Parliamentary Assembly
Assemblée parlementaire
http://assembly.coe.int

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

**AS/Cult/Inf (2013) 02**
17 January 2013

# COMMITTEE ON CULTURE, SCIENCE, EDUCATION AND MEDIA
# COMMISSION DE LA CULTURE, DE LA SCIENCE, DE L'ÉDUCATION ET DES MÉDIAS

## Ethics in science and technology
## L'éthique dans la science et la technologie

Rapporteur: Mr/M. Jan KAŹMIERCZAK, Poland, European People's Party Group
Pologne, Groupe du Parti populaire européen

This document reproduces the replies received to the questionnaire sent through the agency of the European Centre for Parliamentary Research and Documentation (ECPRD) to research departments of national parliaments in the Council of Europe Member States and Observer States.

The detailed replies are copied in the document in the original language they were sent (French or English).

*Ce document reproduit les réponses reçues au questionnaire envoyé par l'entremise du Centre européen de recherche et de documentation parlementaires (CERDP) aux départements de recherche des parlements nationaux des pays membres du Conseil de l'Europe et des pays observateurs.*

*Les réponses détaillées sont copiées dans le document dans la langue d'origine (français ou anglais) dans laquelle elles ont été envoyées.*

**A. Questionnaire**

**B. Table with replies by country - alphabetical order /**
***Tableau des réponses par pays - ordre alphabétique***

***C.*** **Table with examples of legislation in European countries related to ethics in science and technology /**
***Tableaux avec les exemples de législation dans les pays européens, concernant l'éthique dans la science et la technologie***

**D. Summary of replies to the questionnaire /**
***Synthèse des réponses au questionnaire***

**E. Detailed replies by country - alphabetical order /**
***Réponses détaillées par pays - ordre alphabétique***

## A. Questionnaire

### Background

The Committee on Culture, Science and Education[1] is preparing a report on "The ethics of science"[2] which intends to explore the ethical repercussions of scientific activities (ethics of scientific research), but also ethical aspects concerning the behaviour of the society of scientists (ethics of scientists), aiming to identify ethical risks and the possibility of developing a common ethical reference framework.

In order to gather accurate information on domestic legislation and regulations in this area the Committee on Culture, Science and Education, would be grateful if you could reply to the appended questionnaire.

### *Contexte*

*La Commission de la culture, de la science et de l'éducation[3] élabore actuellement un rapport sur « L'éthique de la science[4] » qui entend traiter des incidences éthiques des activités scientifiques (l'éthique de la recherche scientifique), mais aussi des aspects éthiques relatifs au comportement de la communauté des chercheurs (l'éthique des chercheurs) en vue d'établir les risques éthiques et d'élaborer éventuellement un cadre de référence commun de l'éthique.*

*Pour réunir des informations exactes sur la législation et la réglementation des pays dans ce domaine, la Commission de la culture, de la science et de l'éducation vous serait reconnaissante de bien vouloir répondre au questionnaire ci joint.*

### Questionnaire

1. In your country, what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research (outline and overview of the current state of play)?

   *Quelles lois, réglementations et recommandations/directives officielles sont en vigueur dans votre pays concernant les questions clés que sont la responsabilité sociale en matière de conduite de la recherche scientifique et l'éthique de la recherche scientifique ?*

2. Which institutions in your country are responsible for monitoring the ethical aspects of scientific research, i.e. possible danger to humans or the environment, as well as possible scientific misconduct? What procedures are used by these institutions?

   *Quels sont, dans votre pays, les institutions qui sont chargées de contrôler les aspects éthiques de la recherche scientifique ? Quelles procédures utilisent ces institutions ?*

3. What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?

   *Quels sont, d'après vous, les problèmes qui existent au niveau du fonctionnement du système juridique et institutionnel de votre pays s'agissant de contrôler le respect de l'éthique dans les activités scientifiques ? Quelles améliorations faudrait-il apporter et mettre en œuvre ? Qu'attendez-vous des institutions européennes ?*

4. Could you indicate the main organisations representing scientific society in your country, which could provide the Committee on Culture, Science and Education with their views on these issues?

