) Genetic research is allowed only with patient's preliminary written consent. Before the patient gives his or her consent, he shall receive all information regarding the research, in particular, the research project purpose, tasks, and terms; possible risks and benefits for his or her health. Genetic research without patient's preliminary written consent is allowed only in a case of emergency clinical situation when the individual is not able to give his or her consent and only if such kind of research produces a direct benefit for his or her health. In such cases the preliminary written consent shall be obtained from the patient's legal representative and permission of Central Medical Ethics Committee is required as well. Patient's consent shall be obtained as soon as reasonably possible.

The researchers shall proceed only with coded personal, health and genetic data. The State Genome Register collects all data about into the genetic research involved persons, which allows identify the individual who donated them. The State Genome Register is permitted to decode data only in order to destroy a tissue sample, a description of DNA or a health description or genealogy, to enable access to data on a gene donor stored in the Genome Database (except genealogies) at the request of the gene donor, to renew, supplement or verify a health description of a gene donor unless the gene donor has prohibited that, to issue a health description of a gene donor to the doctor of the gene donor at the request of the doctor of the gene donor and with the consent of the gene donor or without the consent of the gene donor in emergency cases. According to the Article 21 of Human Genome Research Law the control over processing of personal data and biological material is carried out by the State Data Inspection[7].

c) Only in a case when researcher uses the biological material which contains information that could reasonably be used by anyone to identify individuals who donated them or to whom they relate.

d) No, it is possible only with preliminary written patient's consent.

e) In accordance with general principles of Human Genome Research Law genetic research can be carried out only if it has potential to generate scientific understanding that may be a basis for improvements in human health and only with preliminary written patient's consent. The Law states only one exception - research in emergency situation without patient's preliminary written consent. Taking into account above mentioned the biological material samples taken for genetic research should not be used for any other purposes, including forensic purposes. Moreover the biological material samples which are obtained for forensic purposes, should not be used for genetic research without patient's preliminary written consent too.

[7] The State Data Inspection is established in accordance with the Personal Data Protection Law as institution, which ensures the protection of personal data.

O.Rozenkopfs, L.Rudze

National Regulations on Ethics and Research in Latvia

1.Introduction

There is full recognition by Latvia of the importance of data protection in connection with accession to the Schengen Convention as well as cooperation with Eoropol. National data protection legislation, transposing directive 95/46/EC on the protection of individuals with regard to the processing of personal data, was adopted on 23 March 2000. The Council of Europe Convention was ratified on 5 April 2001.The State Data Inspection, the implementation institutions - was established on 1 January 2001. At present, there is an ongoing discussion with the Commission on institutional solutions for the Inspection, namely whether institutional subordination to the Ministry Of Justice complies with the independence criteria envisaged by the directive.Setting the time frame for the process of adoption and implementation of the European Union's acquis communautaire, the Latvian government adopted 1 January 2003 as the date on which Latvia will be prepared for accession to the European Union.

2.National Overview

Type of government: democratic, parliamentary republic.Legislative power is in the hands of a single chamber parliament - the Saeima, consisting of 100 deputies. Parliamentary elections take place every four years. The country's head of state is the President, who is elected by the Saeima for a period of 4 years. The President signs laws, chooses the Prime Minister (who heads the government) and performs representative functions. The Ministry of Justice is the central executive institution through which the Cabinet of Ministers implements the tasks and functions prescribed by the Satversme (Constitution) and laws. The Ministry of Justice develops and implements the State policy in the field of justice. In accordance with the aforementioned by-laws, the Ministry of Justice has the following functions:

- to formulate drafts of laws and other normative acts, co-ordinating them with European Union norms and international agreements binding on Latvia;
- to evaluate the compliance of normative acts to the European Union norms and international agreements binding on Latvia and to prepare relevant proposals regarding their improvement;
- to ensure; in accordance with its competence; the implementation of international agreements binding on Latvia;
- to validate legal documents;

Ethics Committees that review Biomedical research in Latvia

- CENTRAL MEDICAL ETHICS COMMITTEE OF LATVIA
- THE INDEPENDENT ETHICS COMMITTEES FOR INVESTIGATION OF DRUGS AND PHARMACEUTICAL PRODUCTS
- ETHICS COMMITTEE OF THE LATVIAN INSTITUTE OF CARDIOLOGY FOR CLINICAL AND PHYSIOLOGICAL RESEARCH, AND DRUG AND PHARMACEUTICAL PRODUCT CLINICAL INVESTIGATION
- ETHICS COMMITTEE of MEDICAL ACADEMY of LATVIA
- ETHICS COMMITTEE ON LABORATORY ANIMAL USE IN BIOMEDICAL RESEARCH

Central Medical Ethics Committee of Latvia

set up by Cabinet of Ministers of Republic of Latvia 25.03.1998.
Legal basis of the Committee is Rule of Cabinet of Ministers of Latvia.
Committee consists of 14 members-doctors, nurses, scientists, pharmaceutics, and lawyers, representative of religion, representative of disabled, representative of retired.
Statute of Ethics Committee governs the recruitment of the Committee members.
Recruitment based due to proposal of Ministry of Welfare, appointment by Cabinet of Ministers.
Type of Committee is standing body.
Committee is independent.
Serve longs 4 years, possible renewal 4 years.
Matters referred to the Committee in written form. Resolutions adopted by majority vote.
Committee releases its views as opinions, recommendations in written form.
Fate of minority or divergent opinions is reflected in protocol. Debates within Committee are open to the public.
Committee organises events open to the general public.
Committee makes public its recommendations on TV, Radio and Newspapers.
Main topics are biomedical research.

Main issues on which Committee has given its views are: evaluation of researches projects, evaluation of elaborated devices for medical procedures, recommendation to refined experimental techniques.

Committee convenes by Chairman once in month, more often if necessary. Cabinet of Ministers approves the Chairman. Members of Committee elect the Vice-Chairman. The Vice-Chairman executes the authorities of the Chairman in his/her absence. The Chairman presents the cases verbally. The Chaiman is legally competent when the Chairman or Vice-Chairman and more than half of the members are present.

During the evolution of a project the Committee may obtain additional information from the investigator or summon the investigator to a meeting with the Committee. Simple majority decides each case when voting takes place. The Chairman's vote is decisive in case of parity of votes. A member shall inform the Committee of circumstances that may raise doubts about the competence of the member. A member cannot participate in the handling of a project that concerns his or her personal or commercial interest. Committee decides whether a member has such an interest in which case that member is excluded from participation in the handling of that issue.

The Committee shall obtain a consultant statement in cases where the Committee is without the necessary professional expertise. The decisions of the Committee shall be given within 4 weeks in written form. The secretary of the Committee registers the cases received and take minutes of the Committees meetings.

Tasks of the Committee are:

To ensure that:

- The risks that might be connected with implementation of a project have been properly assessed.
- The patients or healthy volunteers, participating in the project will be informed in writing about its content, foreseeable risks and advantages, and than their free and explicit consent will be obtained and given in writing.
- Information will be given to, and consent obtained from, the closest relatives, guardian or donor in such cases where the study is carried through under circumstances [incomplete sentence?]. Information sheets make it clear that patients and healthy volunteers or relatives, guardian or donor can retract their consent at any time.

A Committee follows up individual projects and demand that the final scientific report or publication is submitted to the Committee.

According to the Law of Pharmacy Committees of Clinical trials of Drugs and pharmaceutical products is set by Cabinet of Ministers of Republic of Latvia.

***Law on Pharmacy (approved 10.04.1997, amendments on 19.03.1998. 17.12.,1998, 01.06.2000, into force from 05.08.1997**]*

6.
The Minister for Welfare shall, within the scope of his or her competence:

- approve the model by-law for the medicament clinical investigation ethics committees and co-ordinate the membership of such committees;
- determine the requirements for good manufacturing practice, good distribution practice, good clinical practice of drugs, for the supervision of side-effects caused by the use of drugs, as well as the procedures for co-ordination of the advertising of drugs;
- determine the auxiliary substances to be indicated in the labelling and instructions for use of drugs and the requirements for legibility of the labelling and instructions for use of drugs.

The Minister of Welfare confirms the Master Statutes of the Ethics Committees for clinical trials of Drugs and coordinates personnel of the above-mentioned committees. The Master Statutes of the Ethics Committees (enacted by the Minister of Welfare in August 6, 1998) and the Pharmaceutical Law, established independent Ethics Committees to give ethical assessment prior to a clinical trial. Ethics Committees must include both medical persons and non-medical laypersons.

Ethics Committee on Clinical Trials of Drugs consists of 14 members (Physicians, pharmacologist, journalist, lawyer and computer specialist).

Ethics Committee on Clinical Trials of Drugs by Latvian Institute of cardiology has 9 members (6 physicians, biologist, biochemist and laboratory assistant).

The Independent Ethics Committee for investigation of drugs and pharmaceutical products consists of 12 members (physicians, economists, pharmacologists, lawyers, psychologist, expert from drug agency, laypersons)

A clinical trial of Drugs and pharmaceutical products may start only after a written approval from the independent Ethics Committee for clinical trials and Drugs and a written permission from the State agency of Medicines are obtained. Documents can be submitted to the State Agency of Medicines and independent Ethics Committee for clinical trials of Drugs at the same time. An application together with supporting documentation shall be submitted to the independent Ethics Committees for clinical trials of Drugs.
The following must be submitted:

- Signed protocol and amendments (should be translated into Latvian);
- Investigator's brochure;
- Information given to trial subject and informed consent form (should be translated into Latvian and Russian)
- Insurance Statement;
- Curriculum vitae of investigators and sub-investigators;
- Advertisement for subject recruitment;
- Agreement of the Head of Hospital (Clinic, Health Centre) to perform the clinical trial.

3.Research involving Persons

Regulation on Clinical Trials of Drugs and Pharmaceutical Products (Nr 312, 12.09.2000- Cabinet of Ministers)

2.

Clinical trial shall be initiated only in the case the anticipated benefits from the clinical trial justify risk to the healthy person or patient who voluntary participate in the clinical trial (hereinafter: “trial subject”) and receive investigational product, or participate in the control group and receive comparator product (product with a known effect or pharmaceutical form without an active substance used for the clinical trial data control).

7.

The medical care given to, and all medical decisions made on behalf of subjects shall be the responsibility of an appropriately qualified health care practitioner with a certificate evidencing persons rights to perform without assistance treatment in the field associated with the specified clinical trial field (hereinafter: “investigator”). Investigator shall be selected by the sponsor having regard to his/her qualification and experience. Sponsor ensures further training for the investigator, if required.

8.

Prior to the initiation of the clinical investigation, investigator shall inform in writing the trial subject of the trial objectives, methods to be used, the anticipated benefits and risks, trial duration, compensation for participating in the clinical trial, if any, as well as of the procedure treatment expenses will be covered in the event of a trial-related injury. Written information and other materials to be provided to the trial subject shall be in a language he/she has a good command of.

9.

Written information for the trial subject shall contain message that the trial subject may withdraw from the trial, at any time, without mentioning motives, as well as ensure that the withdrawal from the trial will not affect further medical care of the trial subject negatively.

11.

When deciding about participation of a child in a clinical trial, if the child has reached seven years of age, the child’s own desire shall be taken into account.

12.

Inclusion of unconscious persons or persons without legal capacity in a clinical trial is possible only in the case the investigator justly believes this to be in favour of the respective person and in the event the Medicines Clinical Trial Ethics Committee (hereinafter: “Ethics Committee”) gives its consent. In the event the person is unconscious, written consent for participation in the clinical trial shall be obtained from the closest relatives of the person, with priority to spouse, parents or children’s opinion; in the case the person is without legal capacity - to legally acceptable representative’s opinion.

13.

Clinical investigation is forbidden in women during pregnancy and lactation, except cases when clinical investigation otherwise is impossible, and the risks during clinical investigation are proportional to the anticipated benefits to the embryo, foetus or infant.

14.

Trial subject in need for active disease treatment shall not be included in the control group where the trial subject receives reference product without the active substance.

17.

To ensure protection of the trial subject's identification data, investigator assigns identification code to each trial subject, which is used instead of the trial subject's name and surname, when the sponsor reports to the State Agency of Medicines and Ethics Committee.

20.

To ensure trial subject's rights and protection in the clinical trial, the sponsor is responsible for insurance of the trial subject covering possible injury and damages during the trial when administering the investigational product or performing other procedures in accordance with the protocol.

22.

The sponsor shall ensure the supply of investigational product for the clinical trial, manufactured, packed and labelled in conformity with respective normative deeds.

31.

In order to obtain the favourable opinion of an Ethics Committee, the sponsor or the person authorised by the sponsor shall submit the following documents to the Ethics Committee:

31.1.

application for the clinical trial signed by the sponsor (hereinafter: "application");

31.2.

protocol *and* amendments to the protocol, if any, in Latvian signed by the sponsor and the investigator (for foreign applicants *the referred documents shall be submitted in compliance with the requirements stipulated by Language Law*);

31.3.

trial subject's informed consent form laid down by the sponsor in Latvian, and also in other languages if required;

31.4.

other written information regarding the specific clinical trial to be provided to the trial subjects, in Latvian, and also in other languages if required;

31.5.

description of the trial subjects involvement activities in Latvian, *(for foreign applicants, the referred document shall be submitted in compliance with the requirements stipulated by Language Law)*;

31.6.

compilation of data from previous investigational product studies (hereinafter: "Investigator's Brochure") in Latvian, *(for foreign applicants, the referred document shall be submitted in compliance with the requirements stipulated by Language Law)*;

31.7.

Descriptions of experience and qualification of investigators and other persons involved in the clinical trial (selected and supervised by the investigator at the trial site (hereinafter: "subinvestigator"));

31.8.

documents regarding compensation for the trial subject for participation in the clinical trial, if provided, as well as insurance conditions and a copy of the policy*, or a certificate confirming* insurance of the trial subject in the case of a possible injury related to the clinical trial;

31.9.

consent of the medical institution for performing the clinical trial;

31.10.

authorisation issued by the sponsor, if the clinical trial documents are submitted by a person authorised by the sponsor.

33.

The Ethics Committee shall provide an opinion in writing within 30 days of receipt of documents referred to in article 31 of these Regulations.

34.

If the Ethics Committee states during the examination of the application that the submitted documentation is incomplete or additional information on the planned clinical trial is required, the Ethics Committee has the right to require supplementary documents. The Ethics Committee shall provide a written opinion no later than within 30 days after receipt of all required documents.

43.

To ensure that the clinical trial is conducted in compliance with these Regulations, activities of every person involved in the clinical trial shall be subjected to adequate quality control *and surveillance*:

43.4.

surveillance performed by the State Agency of Medicines in terms of its reference.

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

Gene donor shall receive:

- Information about aims and content of the Genome project;
- Information about taking of tissue sample, questionnaire, medical records;

Information about potential informational risks;

- Information about right to withdraw his or her consent, right to apply for the destruction of tissue samples or data which enables decoding;
- Information about the fact, that there will be no personal financial benefits for gene donors;Information about data protection system.

A written informed consent of the gene donor shall be prepared in two copies and signed by the gene donor and main processor. One copy shall be stored in State Genome Register; other copy is given to gene donor.

Main Processor shall give each tissue sample, DNA description, health description and genealogy a unique code. The code shall be indicated on the written informed consent of the gene donor. Main Processor shall appoint specific persons, who perform coding, and who issue coded tissue samples, DNA descriptions or health descriptions. The State Data Inspection shall approve the method of generating the codes.

The main processor shall deliver the written consent together with the code indicated thereon to the State Genome Register and it shall be the only possible key for decoding. The State Genome Register shall appoint the specific persons who perform decoding and have access to written consents of gene donors.

4. Research involving Human Biological Material (blood, organs, tissues, cells, DNA)

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.

Council of Ministers authorizes the Main Processor of the Genome Database. The Main Processor organise the taking of tissue samples, preparation of health descriptions and genealogies, code, store and destroy tissue samples, code, store, destroy and issue health descriptions and genealogies, perform genetic research, and collect, store, destroy and issue genetic data.

The Main Processor shall store coded tissue samples, DNA descriptions and health descriptions within the territory of Republic of Latvia. The Central Medical Ethics Committee may, grant permission for limited number of tissue samples to be stored abroad, if appropriate research methods are not possible in Latvia.

Supervision over the collection, coding and decoding, and processing of tissue samples, descriptions of DNA, health descriptions and genealogical data shall be exercised by the State Data Inspection. The Central Medical Ethics Committee shall supervise over the ethical issues during creation of the Genome Database and processing of the data according to generally recognised ethical rules and international conventions.

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)
Regulations of Cabinet of Ministers on Kidney Transplantation

A living person may, under certain conditions, consent to the removal of an organ or tissue for the purpose of implantation into another person; Live organ donation is currently confined primarily to kidneys. The transplantation of organs removed from a living donor takes place generally between persons having a close personal relationship

Organs or tissues may be removed from a deceased person and implanted into another person. Organs removed from deceased persons should only be allocated to patients registered on an official waiting list
Doctors following an agreed procedure confirm the death and only this form of death certification can permit the transplantation to go ahead. The retrieval team must satisfy themselves that the required procedure has been completed before any retrieval operation is started.

The medical team, which certifies death, should not be the same one that is involved in any stage of the transplant process.
A person who is undergoing a procedure for his/her own medical benefit may consent to any removed organ or tissue being implanted into another person.

If a person has made known their wishes for giving or denying consent during their lifetime, these wishes should be respected after his/her death. If there is an official facility for recording these wishes and a person has registered consent to donation, such consent should prevail: removal should go ahead if it is possible. By the same token, it may not proceed if the person is known to have objected. Nonetheless, consultation of an official register of last wishes is valid only in respect of the persons entered in it.

The human body and its parts must not, as such, give rise to financial gain or comparable advantage.

Reproductive organs and tissues (comprising ova, sperm and their precursors) are excluded from the scope of the regulations because organ and tissue transplantation is deemed to have different implications from those of medically assisted procreation and therefore should not be governed by the same rules.

Transplantation of embryonic and foetal organs and tissue, including embryonic stem cells are also excluded from the scope of this regulations.

The person from whom the material is removed is generally designated by the word donor and the person into whom the material is implanted by the word recipient. Furthermore tissues such as bone may be processed and the resulting products implanted into more than one recipient. Similarly, cells may be cultured to supply more than one recipient.

The safeguards in the Regulations apply to all possible steps in the transplant process and to all possible recipients.

The competence of a doctor or other health care worker to take part in a transplant procedure is determined in the Act.

Regulations require that organ and tissue implantation is only performed in accordance with a clear and specific medical indication for the recipient and not for any other reason such as a perceived social benefit. The recipient must have a defined medical problem, which should be improved by a successful transplant before a transplant can be performed. The potential benefit of the procedure to the recipient must outweigh any risk. At all times, a decision to transplant must be taken only in the best interests of the patient.

The recipient shall be informed beforehand of the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention. When the recipient is too ill to be able to give informed consent, in particular in emergency cases, the information shall also be given to the person or body providing the authorisation to the implantation.

Regulation of Ministry of Welfare of Latvia on Blood Safety **No. 260, September 20, 1995**

These regulations cover blood and the products derived from blood for use in transfusion medicine, preparation, use and quality assurance of blood components

5.Research involving Human Embryos and Embryonic Stem Cells

There is not any regulations which defined embryo in Latvia.

Law on Reproductive and Sexual Health (approved 31.01.2002, in force on 01.07.2002)

Regulation of Ministry of Welfare of Latvia on Human Medical Assisted Reproduction **(No 173/1999)**

- Creation of human embryos for research is prohibited;
- Cloning of a human being is prohibited;
- Research on embryos in vitro is allowed under Regulation of Ministry of Welfare, which now is prepared.

6. Personal Data

General law on data protection (***Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data; Personal Data Protection Law***), which applies to the processing of all types of personal data. Personal Data Protection Law implements the Directive 95/46/EC into the national legislation;

In accordance with the Article 2 of Personal Data Protection Law personal data is any information related to an identified or identifiable natural person. In principle it is no matter who can identify the data subject. Data could be treated as not identifiable and accordingly not as personal data only in case of they contain information that can not reasonably be used by anyone to identify individuals who donated them or to whom they relate. Personal Data Protection Law does not give direct answer to the question about its extension to the dead. However in the practice it is accepted to consider that in separate cases Personal Data Protection Law covers proceeding with dead data (for instance, genetic research or operation with the health records).