   *Pouvez-vous indiquer les organisations principales qui représentent la communauté scientifique dans votre pays, qui seraient susceptibles de transmettre à la commission de la culture, de la science et de l'éducation leur avis sur cette question?*

---

[1] Currently Committee on Culture, Science and Education and Media
[2] On 2-4 October 2012 in Strasbourg, the committee decided to change the title to: "Ethics in science and technology"
[3] *Actuellement Commission de la culture, de la science, de l'éducation et des médias*
[4] *Les 2-4 octobre à Strasbourg, la commission a changé le titre en « L'éthique dans la science et la technologie »*

## B. Table with replies by country - alphabetical order / *Tableau des réponses par pays - ordre alphabétique*

| **Country[5] / *Pays[6]*** | **Reply / *Réponse*** | **Question 1** legislation / *législation* | **Question 2** monitoring / *suivi* | **Question 3** issues / *problématiques* | **Question 4** scientific org / *org scientifiques* |
|---|---|---|---|---|---|
| Albania / *Albanie* | | | | | |
| Andorra / *Andorre* | x | | | | |
| Armenia / *Arménie* | | | | | |
| Austria / *Autriche* | x | x | x | x | x |
| Azerbaijan / *Azerbaïdjan* | | | | | |
| Belgium / *Belgique* | x | x | x | | x |
| Bosnia and Herzegovina / *Bosnie-Herzégovine* | | | | | |
| Bulgaria / *Bulgarie* | x | x | x | | x |
| Croatia / *Croatie* | x | x | x | x | x |
| Cyprus / *Chypre* | x | x | x | x | x |
| Czech Republic / *République tchèque* | x | x | x | | x |
| Denmark / *Danemark* | | | | | |
| Estonia / *Estonie* | x | x | x | x | |
| Finland / *Finlande* | x | x | x | x | |
| France | x | x | x | x | x |
| Georgia / *Géorgie* | | | | | |
| Germany / *Allemagne* | x | x | x | | x |
| Greece / *Grèce* | x | x | x | x | x |
| Hungary / *Hongrie* | x | x | x | | x |
| Iceland / *Islande* | x | x | x | | x |
| Ireland / *Irlande* | | | | | |
| Italy / *Italie* | x | x | x | x | x |
| Latvia / *Lettonie* | x | x | | | x |
| Liechtenstein | | | | | |
| Lithuania / *Lituanie* | x | x | x | | x |
| Luxembourg | | | | | |
| Malta / *Malte* | | | | | |
| Republic of Moldova / *République de Moldova* | x | x | x | | x |
| Monaco / *Monaco* | | | | | |
| Montenegro / *Monténégro* | x | x | x | x | x |
| Netherlands / *Pays-Bas* | x | x | x | | x |
| Norway / *Norvège* | x | x | x | x | x |
| Poland / *Pologne* | x | x | x | x | x |
| Portugal | x | x | x | | x |
| Romania / *Roumanie* | x | x | x | | x |
| Russian Federation / *Fédération de Russie* | x | x | x | x | x |
| San Marino / *Saint-Marin* | | | | | |
| Serbia / *Serbie* | | | | | |
| Slovak Republic / *République slovaque* | x | x | x | | x |
| Slovenia / *Slovénie* | x | x | x | x | x |
| Spain / *Espagne* | x | x | x | | x |
| Sweden / *Suède* | x | x | x | x | x |
| Switzerland / *Suisse* | x | x | x | x | x |
| "The former Yugoslav Republic of Macedonia" / « *L'ex-République yougoslave de Macédoine* » | x | x | x | | x |
| Turkey / *Turquie* | | | | | |
| Ukraine / *Ukraine* | | | | | |
| United Kingdom / *Royaume-Uni* | x | x | x | x | x |

[5] Decision not to reply received from: Denmark, Israel, United States of America
[6] *Décision de ne pas répondre reçue de : Danemark, Israël, Etats-Unis d'Amérique*

## C. Table with examples of legislation in European countries related to ethics in science and technology[7] / *Tableaux avec les exemples de législation dans les pays européens, concernant l'éthique dans la science et la technologie*[8]

List of sectors /*Liste des secteurs* :
a: medical and health research / *recherché médicale et de santé*
b: biotechnology including GMOs / *biotechnologie y compris OGMs*
c: other sciences and technology / *autres sciences et technologies*
d: animal testing / *tests sur les animaux*
e: social sciences and humanities / *sciences sociales et humaines*
f: general provisions (codes) to regulate research / *clauses générales (codes) pour règlementer la recherche*