National legislation foreknows some exceptions concerning data subject's rights with design to protect the public safety or patient's interests in case of medical intervention.

In accordance with the Law On Medical Treatment only medical practitioners shall provide patient information related to his/her health. According to the Article 41 of this law doctor may provide incomplete information to the patient regarding the diagnosis and prognosis of the disease if he or she considers that such information may cause deterioration of the state of health of the patient.

Law on Medical Treatment

50.

(1**)** Information regarding the medical treatment of a patient, the diagnosis and prognosis of a disease (hereinafter – information regarding a patient), as well as information obtained by medical practitioners during the medical treatment process regarding the private life of a patient and his or her closest relatives, shall be confidential.

(2) Information regarding a patient may be provided to:

- other medical practitioners for the purpose of achieving the objectives of the medical treatment;

- the Medical Commission for Expert-Examination of Health and Working Ability(MCEEHWA); and

- the Quality Control Inspection for Expert-Examination in Medical Care and Ability to Work.

(3**)** Information regarding a patient shall be provided to a court, the Office of the Prosecutor, the police, the State Centre for the Protection of the Rights of the Child (inspectors), an Orphan's court (a parish court), as well as to investigative institutions only at the written request of such institutions if there is a permission signed by the head of the medical treatment institution.

(4) Information regarding a patient may be used in scientific research if the anonymity of the patient is guaranteed or his or her consent has been received.

(5) State military service administrations of the Ministry of Defence are entitled to request from medical treatment institutions.

Law on Data Protection

7.

Personal data processing is permitted only if not prescribed otherwise by law, and at least one of the following conditions exist:

1) the data subject has given his or her consent;

2) the personal data processing results from contractual obligations of the data subject;

3) the data processing is necessary to a system controller for the performance of his or her lawful obligations;

4) the data processing is necessary to protect vitally important interests of the data subject, including life and health;

5) the data processing is necessary in order to ensure that the public interest is complied with, or to fulfil functions of public authority for whose performance the personal data have been transferred to a system controller or transmitted to a third person; and

6) the data processing is necessary in order to, complying with the fundamental human rights and freedoms of the data subject, exercise lawful interests of the system controller or of such third person as the personal data have been disclosed to.

11.

The processing of sensitive personal data is prohibited, except in cases where:

1) the data subject has given his or her written consent for the processing of his or her sensitive personal data;

2) special processing of personal data, without requesting the consent of the data subject, is provided for by regulatory enactments which regulate legal relations regarding employment, and such regulatory enactments guarantee the protection of personal data;

3) personal data processing is necessary to protect the life and health of the data subject or another person, and the data subject is not legally or physically able to express his or her consent;

4) personal data processing is necessary to achieve the lawful, non-commercial objectives of public organisations and their associations, if such data processing is only related to the members of these organisations or their associations and the personal data are not transferred to third parties;

5) personal data processing is necessary for the purposes of medical treatment, is carried out by a medical practitioner or a medical treatment institution and an adequate level of protection of personal data is ensured; or

6) the processing concerns such personal data as necessary for the protection of lawful rights and interests of natural or legal persons in court proceedings.

16.

A data subject has the right to request that his or her personal data be supplemented or rectified, as well as that their processing be suspended or that the data be destroyed if the personal data are incomplete, outdated, false, unlawfully obtained or are no longer necessary for the purposes for which they were collected. If the data subject is able to substantiate that the personal data included in the personal data processing system are incomplete, outdated, false, unlawfully obtained or no longer necessary for the purposes for which they were collected, the system controller has an obligation to rectify this inaccuracy or violation without delay and notify third parties who have previously received the processed data of such.

29.

The protection of personal data shall be carried out by the State Data Inspection which shall be subject to the supervision of the Ministry of Justice. The State Data Inspection shall be managed by a director who shall be appointed and released from his or her position by the Cabinet pursuant to the recommendation of the Minister for Justice.

There are some specific requirements for prior checking concerning medical research. Human Genome Research Law regulates the usage of identification numbers in genetic research. In order to ensure the highest standard of data protection, Main Processor shall give each tissue sample, DNA description, health description and genealogy a unique code immediately after receipt of these data in the Genome Database. Main Processor shall replace with a code all data, which enables the reverse identification of the gene donor, including the name, personal code and residence. The code shall be indicated on the written informed consent of the gene donor. Main Processor shall appoint specific persons, who perform coding, and who issue coded tissue samples, DNA descriptions or health descriptions. The State Data Inspection shall approve the method of generating the codes.

7. Genetic information

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

Council of Ministers authorizes the Main Processor of the Genome Database. The Main Processor organise the taking of tissue samples, preparation of health descriptions and genealogies, code, store and destroy tissue samples, code, store, destroy and issue health descriptions and genealogies, perform genetic research, and collect, store, destroy and issue genetic data. The Main Processor has the right to delegate the rights of processing, except for coding and decoding, to an authorised processor. The Main Processor shall store coded tissue samples, DNA descriptions and health descriptions within the territory of Republic of Latvia.

The State Genome Register under the supervision of the Ministry of Welfare shall be founded to create the database of personal data of gene donors.
The Central Medical Ethics Committee may, grant permission for limited number of tissue samples to be stored abroad, if appropriate research methods are not possible in Latvia. The Central Medical Ethics Committee shall supervise over the ethical issues during creation of the Genome Database and processing of the data according to generally recognised ethical rules and international conventions.

Supervision over the collection, coding and decoding, and processing of tissue samples, descriptions of DNA, health descriptions and genealogical data shall be exercised by the State Data Inspection.

Gene donors have the right to access their data stored in the Genome database and the right to genetic counselling. Gene donors have the right to submit additional information on themselves to the Main Processor, as well as the right to prohibit the supplementation, renewal and verification of descriptions of their state of health stored in the Genome Database. Gene donor has the right at any moment to withdraw his consent to be a gene donor for the Latvian Genome Database.

8. Research involving Animals

Ethics Committee on Laboratory Animal Use in Biomedical Research

Ethics Committee on Laboratory Animal Use in Biomedical Research acts in the status of the Committee of the Latvian Council of Science and in accordance to these Regulations. Its activities touch all the aspects connected with the use of laboratory animals in biomedical and veterinary medical investigations, including laboratory animal obtaining sources, laboratory animal breeding, transportation, housing, use in experiments. The task of the Ethical Committee is to look at from an ethical point of view, all new scientific projects which plan the use of laboratory animals, and which have applied for possible financing to the Latvian Council of Science, or any other expert committee.

Goals and fields of activities:

1. To assist the certified and competent specialists, as well as all the others involved in the breeding and use of laboratory animals, to implement in their work the recommendations, directives and regulations of the European Convention of 1986 “Protection of vertebrate animals used for experimental and other scientific purposes”:
- to co-operate with corresponding laboratory animal breeding facilities and research institutions in any field connected with laboratory animals;
- to give recommendations and consultations to the researchers, who apply for the financing to the Latvian Council of Science, or any other expert committee and whose research projects plan the use of laboratory animals;

2. To ensure that the scientific projects planning the use of laboratory animals:
- limit as much as possible the amount of used laboratory animals and their sufferings, as well as unnecessary use of animals or their organs, on the basis of the high quality of the scientific experiments as well as laboratory animals;
- use laboratory animals economically and in a humane way;
- promote development and use of alternative methods;
- use thoroughly elaborated methods in the experiments with laboratory animals, including appropriate analgesia, anaesthesia and euthanasia, providing the implementation of the improvements in routine practice.

3. To participate actively in the development of the legislation concerning the protection of laboratory animals used in biomedical and veterinary medical research.

4. To optimise the welfare conditions of laboratory animals:

- in co-operation with the State Veterinary Department to develop the regulations on the inspections of laboratory animal breeding facilities and the research laboratories, where the laboratory animals are used for the investigations, in order to control routine conditions and improvements of the environment;
- to supply the scientific community with information concerning the current situation in laboratory animal science in order to give an opportunity to the researchers to evaluate the level of welfare of laboratory animals , which they use in the experiments;
- to follow the regular organisation of training and practical workshops for obtaining basic competence to work with laboratory animals.

5. To popularise knowledge about the welfare of laboratory animals:
- to ensure that every researcher, who uses laboratory animals either directly or indirectly, is informed about the problems of laboratory animal welfare;
- to assist in the popularisation and understanding of knowledge about laboratory animals, organising constructive discussions on ethical problems;
- to ensure that every researcher, who works with laboratory animals, is able to express his/her concern, thoughts or ideas about this work.

There are 13-15 members in the Ethical Committee:

- representatives of the Latvian Council of Science;
- laboratory animal breeders;
- representatives of the State Veterinary Department;
- representatives of the Ministry of Welfare;
- laboratory animal users from different research institutions;
- representatives of the environment protection organisations;
- representatives of the Baltic Laboratory Animal Science Association.

Latvian Council of Science accepts the list of the members of the Ethical Committee and appoints the Chairperson.

***Law on Animal Protection*, (accepted January 1, 2000, amendments on 27.12.2002 Regulation of Cabinet of Ministers Nr. 576)**

Cruel treatment of animals is prohibited, that is:

1) the killing of an animal, except in the cases provided for in this Law;
2) the mutilating, tormenting and torturing of an animal;
3) leaving an animal without care;
4) leaving an animal in a helpless situation;
5) annoying and baiting an animal, except in the cases when it is necessary for the training of a work animal;
6) the organisation of animal fights, the involvement of animals in such fights and support of such fights;
7) the use of animals for religious rituals, lotteries and giving animals as gifts at public events except for farm exhibitions;
8) the use of an animal as a target for training in shooting or in competitions;
9) the use of animals for the training of animals of other species, except for the training of hunting dogs;
10) the use of animals, making them exceed their natural capabilities;
11) the showing of animals in travelling menageries;
12) the offering and use of a female animal for the sexual satisfaction of a male animal without the intent of obtaining offspring;
13) the carrying out of other such actions which cause or may cause mutilation or death, or create suffering for an animal, except in cases when such actions have been carried out for treatment, experimental or scientific purposes or in cases when the life or health of a human being is being threatened.

The Animal Protection Ethics Council shall be a consultative authority, which shall educate the general public and give recommendations to State institutions in the sphere of animal protection. It is comprised of representatives of the State, scientific institutions and public organisations.

24.

(1) Specially raised animals (laboratory animals), or where the permission of owners is obtained, other animals, may be used for experimental and scientific purposes.

(2) Wild animals may be used for experimental and scientific purposes if it is not possible to achieve the objective by other means.

(3) The number of animals to be used for experimental and scientific purposes shall be reduced by improving experimental methods and, if possible, experiments with animals shall be replaced by alternative methods of research.

25.

After evaluation of an opinion by the Animal Protection Ethics Council, the State Veterinary Service shall issue a permit for the use of animals for experimental and scientific research.

26.

In acquiring professional education in biological, medical and veterinary medicine it is permitted to use laboratory animals and other animals during the study process, if it is not possible to achieve the objective by other means

32.

(1) Collections of wild animals (zoological gardens, animal parks, aquariums, terrariums and others) may be established for scientific, educational and species-saving purposes.

(2) Wild animal collections may be established only with a permit from the Ministry of Environmental Protection and Regional Development and a permit from the State Veterinary Service.

36.

(1) An animal shall be transported by an appropriate means of transport, ensuring conditions not harmful to its health.

9. GMOs

***Regulation of Cabinet of Ministers for the Use and Distribution of GMO* (Regulation No 323/2000)**

(Regulation provides requirements for use, deliberate release into environment and placing on the market of GMOs)

1. These Regulations provide the general requirements for the contained use, deliberate release into the environment and placing on the market of genetically modified organisms (hereafter - modified organisms) or their components, in order to prevent harm to human health, animals, biological diversity, property or the environment which may be caused by the use and distribution of modified organisms.

Regulation of Cabinet of Ministers No 46 on Labelling of Foodstuffs
(February 12, 2000) with the Amendment (August 14, 2001)

Compulsory indication on the labelling of certain foodstuffs produced from GMOs; Labelling of foodstuffs containing additives and flavourings that have been genetically modified.

Regulation No 322: Monitoring Council of GMOs, October 15, 2000

Establishment and functions of the Monitoring Council of GMOs – co-ordinating and consultative institution.

LITHUANIA

LITHUANIAN BIOETHICS COMMITTEE

www.sam.lt/bioetika

THE NETHERLANDS

CENTRAL COMMITTEE ON RESEARCH INVOLVING HUMAN SUBJECTS (CCMO)

www.ccmo.nl

List of opinions

- interpretation Declaration of Helsinki, articles 29 and 30
- publication policy
- behavioural research and the Medical Research Involving Human Subjects Act
- non-therapeutical reserach with minors and incapacitated subjects
- organisation and structure of ethics committees
- role of directors hospitals in multicenter research

Text for delegates:
- most of the above notes are included in the Manual for the review of medical research involving human subjects. The manual is available via de CCMO-website see http://www.ccmo.nl/item/pub/IPpub.cgi?ipP=frameset_eng&ipP2=vragen_eng

THE NETHERLANDS

THE HEALTH COUNCIL

www.gr.nl/index.php?phpLang=en

List of opinions

28 August 2003	Pathogen reduction in blood products
26 August 2003	Health and the environment: monitoring options
25 August 2003	Tetanus prophylaxis in injuries
18 August 2003	Pneumococcal vaccine in elderly adults and risk groups
11 August 2003	Vaccination of children against hepatitis B.
29 July 2003	Controlling Legionnaire's Disease
19 June 2003	New Options for Organ Donation
19 June 2003	Health Council of the Netherlands; Reports 2002
10 June 2003	Foods and dietary supplements with health claims
16 May 2003	2003 Ethics and health monitoring report - Health Council of the Netherlands (Gezondheidsraad)
28 April 2003	Overweight and obesity
15 April 2003	Strong inorganic acid mists containing sulphuric acid; Evaluation of the carcinogenicity and genotoxicity.
20 March 2003	Benchmark dose method: health-based recommended exposure limits in new perspective
3 March 2003	Health-based Reassessment of Administrative Occupational Exposure Limits; Contents7
3 March 2003	Health-based Reassessment of Administrative Occupational Exposure Limits; *n*-Butylamine
3 March 2003	Health-based Reassessment of Administrative Occupational Exposure Limit'; Calcium carbonate
3 March 2003	Health-based Reassessment of Administrative Occupational Exposure Limits; Dibismuth tritelluride
3 March 2003	Health-based Reassessment of Administrative Occupational Exposure Limits; Oxalonitrile
3 March 2003	Health-based Reassessment of Administrative Occupational Exposure Limits; Paraffin wax (fume)
3 March 2003	Health-based Reassessment of Administrative Occupational Exposure Limits; 2,4,5-T
3 March 2003	Health-based Reassessment of Administrative Occupational Exposure Limits; 2,4,5-T/PART2
3 March 2003	Health-based Reassessment of Administrative Occupational Exposure Limits; Valeraldehyde
27 February 2003	Public awareness about genetics
18 February 2003	Nickel and its compounds
18 February 2003	ß-Chloroprene
18 February 2003	Metallic lead
18 February 2003	Tetrachloroethylene (PER)
13 February 2003	Fytosterolen (3) / Phytosterols (3)
12 February 2003	Dietary Reference Intakes: vitamin B_6, folic acid and vitamin B_{12}.
4 February 2003	Health effects of exposure to radiofrequency electromagnetic fields: Recommendations for research
3 February 2003	Contours of the Basic Health Benefit Package
27 January 2003	Formaldehyde; Health-based recommended occupational exposure limit
14 January 2003	Tetrachloroethylene (PER)

	ISBN-number	name opinion	date
2001/24E	90-5549-415-1	Toxicity testing: a more efficient approach	20-11-2001
2001/25E	90-5549-416-X	Microbial risks of recreational waters	27-11-2001
2001/27E	90-5549-414-3	Universal vaccination against meningococcal serogroup C and pneumococcal disease	31-12-2001
2002/01E	90-5549-411-9	Mobile telephones	28-01-2002
2002/03E	90-5549-420-8	The benefit of population screening for breast cancer wit rnammography	07-03-2002
2002/04E	90-5549-453-4	Dementia	12-03-2002
2002/07E	90-5549-432-1	Bloodproducts and Parvovirus B19	30-05-2002
2002/09E	90-5549-443-7	Stem cells for tissue repair	27-06-2002
		Research on therapy using somatic and embryonic stem cells	
2002/17E	90-5549-487-9	Recommended exposure limits for polychlorinated biphenyls in soils and sediments, for the protection of ecosystems	16-12-2002
2002/04E	90-5549-454-2	The future of ourselves	08-10-2002

POLAND

DRAFT PROGRAMME OF ELABORATION OF THE AMENDMENT OF POLISH CODE OF MEDICAL ETHICS

www.nil.org.pl

6 September 2002 – Draft program of elaboration of the amendment of polish Code of Medical Ethics.

21 February 2003 – first version of the amendment.

27 June 2003 – the second version of the amendment.

6 August 2003 – the third version of the amendment which will be presented during the General Assembly of the Polish Medical Board on 19/20 September 2003.

The final decision about the text will be taken by the Assembly (Proposed new articles in the Code contain ethical options about cloning, medically assisted procreation, relationships of doctors with medical industry, human genome protection, prenatal diagnostic, biomedical experiments, and some other less important problems. The amendment is dealing with ethical problems connected with the Convention of Human Rights and Biomedicine.).

The Committee also prepared some draft opinions for the Polish authorities about the projects of additional protocols to the Convention.

- 3 February 2003 Opinion about Patient Empowerment: Legal, ethical and social aspects of patient emp.

- Draft Comment of Draft on sick professional physicians (CPME 2002/093).

PORTUGAL

www.cnecv.gov.pt

RUSSIAN FEDERATION

RUSSIAN ETHICS COMMITTEE

During last few years Russia has been paying much attention to ethic problems of human cloning and mainly to the issues related to “therapeutic cloning” – transplantation of common stems in order to cure people.

The Ethic Committee of Russia gives strong support to many European countries in the question of vetoing human cloning. At the same time, taking into account the wide spread of moronic diseases and ineffectiveness of its curing we consider it important to encourage and support research projects aiming at gaining common stems out of unused gametes after extracorporal insemination, as well as out of marrow, skin and other somatic sources. Despite contradicting research findings The Committee consider that usage of common stems in infarction and cerebrum disease curing is possible, though it should be strictly supervised. We should pay our attention to rapidly developing commercialization of cell therapy and the danger of criminalization of this sphere of medicine and biology (selling of gametes, money stimulations of late abortions, selling of gametes, etc.).

SUISSE

COMMISSION NATIONALE D'ETHIQUE POUR LA MEDICINE HUMAINE (CNE)

Liste des avis

Prise de position de la CNE sur le régime du délai, le 2 mai 2002

La recherche sur les cellules souches embryonnaires, juin 2002 (voir brochure séparée)

Aspects éthiques de la loi sur la recherche embryonnaires, décembre 2002

Prise de position sur le clonage reproductif de l'être humain, le 16 janvier 2003

UKRAINE

UKRAINIAN NATIONAL BIOETHICS COMMISSION

List of opinions

Main opinion which was prepared after November 2001 was developed proposal of the First National Congress of Bioethics:

«OBLIGATION FOR ALL MEDICAL AND BIOLOGICAL DISSERTATION PROJECTS TO PRESENT FOR THE SCIENTIFIC COUNCIL THE BIOETHICAL REVIEW OF THIS INVESTIGATIONS»

UNITED KINGDOM

HUMAN GENETICS COMMISSION

www.hgc.gov.uk

List of opinions

1. "Inside Information - Balancing interests in the use of personal genetic data" May 2002.

2. "Genes Direct - Ensuring the effective oversight of genetic tests supplied directly to the public" March 2003.

All our publications can be downloaded from the internet at: www.hgc.gsi.gov.uk
Copies can be ordered from,: Prolog, PO Box 777, London SE1 6XH, Fax: 01623 724524, email: doh@prolog.uk.com.