| **Country / *Pays*** | **Reply/ *Réponse*** | **a** | **b** | **c** | **d** | **e** | **f** |
|---|---|---|---|---|---|---|---|
| Albania / *Albanie* | | | | | | | |
| Andorra / *Andorre* | x | | | | | | |
| Armenia / *Arménie* | | | | | | | |
| Austria / *Autriche* | x | x | x | | x | | x |
| Azerbaijan / *Azerbaïdjan* | | | | | | | |
| Belgium / *Belgique* | x | x | x | x | x | | x |
| Bosnia and Herzegovina / *Bosnie-Herzégovine* | | | | | | | |
| Bulgaria / *Bulgarie* | x | x | | | | | x |
| Croatia / *Croatie* | x | x | x | | x | | x |
| Cyprus / *Chypre* | x | x | x | | | | |
| Czech Republic / *République tchèque* | x | x | x | | | | |
| Denmark / *Danemark* | | | | | | | |
| Estonia / *Estonie* | x | x | x | | x | | x |
| Finland / *Finlande* | x | x | x | | x | x | x |
| France | x | x | x | | | | x |
| Georgia / *Géorgie* | | | | | | | x |
| Germany / *Allemagne* | x | x | x | | x | | x |
| Greece / *Grèce* | x | x | x | x | x | | |
| Hungary / *Hongrie* | x | | | | | | x |
| Iceland / *Islande* | x | x | x | | | | x |
| Ireland / *Irlande* | | | | | | | |
| Italy / *Italie* | x | x | x | | | | x |
| Latvia / *Lettonie* | x | | | | | | x |
| Liechtenstein | | | | | | | |
| Lithuania / *Lituanie* | x | x | x | | | | x |
| Luxembourg | | | | | | | |
| Malta / *Malte* | | | | | | | |
| Republic of Moldova / *République de Moldova* | x | x | | x | | | x |
| Monaco / *Monaco* | | | | | | | |
| Montenegro / *Monténégro* | x | | | | | | x |
| Netherlands / *Pays-Bas* | x | x | x | | x | | x |
| Norway / *Norvège* | x | x | x | x | | x | x |
| Poland / *Pologne* | x | x | x | | | | x |
| Portugal | x | x | x | x | | | |
| Romania / *Roumanie* | x | | x | | | x | x |
| Russian Federation / *Fédération de Russie* | x | x | x | | | | x |
| San Marino / *Saint-Marin* | | | | | | | |
| Serbia / *Serbie* | | | | | | | |
| Slovak Republic / *République slovaque* | x | x | x | | | | x |
| Slovenia / *Slovénie* | x | x | | | x | | x |

[7] Non exhaustive, reflects only examples provided in replies to the questionnaire
[8] *Non exhaustif, l'information reflète uniquement les exemples fournis par les réponses au questionnaire*

| **Country / *Pays*** | **Reply/ *Réponse*** | **a** | **b** | **c** | **d** | **e** | **f** |
|---|---|---|---|---|---|---|---|
| Spain / *Espagne* | x | x | x | | | | x |
| Sweden / *Suède* | x | x | x | | | | x |
| Switzerland / *Suisse* | x | x | x | x | x | | x |
| "The former Yugoslav Republic of Macedonia" / « *L'ex-République yougoslave de Macédoine* » | x | | | x | | | x |
| Turkey / *Turquie* | | | | | | | |
| Ukraine / *Ukraine* | | | | | | | |
| United Kingdom / *Royaume-Uni* | x | x | x | | x | x | x |

List of sectors /*Liste des secteurs* :
a: medical and health research / *recherché médicale et de santé*
b: biotechnology including GMOs / *biotechnologie y compris OGMs*
c: other sciences and technology / *autres sciences et technologies*
d: animal testing / *tests sur les animaux*
e: social sciences and humanities / *sciences sociales et humaines*
f: general provisions (codes) to regulate research / *clauses générales (codes) pour règlementer la recherche*

## D. Summary of replies to the questionnaire

Legislation and guidelines

The level of regulation and accompanying mechanisms for its implementation are very diverse across Europe, but in general all countries have adopted laws and regulations ranging under one or more of the following areas a) medical and health research; b) biotechnology including GMOs; c) other sciences and technology; d) animal testing; e) social sciences and humanities; and f) general provisions (codes) to regulate research, the work of scientists and scientific integrity, including provisions for research within higher education.

Some national **Constitutions** contain relevant provisions, namely concerning the promotion of freedom of scientific research (Italy, Montenegro, Poland, the "former Yugoslav Republic of Macedonia", the protection of human dignity with regard to the application of biology and medicine (Montenegro) and the requirement of voluntary consent for scientific experiments (Bulgaria, Poland).

**National research programmes** represent the principal research planning and coordination instrument and, through integration in the **European Research Area,** are in principle linked to the strategic objectives and ethical requirements under the EU seventh Framework Programme for Research (FP7).

Moreover, ratification of the **Oviedo Convention** and its Protocols, transposition of **EU Directives** and European Researchers' Charter were good incentives to advance legislation which reflects ethical concerns and principles nationally.

The example to highlight is the "Code of ethics for scientific research"[9] which was adopted in Belgium in 2008, outlining **general ethical principles** to be applied in all areas of scientific research. The code was jointly drafted by prominent experts from the Academies of Science, Medicine and Fine Arts under the auspices of the Federal Service for Scientific Policy. Another example is the "Code of Ethics of Scientists"[10] drafted by the Estonian Academy of Sciences to highlight the moral dimension of science and the social responsibility of scientists. Several other countries such as Finland[11], Hungary, Latvia, the Netherlands and Norway[12] have also undertaken similar initiatives. However, most countries lack overarching general guidelines to be applied in all areas of research.