Opinions attached:

3. Memorandum to the House of Commons Science and Technology Committee on the Medical Research Council/Wellcome Trust/Department of Health UK Biobank

4. Response to "Human Bodies, Human Choices" consultation report on the law on human organs and tissues in England and Wale

****

Memorandum to the House of Commons Science and Technology Committee on the Medical Research Council/Wellcome Trust/Department of Health UK Biobank study

This statement is available in portable document format.

1. The Human Genetics Commission welcomes the opportunity to assist the Science and Technology Committee's consideration of the setting up of the Biobank genetic research database. HGC has considered some of the issues raised by this major research programme as part of our consideration of the protection of personal genetic information. In May 2002 we published a report entitled "Inside Information - balancing interests in the use of personal genetic data"

2. In preparing our report we took account of a large number of very detailed contributions from a wide range of individuals and organisations. These included the Medical Research Council (MRC) and the Wellcome Trust who were considering the funding for the Biobank study. The decision to fund the study was taken in late April 2002 when our report was in the final stages of preparation. We accepted that the Biobank Funders (i.e. representatives from the MRC, Wellcome Trust and Department of Health) would not be able to contribute to detailed consideration of some of the Biobank issues until funding was secured. Therefore, our report was necessarily rather general and was intended to provide a basis for more detailed consideration by the Funders in collaboration with HGC and others.

Summary of HGC's position

3. Before considering the detailed consideration of the proposals for UK Biobank, the Commission would like to formally record that we believe that this is an extremely important and valuable research project if the benefits of advances in genomics are to converted into a more detailed understanding of complex diseases. We believe that this is possibly a unique opportunity and that it must succeed. In particular, we consider that the UK Biobank is such a long-term project that there should be sufficient investment in its establishment to allow as-yet unasked questions to be answered 5, 10 or 20 years hence.

4. We have considered some of the difficult detailed aspects of the protocol and governance arrangements. The UK Biobank has joint funding from the MRC, Wellcome Trust and Department of Health which was approved on the basis of carefully developed draft protocols for scientific and technical organisation, as well as provisional proposals for consent and ethical oversight arrangements.

5. Following the funding decision all aspects of the protocol need to be finalised, but this can only be achieved once the complex organisation is more established. Arrangements are in progress to put in place the agreed management structures which include Appointment of the Chief Executive;

Selection of the 'hub and spokes' centres which will then work together to develop more detailed final proposals in all these areas.

6. The development of final protocols is strongly dependent also on the appointment of:

the scientific management board (SMB) which will co-ordinate the development of the scientific and technical aspects of the final protocol

an independent oversight body (IOB) which will play a key role in setting the ethical and societal guidelines for the project.

7. We note that in some cases there are "chicken and egg" questions that cannot be addressed until the structures of the Biobank are established and staff appointed. However, we believe that it is important to consider all possible aspects, even if they cannot easily be resolved at this stage.

8. We remain extremely interested in the detailed consideration of these important elements and remain willing to consider and comment on any proposals. We also may need to reserve the right to provide advice separately to Health and Science Ministers if we feel that there are any important aspects that require more formal consideration by HGC.

9. Finally, we remain concerned about the importance of ensuring confidentiality of material and data in the UK Biobank. We believe that there should be a clear Ministerial statement to confirm that there will be no police access to the database. However, we also recognise that it will not be possible to ensure total confidentiality and therefore we believe that there is a much broader need to prevent research volunteers suffering unfair discrimination in the unlikely event that identifiable and sensitive genetic information is released from the UK Biobank.

HGC's role in setting up the UK Biobank

10. The early work on the establishment of a large population biomedical cohort began shortly before HGC was established in December 1999. The issues that were raised by the proposed study, and by plans in Iceland and other countries, was behind the decision by HGC to consider the protection of personal genetic information as its first main work item. We also collaborated with the House of Lords Science and Technology Committee in the preparation of their very thorough report on Human Genetic Databases which was published in April 2001.

11. The HGC Secretariat was involved in the initial scoping work by the Wellcome Trust and MRC. Individual members of HGC have also been involved in the preparation of the Biobank protocol and in the consideration of the practical (for example, in primary care) and ethical issues that it raised. This culminated in a major workshop on ethical issues in April 2002.

12. Since mid-2001 the Biobank Funders have held a series of informal meetings with the HGC Working Group or Business Committees to discuss areas of common interest. However, HGC has been slightly frustrated by our inability to consider some specific aspects of Biobank in public HGC meetings until such time as a formal funding decision was made. Whilst we respect the difficulty that Funding bodies may have had discussing the details during these early stages, this has hampered our detailed examination of some of the issues.

13. That aside, we have considered the available information on UK Biobank in the preparation of the HGC report "Inside Information; balancing interests in the use of personal genetic data" which was published in May 2002. A summary of the relevant general aspects of the report is at Annex A to this Memorandum.

14. Since the funding decision in April 2002 we have been able to have more detailed discussions with the Funders. On 19 November 2002 we held an information-gathering meeting at which representatives from the MRC and Wellcome Trust outlined progress on the scientific protocol and the governance arrangements. This memorandum reflects the points raised in that meeting and the discussion by the Commission on 20 November 2002. Details of these can be found on the HGC website (www.hgc.gov.uk)

Summary of points discussed on 19 November

15. The scientific validity of the study design for recruitment strategies is still being debated. This will need to be finalised, along with sampling techniques, sample preparation and storage, and genotyping and phenotyping procedures. This will be a task for the SMB in conjunction with the hub and spoke scientists, whose appointment is still pending. We understand that these will not be in place until mid-2003.

16. Two points in particular are worth highlighting. We heard from Dr Andrew Lyall about the importance of proteomics (the study of the proteins produced by living organisms) as a means of discovering the link between genes and environment and of providing targets for drugs and antibody therapies. There are currently no plans to take or store samples in Biobank in a way that would allow later proteomic analysis. This is partly for reasons of economy - each sample would require additional treatment to preserve the proteins. The arguments for considering proteomics are similar to those for the establishment of cell lines, namely that future researchers will benefit from a far-sighted initial investment in establishing the UK Biobank.

17. We also heard concerns from Professor Alan Wright about the possibility that the methods used to identify links between single genes and disease might not work for diseases in which a large number of genes had a minor effect. He considers that this possibility means that the Biobank should be more broad-based to allow its use to address other scientific issues, not least gene discovery. This would include, among other things, ensuring that suitably sized subgroup is included with available siblings, and where possible their parents, within Biobank. Finally, the lifestyle information gathered by Biobank could potentially be very important for wider health and social science research. In setting up the Biobank the Funders should talk to a wider range of clinicians (such as gerontologists and social geriatricians) and academic researchers who are concerned with issues in later life, including retirement, family support and kin relationships.

18. We are concerned to ensure that the Funders consult widely with other groups and companies to establish whether simple changes at the outset could dramatically improve the value of Biobank for a wide range of research. If these changes require additional funding or infrastructural changes, then the Government, biomedical charities and industry should be approached for additional funding.

19. Complex technology development is required for data storage and retrieval. There is currently no way to access NHS patient records, a key component of the UK Biobank programme. Even if this can be developed soon, the UK Biobank will need to make allowances for routine direct monitoring and audit of GP records. We were also told by an expert information technology developer, that achieving more or less complete data security may be impossible using existing encryption techniques. He suggested that the situation could be improved, though not made completely secure, through use of inference control for people accessing the databases. We cover this in more detail below.

HGC's recommendations large-scale genetic databases and UK Biobank

20. The general principles that were established in the preparation of the Inside Information report (Annex A) were important in shaping the Commission's conclusions and recommendations on various aspects of the use of personal genetic information in research. The report covered in some detail the various types of genetic research and the continuum in some cases between clinical care, research and commercialisation. The report sought to make clear that research might have direct or indirect benefits to the individual participants. Some research may only be predictive at the population level and the benefits may be distant or uncertain, however, all such 'blue skies' research is vital. Therefore the report concluded that as many people as possible should feel able to participate in genetic research, confident of the security and confidentiality and that ethical standards will be upheld.

21. Our conclusions apply to all forms of genetic research. However, there are some aspects of large research databases that were felt to require more detailed consideration. Our report was drafted in the light of initial discussions on the Biobank study, on similar databases in other countries - notably Iceland and Estonia - and also on previous UK experience, particularly of the databases considered by the House of Lords Science and Technology Committee.

22. There were felt to be three main additional considerations:

Consent and confidentiality

Ownership and benefits

Oversight and compliance

Consent and confidentiality

23. Our report also considered in some detail the arrangements for seeking consent. In particular, the HGC debated the possibility of seeking blanket consent to research studies to avoid potentially intrusive approaches for fresh consent at a later stage. The report noted the practical need for broad consent in the face of a fast-moving technology. It concluded that it is acceptable to seek general consent in cases where there is to be irreversible or reversible anonymisation of data and samples. The report also concluded that best practice required that the consent should make clear the arrangements for subsequent withdrawal from a research study.

24. One central theme of our discussions on the scope of consent was that it should not deceive the participant about what might be done with their sample or information. This applies to some of the potentially controversial aspects of the UK Biobank, particularly data security and third party access and ownership or intellectual property. It was also considered important to draw attention to possibly more controversial research plans, for example the possibility of creating cell lines for more intensive biological analysis from some participants.

25. The organised collection of a large number of tissue samples and identifying information (including detailed information on lifestyle factors) as well as the ability to link information about genetic characteristics to information about past exposures or diet and to future health are crucial to the function of the UK Biobank. Such information is potentially of interest to other individuals, to commercial companies (outside of medical research) and to law enforcement bodies. We were concerned by the comments made by the Information Commissioner about the exclusions in the Data Protection Act (DPA) which may allow access to such information. There is considerable experience of large research studies, but the scale and duration of the planned Biobank may raise new considerations about ownership of the information and commercial access to samples and consequent intellectual property rights.

26. It was clear from our consultation and opinion surveys that the issue of confidentiality of the information, and access by commercial interests, was of major concern. The consultation revealed some disquiet over this matter, but the report stressed the important role of commercial sponsors. The report concluded that the question of commercial involvement needs to be clearly explained when seeking consent. In some cases it might be necessary to limit the degree of commercial involvement, for examples only to companies engaged in health-related research.

27. We have spent considerable time discussing the question of personal feedback of research results. However, there is a wider concern about the possible use of the access provisions of the DPA which may allow an individual to request access to their own data and even results of genotype analyses. Such requests may be from pure curiosity or they may be as the result of pressure from family members, employers or others. We are of the view that such disclosures should be discouraged, not least because there is a risk of impersonation being used to deceitfully gain access. We understand that the Biobank Funders have sought an opinion from leading Counsel and we would be very interested to consider the implications of that advice. We draw your attention to this potential uncertainty and the possible need for legislative clarification.

Confidentiality and data security

28. In our report we addressed the anonymisation of genetic information (i.e. interrupting the link between identifiable individuals and their genetic information). This may be an important factor in obtaining consent to a research study. We heard that in the light of “DNA fingerprinting” techniques it was never possible to truly anonymise genetic material. However, we concluded that methods were available to ensure that irreversible anonymisation was possible. We recommended that the Government funded research into the techniques of encryption to ensue data security. Ultimately, the report concluded that the procedures used to ensure anonymisation and confidentiality are carefully considered and explained to the research participants when seeking consent.

29. We were impressed by the points made by Dr Ross Anderson from Cambridge who felt that there was a risk that encryption could become a technical ‘comfort blanket’ that led to complacency about other aspects of data integrity. Dr Anderson commented on the importance of inference control that would prevent information being obtained by a series of overlapping data queries. The techniques are well established in other countries for handling health records and census returns. One important aspect of this is a cut-off so that any query result that gave a result on fewer than a specified number of individuals would not be allowed.

30. We feel that we should raise this matter with those responsible for establishing electronic NHS records and look for assurances that there will be effective mechanisms to prevent unauthorised disclosure. In particular, the operation of such systems needs to be properly monitored and effective action taken if there are breaches.

31. As well as planned access by outside agencies, there is also the more likely scenario of weak or ineffective procedures and systems by the various elements of the Biobank study. Our report therefore recommended that the operators of the Biobank (and other research databases) should be required to take rigorous steps to ensure that unauthorised access or disclosures are prevented. For example, there should be careful arrangements for vetting staff and for ensuring that maintenance of confidentiality should be a condition of employment. Any material breach of this should result in dismissal.

32. Because we concluded that complete confidentiality of databases is impossible to achieve, we wish to repeat our recommendation that misuse of Biobank data information should be made a punishable offence. We have recommended the creation of a criminal offence for the unauthorised or non-consensual testing or analysis of genetic material. We sincerely hope that this will be something that the Government will act upon, and we believe that this will be a further deterrent against the unauthorised disclosure of information.

33. Ultimately there will remain a remote possibility that identifiable information will be released from the UK Biobank and that this must be clearly explained when seeking consent. The safeguards to ensure confidentiality will need to be clearly spelt out, along with the possible nature and type of breaches of confidentiality.

34. However, it should be recognised that if information is released the research participant should not suffer harm in the sense of unfair discrimination by employers or insurance companies. We have noted the clear statement by the Association of British Insurers, the UK Forum for Genetics and Insurance and the British Society for Human Genetics that insurers will not consider results from research studies. We would also recommend similar assurances from some of the key employer's organisations. In the longer term we have clearly recommended to Government that there should be consideration of specific legislation to prevent unfair discrimination, and we await their response.

Access by police and law enforcement agencies

35. In our view UK Biobank will be so much larger and more organised than other research or clinical databases that it may be attractive as a source of police intelligence. It is feasible that the same genotyping methods (SNP profile) used on Biobank samples could be applied to a sample from a crime scene. The police might request (informally or via a warrant) that the SNP profile from the crime sample is checked against samples in the Biobank in order to see if there is a match. There would need to be a further step to de-encrypt the identifier to produce a name or other intelligence.

36. Our report recommended that genetic research databases established for health research should not be used for other purposes and that this should be put beyond doubt, by legislation if necessary. We are still awaiting a formal Government response to this and other recommendations. We have detected some concerns that there may be circumstances in which it would be in the best interests of society to give the police access to help to solve serious crimes. However, we must balance against this the potential impact on such an expensive and long-term research programme as the UK Biobank.

37. We continue to believe that this matter should be put beyond doubt well before volunteers are sought for UK Biobank. We accept that legislation may not be possible in a reasonable time frame and that there may be questions about how any legislation can cover all conceivable biomedical research databases. We feel that this is sufficiently important to merit a statement to Parliament by the Home Secretary or other senior Minister. This should clearly state that the police would never request access to the UK Biobank, or failing, that make clear the circumstances under which police access might be sought for particularly serious crimes. This information could then be given to individuals when seeking consent.

Ownership and benefit-sharing

38. Any large database such as Biobank must make provision for authorised access to data and samples by collaborating researchers. We have considered one aspect of this that seemed to raise concerns amongst some respondees. This is the question of access by commercial organisations, and the linked question of the ownership of the intellectual property rights that may accrue.

39. The example of the deCODE database in Iceland was raised by a number of respondees to our consultation and in the evidence presented to the House of Lords. The HGC felt that the question of who stood to benefit was complex. Biomedical research, and hence all of society, stands to benefit in the long term. However, much of the work will be done by commercial companies who stand to make profits from their investment in genetics research (which is bound to be more extensive than any one database). HGC acknowledges both the importance of commercial companies in biomedical research and also the moral concerns of individuals who make an altruistic contribution to research. It concluded that altruistic acts by individuals might be encouraged if companies using the data were prepared to reciprocate this community interest. It concluded that population genetic databases, established with and supported by public funding, contribute a national asset. Whilst acknowledging the need for commercial access and a reasonable period for commercial opportunities, the terms of access should be such that there is at least some benefit to public-domain biomedical knowledge.

40. We continued this discussion in the light of the detailed arrangements for the setting up of Biobank and of the latest position of the MRC, the Wellcome Trust and Department of Health for commercial access to the data. The concept of benefit sharing should be considered again, as this idea was attractive to several respondents surveyed for their views on donation of samples for analysis. There are obvious practical difficulties of any form of financial benefit-sharing where there is not readily identified link between access to Biobank and long-term financial returns.

41. We therefore consider that the benefit must be considered more generally as the sum of medical knowledge. We strongly support the proposed approach that commercial access should be granted on a non-exclusive basis. The experience of the publicly-funded Human Genome Project was noted and supported by HGC.

Future oversight of UK Biobank

42. All the above developments need to be in place before consent details can be addressed and together with other ethical issues the appropriate ethics committee can be approached to grant approval. The detailed ethical arrangements for research projects require consideration on a case-by-case basis. There is a recognised mechanism for considering many of these issues in the form of Research Ethics Committees (RECS). Our report recommended that the Government take steps to require all research on human non-anonymised genetic material is subject to review by an independent research ethics committee and is monitored for compliance through clearly specified arrangements. This is something that the Funders are aiming to do as soon as the detailed protocol and study has been finalised.

43. However, in projects of this nature it is not sufficient to rely on a single REC to establish a sound ethical framework. We noted that the initial plans for Biobank foresaw the need for an independent oversight body. In our report we concluded that the governance of large genetic research databases should allow for an independent body that is separate from the owners and users of the database. The composition and role of such bodies would vary, but it should provide for a mechanism to ensure that the long-term questions of access to samples and of wider benefits can be subjected to careful scrutiny.

44. We are also aware that in the case of Biobank such a body would have an important role as an independent body to hold the Biobank management to account and to maintain the necessary degree of independence from the three main Funders. We have recently heard from the Funders about the current thinking on such a body. In our view this body must command the respect of all stakeholders in the UK Biobank. We are extremely attracted to the idea that it should include individuals from different locations who have been recruited as participants into the UK Biobank. This might even include some form of elected representatives from amongst the study participants.

45. One important function of the oversight body will be to consider the wider ethical issues and the implications of any proposed nested studies working with subsets of data from UK Biobank. If these are considered in isolation, for example by an MREC, they may raise no particular concerns. However, such studies may potentially raise difficulties over feedback and re-consent. They may also contribute to a gradual "mission-creep" of the UK Biobank into potentially controversial areas of study that were not envisaged by participants.

We trust that the comments above are helpful to the Committee in considering this matter. We recognise that in places they are the product of only limited and initial consideration. If the Committee requires any additional information or clarification we will be happy to provide it. We also welcome any future conclusions and comments from the Committee that we may take into account in our future discussions of this important and necessary project.

Annex A

Inside Information - balancing interests in the use of personal genetic information

In November 2000 HGC published a discussion document called "Whose hands on your genes?" which set out a series of questions about the storage, protection and use of personal genetic information. The use of personal genetic information in research was covered in some detail. We sought views on the general approach to consent and ownership of donated material and on the establishment of large-scale genetic databases linked to health records. We also considered the wider implications, such as the use of research databases and findings by insurers, employers and by the police force.

The consultation finished in March 2001 and we received over 250 written responses, including 86 detailed responses from organisations and individuals. We sought additional information from organisations, from insurance companies (on genetics and insurance) and also from the recently established HGC Consultative Panel of people affected by a genetic disorder. The HGC Working Group spent a considerable amount of time considering this material and discussed their draft report a number of times at the plenary Commission. The first stage was to consider the general definition and scope and to consider how, if at all, genetic information differed from other private personal information. We then sought to draw up some general principles that should cover the personal genetic information. In the light of this preparatory work, the Commission then considered the detailed issues around clinical uses, research uses, insurance and employment and forensic uses.

HGC's Inside Information report was published in May 2002. In launching the report Baroness Kennedy QC stressed the importance of the concepts embodied in the title of the report. In particular, there is a careful balance to be struck between respecting the interests of individuals whilst at the same time enabling the use of personal information for the benefit of families, the wider community and society at large. The Commission was anxious to ensure that suitable safeguards were in place and monitored. However, such safeguards should not hinder important biomedical research with unworkable restrictions.