Institutions and monitoring procedures

A majority of countries have **ethics committees** that are established at universities and/or hospitals, to review and approve clinical trials. Frequently they dispose of **ethical codes** to govern their activity. In some countries there is a Central Ethics Committee to coordinate the work of local ethics committees.

Most countries have **National Bioethics Committees** with mandates that vary from ethical review of research projects to an advisory role to the political decision-makers (President, Parliament, Government) issuing opinions on emerging ethical issues in connection to biomedicine, for example on transplants, assisted reproduction, cloning, protection of patients, privacy rights and data collection, use of animals in research, and even on wider topics such as biodiversity, release of GMOs, etc. Those National Bioethics Committees take part in the European and international dialogue on bioethics through the Forum of National Ethics Councils (NEC Forum), which was initiated by the Council of Europe following the entry into force of the Oviedo Convention, and is currently funded and coordinated by the European Commission.

A good **example of structured monitoring system** can be found in Norway, with a national system for research ethics composed of specialised but coordinated national committees for research ethics, which cover different research areas such as medical and health research; sciences and technology; social sciences and humanities. They share a common building and have regular coordination between respective secretariats. In addition, there are seven regional committees for medical and health research, National

[9] Belgium, see website http://www.belspo.be/belspo/organisation/publ/Eth_code_fr.stm
[10] Estonia, see website : http://www.akadeemia.ee/_repository/File/ALUSDOKUD/Code-ethics.pdf
[11] Finland: guidelines on ethical review in the humanities and social and behavioral sciences, see website http://www.tenk.fi/en/ethical-review-human-sciences
[12] Norway : guidelines for research ethics in science and technology, http://www.etikkom.no/Documents/English-publications/Guidelines%20for%20research%20ethics%20in%20science%20and%20technology%20(2008).pdf
and guidelines for research ethics in social sciences, law and humanities, http://www.etikkom.no/Documents/English-publications/Guidelines%20for%20research%20ethics%20in%20the%20social%20sciences,%20law%20and%20the%20humanities%20(2006).pdf

Board of Health Supervision, the National Data Inspectorate and the National Commission for Investigation of Scientific Misconduct.

In Greece[13], **national parliament** also has a specific monitoring role, in addition to drafting studies and holding public debates.

Finland displays a very good model of **self-regulation** within the research community. Organisations that conduct scientific research are primarily responsible for promoting good scientific practice and dealing with alleged misconduct and fraud in science. The National Advisory Board on Research Ethics, which includes representatives from major scientific fields and key supervising authorities, has drafted guidelines[14] which contain procedures for handling alleged violations of good scientific practice and which cover all fields of science. The research community is broadly committed to these guidelines as well as to additional ethical norms for each field specifically.

Issues at stake and recommendations

There is a need to widely establish **research ethics committees** at the level of universities, hospitals and other medical establishments, in order to enhance the understanding and application of ethical principles and related legislation among students and researches in practice. In most countries scientists and research personnel do not receive enough **education and training on research ethics** and they are not fully aware of all requirements.

More dialogue among stakeholders[15] as well as **public debate**[16] on ethical issues emerging from scientific research and development of technologies is advocated locally, nationally and at European level. For example, European and regional platforms could be created to regularly exchange experiences, similarly to the National Ethics Committees (NEC) Forum or the meetings of the former Steering Committee on Bioethics (CDBI) in the Council of Europe (now the Bioethics Committee, DH-BIO).

Moreover, greater **harmonisation** of ethical rules and monitoring procedures is needed at national and also European level, particularly in the biomedical field where complex rules and procedures, as well as numerous monitoring and advisory bodies co-exist.

Ethical reflection and assessment ought to be encouraged **in all fields of research**, using the example and experience gained in bioethics. **General guidelines** outlining overarching ethical principles to be applied in all areas of scientific research should be drafted and coordinated at national and European level.

Governments and parliaments need to give **political priority** to this issue and facilitate adequate administrative and funding support to monitoring and advisory institutions, guaranteeing their independence and effective functioning, so that the **implementation** of ethical principles can be improved in practice. **European support** is also needed, including stronger requirements, building on the very positive impact of ethical requirements under the EU seventh Framework Programme for Research (FP7).

[13] Greece : Parliamentary Special Permanent Committee on Research and Technology
[14] Finland : guidelines on good scientific practice and procedures for handling misconduct and fraud in science, see website http://www.tenk.fi/en/resposible-conduct-research-guidelines
[15] Proposal from Estonia: discussion on institutional set up and monitoring, coordination, membership of advisory or monitoring committees; broadening of mandates, concrete implications for various guidelines, etc.
[16] Reflecting the principles of pluralism, tolerance, participation and constructive dialogue

## *Synthèse des réponses au questionnaire*

Lois et lignes directrices

Le degré de réglementation et les mécanismes de mise en œuvre de la réglementation sont très variables en Europe, mais globalement tous les pays ont adopté des lois et règlements dans un ou plusieurs des domaines suivants : a) recherche médicale et sanitaire ; b) biotechnologies, notamment OGM ; c) autres sciences et technologies ; d) expérimentation animale ; e) sciences sociales et sciences humaines, et f) dispositions générales (codes) visant à réglementer la recherche, les travaux des scientifiques et l'intégrité scientifique, notamment les dispositions concernant la recherche dans l'enseignement supérieur.