The general principles laid down by HGC are particularly relevant to the establishment, and proper oversight, of large research databases such Biobank. The main principle of "respect for persons" is based on widely accepted international norms and which it expressed in the following terms:

"Respect for persons affirms the equal value, dignity and moral rights of each individual. Each individual is entitled to lead a life in which genetic characteristics will not be the basis of unjust discrimination or unfair or inhuman treatment."

However, the report also considered that respect for the autonomy of individuals was not the only value to be taken into account. Individuals live in society, and the interests of others must be considered in the exercise of individual autonomy. We each owe certain duties as members and citizens. For example, although nobody should be compelled to participate in genetic research, the decision to participate or not should be reached in an awareness of the fact that participation may provide help to those suffering from disease.

The report highlighted circumstances in which society would seek to balance the demands of autonomy (for example confidentiality) with the interests of others. This was felt to be sufficiently important to be expressed in as the concept of genetic solidarity and altruism which can be summarised as follows:

We all share the same basic human genome, although there are individual variations which distinguish us from other people. Most of our genetic characteristics will be present in others. This sharing of our genetic constitution not only gives rise to opportunities to help others but it also highlights our common interest in the fruits of medically-based genetic research.

This concept should be taken into account at all stages of the ethical debate over personal genetic information but is not on a par with the principle of respect for persons. That is the overarching principle from which we believe a number of secondary principles may be derived. The report was confined to the aspects that are particularly relevant to genetics. These secondary principles are:

The principle of privacy
The principle of consent
The principle of confidentiality
The principle of non-discrimination.

Copies of the report are available at www.hgc.gov.uk/insideinformation

This page was last updated 28th February 2003

Response to "Human Bodies, Human Choices" consultation report on the law on human organs and tissues in England and Wales

This statement is available in portable document format.

1. The Human Genetics Commission has given attention to Human Bodies, Human Choices and would like to make a number of observations. The Commission believes that this review has been particularly timely and we hope that the work that we have recently undertaken on personal genetic information - which is acknowledged in the consultation report - will be of assistance to the Department of Health and the Welsh Assembly Government in its task of recommending legal reform in this area.

2. The Commission has recently made a number of recommendations to Ministers relating to personal genetic information which could possibly be acted upon in the context of this broader review of the law relating to human tissue. Indeed, the Commission believes that it would be a lost opportunity if legal reform relating to human tissue failed to address very specific issues surrounding the handling and use of human DNA.

3. We address below a number of points raised in the consultation report. Our response is arranged following the order of the sections in that report.

Section 3 - Present legal framework
4. The consultation report points out that the legislation on human tissue is ripe for review. As far as human genetic material (DNA) is concerned there is little specific legislation. There is a strong case for ensuring that future human tissue legislation includes at least some recognition of the particular problems associated with human genetic material. Most human tissue contains genetic material and interest in the uses of genetic information are increasing with advance in genetic knowledge.

5. Question 3A. We draw your attention to the current comprehensive consideration of human genetic information by the Australian Law Reform Commission and the National Health and Medical Research Council (available at www.alrc.gov.au)

6. Question 3B. We believe that it is important to acknowledge the cultural significance not only of the tissue itself but also of the information that the tissue contains. Any regime constructed to deal with human tissue should therefore take account of sensitivities associated with personal genetic information. In this respect we refer to the discussion of this issue in our report Inside Information (paragraphs 1.17-1.20). We concluded that

“The fact that genetic information is considered by many to belong to a particularly sensitive and private category of information may merit giving it enhanced status [in order to] address the sense of possession which many feel about their genetic information [and] the sense of violation of privacy if personal genetic information is wrongfully used.

Section 4 - Scope of the review
7. We note the contents of the draft Code of Practice on the Import and Export of Human Body Parts. For convenience we include here our comments on that document.

8. The import and export of human genetic information is an important feature of diagnosis and research into human genetic conditions. We consider that any Code of Practice should not inhibit this activity inappropriately. However, we question the exclusion of DNA from the scope of this Code (paragraph 4). The obtaining of human genetic material from overseas has raised certain ethical issues and is in some countries a matter of controversy. We think that there should be some ethical oversight of how imported human genetic material was obtained in the country of origin. We would recommend that consideration be given to this issue before the Code is finalised.

Section 5 - defining organs and tissue

9. Although we believe that future human tissue legislation should deal with certain specific genetic issues, we appreciate that some of the rules relating to human tissue itself will not be appropriate for human genetic material. In particular legislation must avoid placing inappropriate restrictions on laboratory work on human DNA. Such DNA may have been purified by recombinant DNA techniques and is replicated in cell culture. It does not contain recognisable human tissue.

10. For this reason, Question 5A is very important. The use of the term 'human materials' would cover human DNA even if it were isolated from human cells, for example using recombinant DNA techniques. It is therefore probably too broad.

11. Question 5B. We agree that the scope of the legislation must be carefully defined and that certain forms of human tissue need not be treated as being of great significance (the examples given in the report are of nail clippings and hair cuttings). However, we are concerned about some potential uses of discarded bodily materials of this nature. In our report 'Inside Information' we pointed out how discarded bodily materials could be subjected to genetic analysis for improper reasons.

12. We note that Section 4 stresses that the new legal framework should provide a statutory basis for regulating all aspects of obtaining, storage, use and disposal of all tissue and organs. We believe that genetic analysis is a very significant potential use of human tissue and must be specifically addressed. If the proposed new legislation excluded such materials from its scope then we believe it would be important to make separate provision relating to their subjection to genetic analysis.

13. One possibility is that the new law could draw a distinction between removed tissue (such as clinical samples or research samples) and discarded tissue. Removed tissue would be subject to appropriate regulation to ensure appropriate safeguards on consent, confidentiality and respectful disposal as set in later sections of the consultation (see below). Discarded tissue, however, would largely fall outside of the scope of the new Human Tissue Act unless it was to be subject to genetic analysis that was not for a lawful purpose (such as by the police). We believe that it is important to strictly control the unauthorised genetic analysis of removed and discarded tissue. Irrespective of whether there is any wider disclosure of genetic information, the principle of genetic privacy that we have adopted would mean that the non-consensual analysis of personal genetic information would constitute an unwarranted intrusion of privacy.

Section 7 - Who would give consent

14. We note that on page 41 concern is expressed about one of the recommendations made by the HGC in Inside Information (p85). This recommendation was that in the absence of any consent given in lifetime to the post mortem genetic testing of tissue it would acceptable for such testing to take place on basis that the dead person would have consented had consent been sought during his or her life. This presumption would only be made in those cases where such testing was necessary for the clinical care of a living relative. We believe that this is compatible with the consent principle which the consultation report advocates in Section 6. The general principle stated there is appropriate for research use of tissue which does not directly benefit a living relative. In such circumstances it is reasonable to insist on obtaining consent from the next of kin.

15. Different considerations apply where a living relative has a strong interest in the testing being carried out and we believe that this interest may be recognised without diminishing our respect for the consent principle in general.

16. The question of property rights of a body or its parts is a difficult one that may have benefited from a more detailed treatment in the consultation report. However, whilst we have considered this in some detail in our work on personal genetic information, it has proved difficult to establish any clear recommendations. In our report on personal genetic information we concluded that best practice in research required that factors such as the fate of samples and commercial involvement should be made clear when seeking consent. In particular, whilst we recognised the value of the "gift" interpretation of samples we also noted the importance of considering any implications for intellectual property and commercial access to research and samples.

17. The later sections of the consultation report refer to property rights and cell lines or tissue engineered products (section 17). In our Inside Information report we endorsed the approach taken by the House of Lords Stem Cell Committee that no specific property rights or consent should apply to cell lines developed from a sample. However, this was on the proviso that the position was made clear before seeking consent and that individuals were free to decline to donate samples.

18. We also note the related point and question 17G about any system that might be put in place to ensure that the donors receive some benefit. We have considered this in some depth in relation to genetic research databases. We have recognised the importance of commercial involvement in such research and the public unease about commercial profit from medical research. We concluded that in return for altruistic donation to research programmes there should be some benefit to the participants, or the wider community from which they are drawn. However, we felt that such benefit-sharing mechanisms could best be established in the light of the particular circumstances. We therefore recommended that national benefit should be taken into account in determining the terms on which commercial involvement was granted to research databases or human tissue samples.

19. Therefore, in response to questions 7P and also to 17F /G, we would agree that the legislation on human organs and tissues provides an opportunity to clarify the issue of property rights for human tissue. We believe that any framework should ensure that those consenting to the use of human organs and tissue are provided with clear information about the eventual use of their samples and to whom the benefits accrue.

Section 8 - Defining consent

20. We have conducted a detailed examination of the legal basis of consent in the context of genetic information. We have adopted the principle of consent as one of the secondary principles underlying our central principle of respect for persons. Therefore, whilst we note the possible alternatives to the use of term in any new legislation, we believe that "consent" has gained a wide acceptance in UK and international law and should be retained.

21. However, we note the concerns expressed about the giving of detailed information to relatives in requesting consent for a post-mortem examination. There are similar concerns in the area of pre-symptomatic genetic testing. In our report we examine the concept of a "right not to know". We conclude that whilst people may not wish to be burdened with bleak knowledge, there are equally circumstances in which such information is necessary for them to exercise personal autonomy. We therefore prefer the term an "entitlement not to know" in recognition of the fact that there may be circumstances where this must be over-ridden. We would hope that it would be possible to adopt this approach, perhaps together with the concept of "authorisation" that is recommended by the review in Scotland, in the legislation, Codes and guidance that are being prepared.

Section 9 - What is removed and why

22. This section details a number of areas in which human tissue may be retained or used (paragraph 9.4). In response to Question 9J about non-clinical or non-scientific uses of human tissues, we wish to comment about the possible omission of genetic testing services that are supplied direct to the public (including genetic testing services, DNA paternity testing or genealogical analysis). Most of such services require the obtaining of a sample of buccal cells, or more rarely, blood samples.

23. We are in the process of consulting on the regulation of such services, but at present we only note that they are regulated by two voluntary Codes of Practice published by UK Health Departments. There is also a variety of general consumer protection and data protection legislation that would apply to such services. We have set out further details in a consultation paper (enclosed for information) and we will comment elsewhere about our emerging conclusions.