Certaines **Constitutions** nationales contiennent des dispositions pertinentes, par exemple en ce qui concerne la promotion de la liberté de la recherche scientifique (Italie, « l'ex-République yougoslave de Macédoine », Monténégro, Pologne), la protection de la dignité de l'être humain à l'égard des applications de la biologie et de la médecine (Monténégro) et l'obligation d'obtenir le consentement volontaire pour les expériences scientifiques (Bulgarie, Pologne).

Les **programmes de recherche nationaux** sont le principal instrument de planification et de coordination de la recherche. Grâce à leur intégration dans l'**Espace européen de la recherche**, ils sont en principe liés aux objectifs stratégiques et aux exigences éthiques énoncées dans le septième programme-cadre de l'UE pour la recherche (FP7).

De plus, la ratification de la **Convention d'Oviedo** et de ses Protocoles, la transposition des **directives de l'UE** et la Charte européenne du chercheur ont permis de faire évoluer la législation, qui reflète les préoccupations et principes éthiques au niveau national.

Un bon exemple est le Code d'éthique de la recherche scientifique[17], adopté en Belgique en 2008, qui renferme les **principes éthiques généraux** à appliquer dans toutes les disciplines de la recherche scientifique. Ce Code a été rédigé conjointement par d'éminents experts de l'Académie royale des sciences, des lettres et des beaux-arts et de l'Académie royale de médecine, sous les auspices du Service public de programmation de la Politique scientifique fédérale. Un autre exemple est le Code d'éthique des scientifiques[18] élaboré par l'Académie des sciences estonienne, qui insiste sur la dimension morale de la science et la responsabilité sociale des scientifiques. D'autres pays, comme la Finlande[19], la Hongrie, la Lettonie, la Norvège[20] et les Pays-Bas, ont adopté des initiatives similaires. Cependant, dans la plupart des Etats, il n'existe pas de lignes directrices générales applicables dans tous les domaines de la recherche.

Institutions et procédures de suivi

Dans la plupart des cas, les **comités d'éthique** ont été créés dans les universités et/ou les hôpitaux afin de contrôler et d'approuver les essais cliniques. Souvent, leurs activités sont régies par des **codes d'éthique**. Dans certains pays, un comité d'éthique central coordonne les travaux des comités d'éthique locaux.

La majorité des Etats se sont dotés de **comités de bioéthique nationaux** dont le mandat va de l'examen éthique des projets de recherche aux conseils aux responsables politiques (président, parlement, gouvernement). Ces instances rendent des avis sur les questions éthiques soulevées par la biomédecine, par exemple les transplantations, la procréation assistée, le clonage, la protection des patients, le droit au respect de la vie privée et la collecte de données, l'utilisation des animaux dans la recherche, et même sur des thèmes plus vastes comme la biodiversité, la dissémination d'OGM, etc. Les comités de bioéthique nationaux participent au dialogue européen et international sur la bioéthique dans le cadre du Forum des CEN, lancé par le Conseil de l'Europe à la suite de l'entrée en vigueur de la Convention d'Oviedo, qui est actuellement financé et coordonné par la Commission européenne.

---

[17] Belgique : voir http://www.belspo.be/belspo/organisation/publ/Eth_code_fr.stm
[18] Estonie : voir http://www.akadeemia.ee/_repository/File/ALUSDOKUD/Code-ethics.pdf
[19] Finlande : Lignes directrices concernant l'examen éthique dans les sciences humaines et les sciences sociales et comportementales (http://www.tenk.fi/en/ethical-review-human-sciences ).
[20] Norvège : Lignes directrices concernant l'éthique de la recherche dans la science et la technologie (http://www.etikkom.no/Documents/English-publications/Guidelines%20for%20research%20ethics%20in%20science%20and%20technology%20(2008).pdf) et Lignes directrices concernant l'éthique de la recherche dans les sciences sociales, le droit et les sciences humaines (http://www.etikkom.no/Documents/English-publications/Guidelines%20for%20research%20ethics%20in%20the%20social%20sciences,%20law%20and%20the%20humanities%20(2006).pdf).