24. We would also point out that there are a significant number of commercial companies who collect tissue samples directly or via NHS clinical centres for use in research. We have no reason to believe that these are not collected ethically, but they would represent another commercial sector that might be affected by any new controls. We also believe that these activities raise very important and potentially controversial issues of property and ownership of human tissues, which we comment on below.

Section 10 - Training, education and research
25. We have noted the draft interim statement of principles for clinical research (paragraph 10.13) includes the requirement that all research using human organs or tissue must be approved by a properly constituted research ethics committee. We would strongly support this and in our report on personal genetic information we similarly concluded that best practice should require that all genetic research on human non-anonymised tissue samples or bodily materials should be subject to review by an independent research ethics committee and should be monitored for compliance through clearly specified arrangements. We have also recommended that the Government should encourage relevant research institutions, professional bodies and funding organisations to establish clear policies aimed at ensuring compliance with the emerging best practice in ethical research.

26. In response to Question 10B we suggest that there are certain categories of genetic material that might alter their legal status in a research context. We have concluded that genetic research on anonymised human samples, especially established cell lines or information derived from anonymised samples or medical records, should not automatically be subject to subsequent ethical oversight. In general we suggest that any sample of human material that has been anonymised should be excluded from rigorous oversight, provided that the sample was collected in an ethical manner. However, we believe that in doing so there should be adequate safeguards to ensure that such samples cannot subsequently be linked to a living individual.

27. We have also noted the comments here about HGC's report in relation to genetics research and look forward to the outcome of the review.

Section 11 - Oversight and compliance
28. We have commented above that the scope of the Human Bodies, Human Choices review appears to include commercial genetic testing companies and DNA paternity testing. The nature and scale of such activities may be pertinent to the possible role of a single oversight body and the requirement for licensing versus registration (Question 11A).

29. We are still awaiting all the responses to our consultation and therefore we cannot supply any precise figures for the scale of such activities to supplement those in paragraph 11.11. However, in our previous report we have noted that approximately 10,000 paternity tests are commissioned per year, many of these related to the work of the Child Support Agency or the Home Office Immigration Directorate. The majority of tests are conducted by 3 or 4 commercial laboratories.

30. We have paid considerable attention to the issues raised here in relation to our current review of the supply of genetic testing services direct to the public. We have not completed our review so we therefore offer the following comments as an interim response to Question 11D. 31. In our consultation we have identified four possible options:

Do nothing - and let existing consumer protection legislation that covers other forms of home testing cover genetic tests too.

Revise the voluntary code of practice for all genetic tests - this would advise on the best way to offer the tests, what information people need before they take them and how the results should be stored and protected.

Stop some genetic tests being offered directly to the public and set up a voluntary code of practice for the rest - this would put restrictions on some types of test (most likely those for serious and life threatening disorders) and mean people have to talk to a health professional before they have these tests.

Stop all genetic tests being offered directly to the public - this would make it an offence for anyone who was not a health professional to offer a test directly to the public.

32. We are increasingly attracted to some form of hybrid system that includes an element of statutory regulation of the provision of genetic testing services to the public. This might be at the level of the new Human Tissue Act that imposes requirements for consent, storage and disposal of tissue samples. There could be a requirement for a licence or registration and compliance with the relevant statutory Code of Practice. Such Codes might be based on the two existing Codes of Practice (the Advisory Committee on Genetic Testing (ACGT) 1997 "Code of Practice and Guidance on Human Genetic Testing Services supplied direct to the public" and the "Code of Practice and Guidance on Genetic Paternity Testing Services" issued by UK Health Departments in 2001. They include specific requirements relating to laboratory standards, advertising and promotion, pre- and post-test counselling as well as record keeping.

33. We have noted that the existing Codes are not supported by effective compliance-checking and enforcement mechanisms. This would be an important aspect of any future system and we have been impressed by the work of the Office of Fair Trading that is soon to be responsible for approving voluntary Codes of Practice.

34. We are, however, aware that the Lord Chancellor's Department is responsible for regulations that require accreditation of laboratories that wish to be approved for court-directed paternity testing. The accreditation process requires compliance with the otherwise voluntary Code of Practice.

35. We stress that these are our initial views based on our deliberations to date and taking into account the proposals in the Human Bodies, Human Choices document. We are aware that there are several other strands to our work, not least the mechanism for evaluating the quality and utility of genetic tests. However, the HGC would be extremely interested in further discussions about future legislation on these matters.

Section 12 - Penalties for non-compliance

36. We have not considered in detail all of the issues about penalties and who commits an offence in this section. However, we can offer the following comments about the gradation of penalties in Questions 12E-F. In the light of publicity around HGC's earlier recommendation for a new offence of the non-consensual testing of DNA, we have discussed the concerns of men who wish to conduct a paternity test on children. Their ability to give a valid consent on behalf of the child will depend on whether they have parental responsibility for the child. The current law is to be amended by the Adoption and Children Bill, which is currently before Parliament. However, we believe that any new offence should take into the possibility that there should be graduated penalties in any new offence, such that testing for personal reasons without a valid consent (e.g. testing of a child by a putative father) might attract a fine. On the other hand, testing by third parties who have no personal connection to the person being tested (such as the example of testing of dental floss by a private investigator) might be liable for imprisonment or a higher fine or both.

Section 15 - Fetal tissue

37. We note the comments in Section 15 about the need to review the Polkinghorne guidelines. The Commission would be very interested in commenting on aspects of such a review that may impact on the use of fetal tissue in genetic research. At this stage we do not have any comments to make on the questions here. However, we would note that in the response to our 'Whose Hands on Your Genes' consultation the Royal College of Obstetricians and Gynaecologists states that fresh tissue rather than stored, is vital for a great deal of research. Although this is acknowledged by the DoH guidelines, the Royal College maintain that this 'principle of separation is more difficult to maintain at local level and creates barriers to research'.

Section 17 - Cell lines and stem cells

38. We would broadly support the requirement for ethical obtaining and establishment of cell lines as set out in paragraph 17.7. In response to Question 17A-B we draw attention to the remarks in our report on personal genetic information. We concluded that

Genetic research on anonymised human samples, especially established cell lines or information derived from anonymised samples or medical records, should not automatically be subject to subsequent ethical oversight. We recognise that human genetic research cannot reasonably be categorised into those projects which may cause concern, harm or distress to the research and those in which the subject has no particular interest. There is a clearly a spectrum of concern and there will be grey areas upon which researchers may wish to seek advice from an established independent research ethics committee, such as an NHS REC.

39. In response to Question 17C we have also highlighted the future potential for anonymised cell lines to be associated with an identifiable person by via DNA fingerprinting or de-encryption of computer and manual records. This is one of the scenarios that led us to recommend the new offence of non-consensual testing or analysis of DNA.

40. The above issue may arise in connection with stem cell lines. We have noted the important debate surrounding the derivation of embryonic stem cells. We also note that the Government does not consider that the use of isolated ES cell lines requires additional ethical oversight. We have briefly considered the wider use of stem cell lines. We note the comments in Section 15 about the need to review the Polkinghorne guidelines. Many of the issues that relate to the derivation of and subsequent use of fetal stem cell lines may equally apply to the use of embryonic or adult stem cell lnes. In particular, there is the possibility that the biological 'parents' of the foetus or embryo may be identified by subsequent research or DNA analysis. This may, indeed, be a requirement of medicines regulations designed to ensure that the source of biological medicines remains free from serious conditions such as HIV infection or CJD. We do not necessarily believe that this requires any additional oversight mechanisms, but we consider that the issues surrounding stem cell lines from any source remain under review.

41. We have noted above our views on question 17F-G about property rights and benefit sharing.

We would like to conclude by stressing the importance of this review in establishing a comprehensive legislative framework for the appropriate control of the myriad uses of human organs and tissue. We have stressed in our report the importance of proper controls to ensure that there is a balance between the interests of the individual and of the wider biomedical community and society. If there is any further help that the Commission could provide to this review we would be happy to consider it.

This page was last updated 9th January 2003

UNITED KINGDOM

NUFFIELD COUNCIL ON BIOETHICS

www.nuffieldbioethics.org

List of opinions

The ethics of research related to healthcare in developing countries
Published April 2002

The ethics of patenting DNA: a discussion paper
Published July 2002

Genetics and human behaviour: the ethical context
Published October 2002

The use of genetically modified crops in developing countries: a discussion paper
Draft Discussion Paper published for comment, June 2003
The final Paper will be published in November 2003.

Pharmacogenetics: ethical issues
To be published September 2003

Further details about each of the Reports are available below:

The ethics of research related to healthcare in developing countries
Published April 2002

Developing countries urgently need research to help relieve the enormous burden of disease that they carry. It is vital that those in wealthy countries, both in the public and private sector, help sponsor this research. But rigorous ethical safeguards must be in place to prevent the exploitation of those who take part in the research.

This Report defines the ethical standards for healthcare research in developing countries. It will provide a framework for anyone who is designing or conducting such research. The Report's recommendations focus on standards of care, consent, ethical review of research and what happens when the research is over.

The ethics of patenting DNA: a discussion paper
Published July 2002

Several thousand patent applications have been made on human genes. But the substantial increase in the rate of patenting of DNA sequences has led to considerable debate about the acceptability of this practice.

This Discussion Paper argues that patents involving DNA sequences should be the exception rather than the rule. It makes recommendations for future policy in the area, including a number of significant changes to the way that patents are granted involving DNA sequences. Most importantly, the tests of inventiveness and usefulness should be more rigorously applied when considering if a patent should be granted. The Paper also notes that some patents that have already been granted are of doubtful validity and makes recommendations to limit the possible adverse effects of these patents.

Genetics and human behaviour: the ethical context
Published October 2002

Researchers in the field of behavioural genetics are attempting to locate specific genes, or groups of genes, associated with behavioural traits and to understand the complex relationship between genes and the environment. This Report considers the ethical, legal and social issues that are raised by research into behavioural genetics. It focuses on human behaviour within the normal range of variation, looking at traits such as intelligence, antisocial behaviour, personality and sexual orientation.

After discussing the historical and scientific background to this research, the Report considers its implications and possible applications. It considers the issues raised by changing or selecting behavioural traits on the basis of genetic information and examines the possible uses of such information in the criminal justice system, and in the contexts of education, employment and insurance.