La Norvège offre un bon **exemple de système de suivi structuré**, avec un système national pour l'éthique de la recherche composé de comités nationaux spécialisés mais coordonnés, qui couvrent différents domaines de recherche comme la recherche médicale et sanitaire, les sciences et les technologies, les sciences sociales et les sciences humaines. Ils partagent un même bâtiment et une coordination régulière est établie entre leurs secrétariats respectifs. Il existe en outre sept comités régionaux pour la recherche médicale et sanitaire, une Agence nationale de surveillance sanitaire, une Inspection nationale des données et une Commission nationale d'enquête sur les pratiques répréhensibles dans le domaine scientifique.

En Grèce[21], outre la rédaction d'études et l'organisation de débats publics, le **parlement national** joue un rôle spécifique en matière de suivi.

La Finlande possède un très bon modèle d'**autorégulation** au sein de la communauté des chercheurs. Les organisations chargées de la recherche scientifique sont responsables au premier chef de promouvoir les bonnes pratiques scientifiques et de s'occuper des cas présumés de pratiques répréhensibles et de fraude dans le domaine scientifique. Le Conseil consultatif national sur l'éthique de la recherche, qui comprend des représentants des principales disciplines scientifiques et des principales autorités de contrôle, a élaboré des lignes directrices[22] présentant les procédures à appliquer en cas de violation présumée des bonnes pratiques scientifiques et couvrant tous les domaines scientifiques. La communauté des chercheurs est globalement très attachée à ces lignes directrices ainsi qu'aux normes éthiques supplémentaires qui portent plus spécifiquement sur chaque domaine.

Enjeux et recommandations

Il est nécessaire de créer largement des **comités d'éthique de la recherche** au niveau des universités, des hôpitaux et des autres établissements médicaux pour faire mieux comprendre et appliquer les principes éthiques et la législation pertinente parmi les étudiants et les chercheurs. Dans la plupart des pays, **l'éducation et la formation à l'éthique de la recherche** dispensées aux scientifiques et au personnel de recherche sont insuffisantes, si bien que ceux-ci ne sont pas pleinement conscients de toutes les exigences.

Un dialogue accru entre les parties prenantes[23] et un **débat public**[24] sur les questions éthiques soulevées par la recherche scientifique et le développement des technologies sont préconisés aux niveaux local, national et européen. Par exemple, des plates-formes européennes et régionales pourraient être créées afin d'échanger régulièrement des expériences, sur le modèle du Forum des Comités d'Ethique Nationaux (CEN) ou des réunions de l'ancien Comité Directeur pour la Bioéthique (CDBI) du Conseil de l'Europe (devenu Comité de bioéthique, DH-BIO).

En outre, une plus grande **harmonisation** des règles éthiques et des procédures de suivi est nécessaire au niveau national mais aussi européen, en particulier dans le domaine biomédical, où coexistent des règles et procédures complexes et de nombreuses instances consultatives et de suivi.

Il faudrait encourager la réflexion éthique et l'évaluation **dans tous les domaines de recherche**, en se fondant sur l'exemple de la bioéthique et sur l'expérience acquise dans cette discipline. Il conviendrait également d'élaborer et de coordonner aux niveaux national et européen des **lignes directrices générales** présentant les principes étiques fondamentaux à appliquer dans tous les domaines de la recherche scientifique.

Les gouvernements et les parlements doivent donner la **priorité politique** à cette question et promouvoir le soutien administratif et financier adéquat aux instances consultatives et de suivi, tout en garantissant leur indépendance et leur bon fonctionnement, afin d'améliorer la **mise en œuvre** des principes éthiques dans la pratique. Il convient aussi d'apporter **un soutien à l'échelle européenne**, notamment sous la forme d'exigences plus fortes, en s'appuyant sur les effets extrêmement positifs des exigences éthiques énoncées dans le septième programme-cadre de l'UE pour la recherche (FP7).

[21] Grèce : Commission parlementaire spéciale permanente sur la recherche et la technologie.
[22] Finlande : Lignes directrices sur les bonnes pratiques scientifiques et les procédures relatives aux pratiques répréhensibles et aux cas de fraude dans le domaine scientifique (http://www.tenk.fi/en/resposible-conduct-research-guidelines).
[23] Proposition de l'Estonie : discussion sur le cadre et le suivi institutionnels, la coordination, l'appartenance à des comités consultatifs ou de suivi ; élargissement des mandats, implications concrètes des diverses lignes directrices, etc.
[24] Reflétant les principes du pluralisme, de la tolérance, de la participation et d'un dialogue constructif.

## E. Detailed replies by country - alphabetical order / *Réponses détaillées par pays - ordre alphabétique*

**Contents[25] / *Sommaire*[26]**


Andorra / *Andorre* ..... 11
Austria / *Autriche* ..... 11-13
Belgium / *Belgique* ..... 13-16
Bulgaria / *Bulgarie* ..... 16
Croatia / *Croatie* ..... 16-18
Cyprus / *Chypre* ..... 18-19
Czech Republic / *République tchèque* ..... 19-20
Estonia / *Estonie* ..... 20-22
Finland / *Finlande* ..... 22-25
France ..... 25-28
Georgia / *Géorgie* ..... 28
Germany / *Allemagne* ..... 28-30
Greece / *Grèce* ..... 30-32
Hungary / *Hongrie* ..... 32
Iceland / *Islande* ..... 32-33
Italy / *Italie* ..... 33-36
Latvia / *Lettonie* ..... 36
Lithuania / *Lituanie* ..... 36-37
Republic of Moldova / *République de Moldova* ..... 37-39
Montenegro / *Monténégro* ..... 39-41
The Netherlands / *Pays-Bas* ..... 41-43
Norway / *Norvège* ..... 43-47
Poland / *Pologne* ..... 48
Portugal ..... 48-51
Romania / *Roumanie* ..... 51-52
Russian Federation / *Fédération de Russie* ..... 52
Slovak Republic / *République slovaque* ..... 53-54
Slovenia / *Slovénie* ..... 54-56
Spain / *Espagne* ..... 56-57
Sweden / *Suède* ..... 57
Switzerland / *Suisse* ..... 57-59
"The former Yugoslav Republic of Macedonia" / « *L'ex-République yougoslave de Macédoine* » ..... 59-60
United Kingdom / *Royaume-Uni* ..... 60-61


[25] Decision not to reply received from: Denmark, Israel, United States of America
[26] *Décision de ne pas répondre reçue de : Danemark, Israël, Etats-Unis d'Amérique*

## Andorra / *Andorre*

Reply provided by Consell General, Parliament of Andorra (20.06.2011)

As a reply to your request 1710 on "The ethics of Science", I am pleased to inform you that in Andorra, we don't have regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research.

## Austria / *Autriche*

Reply provided by the Federal Ministry of Science and Research (16.06.2011)

*Question 1: What are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

There are three laws in Austria touching upon matters of ethics in scientific research directly:

"Bundesgesetz über die Organisation der Universitäten und ihre Studien (Universitätsgesetz 2002)"/Universities Act 2002: This law concerns the organisation of Austrian universities and their studies. With respect to ethics in scientific research it obliges medical universities to set up ethics committees according to the „Krankenanstalten und Kuranstaltengesetz" (BGBl. Nr. 1/1957)

„Krankenanstalten und Kuranstaltengesetz" (BGBl. Nr. 1/1957). This act regulates clinical research in hospitals. Among other things it obliges hospitals to establish ethics committees.

The "Gentechnikgesetz (BGBl. Nr. 510/1994, i.d.g.F)/Austrian Gene Technology Act has entered into force in January 1995 and has been amended various times. It regulates the main aspects of biotechnology and genetic engineering: contained use of genetically modified organisms (GMOs), deliberate release of GMOs into the environment, the placing on the market of products that contain GMOs and the application of biotechnology in human medicine, such as gene analysis and gene therapy. Furthermore the act lays down the rules for the installation and work of an Advisory Board on Genetechnology (Gentechnikkommission) and its three scientific committees, for strict liability for damages due to genetic engineering and punishment for offences against the law. § 3 Z. 5: „Bei genetischen Analysen und Gentherapien am Menschen ist auf die Wahrung der Menschenwürde Bedacht zu nehmen; der Verantwortung des Menschen für Tier, Pflanze und Ökosystem ist Rechnung zu tragen (ethisches Prinzip)."

The "Tierversuchsgesetz" (BGBl. Nr. 501/1989)/Animal Testing Act regulates the use of animals in scientific experiments. The law stipulates the authorization of animal testing as well as animal testing institutions through competent authorities. § 4 Abs. 3 refers to ethics: "Alle an der Durchführung von Tierversuchen beteiligten Personen tragen im Rahmen der ihnen übertragenen Aufgabenstellung eine ethische und wissenschaftliche Verantwortung. Es ist die Pflicht jedes Wissenschaftlers, Notwendigkeit und Angemessenheit des von ihm geplanten, geleiteten oder durchzuführenden Tierversuchs selbst zu prüfen und gegen die Belastung der Versuchstiere abzuwägen."

Apart from legal obligations there are a number of institutions that have an advisory role. Among them are:

Bioethikkommission (Bioethics Commission) at the Bundeskanzleramt (Federal Chancellery) established in 2001: The task of the Bioethics Commission is to advise the Federal Chancellor from an ethical point of view on all social, natural scientific and legal issues arising from the scientific developments in human medicine and human biology. This includes in particular the submission of recommendations for practical use and suggestions for enacting the necessary legal provisions as well as the preparation of expert opinions on specific issues. The Commission exercises its advisory function independently. Its members are appointed by the Federal Chancellor. The Commission consists of experts in the medical field (in particular reproductive medicine, gynaecology, psychiatrics, oncology, pathology), legal experts, sociologists and experts in philosophy, theology and microbiology.

Österreichische Agentur für Wissenschaftliche Integrität (Austrian Agency for Research Integrity) (OeAWI): The Austrian Agency for Research Integrity was set up as an association in accordance with the Austrian Associations Act. The agency was founded by 12 Austrian universities, the Austrian Academy of Sciences, the Vienna Science and Technology Fund (WWTF), IST Austria and the Austrian Science Fund (FWF). The agency is responsible for investigating alleged cases of scientific misconduct in Austria in a professional

manner, evaluating the severity of each offense, and making recommendations on subsequent actions. The tasks of investigation and evaluation have been assigned to an independent body called the Commission for Research Integrity, which includes distinguished scholars from outside Austria.

Some universities and research organizations established or are about to establish ethics committees also outside the realm of clinical research that treat ethical dimensions of research projects and develop ethical guidelines. However, these committees usually only convene meetings when specifically requested e.g. by funding organizations, in particular by the 7th framework programme of the European Commission.

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research, i.e. possible danger to humans or the environment, as well as possible scientific misconduct? What procedures are used by these institutions?*

The following institutions are responsible for monitoring the ethical aspects of scientific research. They have a legal binding mandate:

The Austrian Agency for Health and Food Safety (AGES) is responsible for carrying out diverse tasks related to public health and food safety. Fully owned by both the Federal Ministry of Health and the Federal Ministry of Agriculture, Forestry, the Environment, and Water Management, AGES carries out research, analyses, and inspections in accordance with the provisions of Austrian and EU legislation. The main areas of responsibility of AGES are the prevention and control of diseases in plants, animals, and humans and the Also, as an authority the agency is responsible for licensing medicinal products, medical devices, seeds, or pesticides.

Competent authorities are responsible for monitoring matters concerning animal testing. Each institution approved for animal testing is among other measures inspected without advance notice on a yearly basis.

The Austrian Agency for Research Integrity does not have a binding mandate. It inspects accusations of scientific misconduct upon request by its members (i.e. most Austrian universities and research organizations). The agency advises in cases of scientific misconduct.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

- Not all institutions have established ethics committees yet. Further measures are needed to raise awareness for ethical implication different research projects might have
- In the biomedical field a variety of acts and guidelines already exist on a national and an international level. Any production of further ethical reference papers within this area has to be carefully considered.
- There are no overarching very general guidelines with respect to ethics in scientific research. These could for example be issued by and signed by Austrian universities and research organisations.

*Question 4: main organisations representing scientific society*

Universities Austria: Universities Austria is a non-profit association under private law. Its purpose is to assist the Austrian universities in the fulfilment of their tasks and responsibilities and thus to foster scholarship and research. Universities Austria handles the internal coordination of the 21 public Austrian universities, it represents them in national and international organisations and is the public voice of the universities. Furthermore, Universities Austria provides administrative and organisational support to the National University Federation (Dachverband der Universitäten). Universities Austria is funded through membership fees, paid by the universities. The fees are graded according to the size of the institutions.

The Austrian Science Fund (FWF) is Austria's central funding organization for basic research. The purpose of the FWF is to support the ongoing development of Austrian science and basic research at a high international level. In this way, the FWF makes a significant contribution to cultural development, to the advancement of our knowledge-based society, and thus to the creation of value and wealth in Austria.

The Austrian Research Promotion Agency (FFG) is the national funding agency for industrial research and development in Austria. As a "one-stop shop" offering a diversified and targeted programme portfolio, the FFG gives Austrian businesses and research facilities quick and uncomplicated access to research funding.

The Austrian Academy of Science: To meet its statutory mission of promoting the sciences in every respect,

and in the awareness of its social, cultural and economic responsibility, the Academy promotes and conducts application-oriented basic research. Renowned researchers from Austria and abroad have formed a comprehensive knowledge pool covering a wide array of disciplines for the sake of progress in science as a whole. All of the Academy's activities are closely networked at national, EU, and international level with university and non-university partners.

The Austrian Agency for Research Integrity (see above)

## Belgium / *Belgique*

Reply provided by the Belgian House of Representatives and Senate (10.05.2011)

*Observations préliminaires* :

1. L'objet du questionnaire qui nous est soumis est tellement vaste qu'il nous est impossible de répondre de manière exhaustive, d'autant qu'en tant que fonctionnaires parlementaires, nous ne possédons pas les compétences requises pour approfondir comme il se devrait une matière aussi spécifique qui n'a qu'un lien ténu avec le droit ou avec les procédures et activités parlementaires.
2. Pour plus de cohérence et compte tenu de la diversité des éléments d'information que nous sommes parvenus à recueillir, nous avons décidé de globaliser les réponses aux questions 1 et 2.
3. Nous ne répondrons pas à la question 3. La réponse à cette question doit, en effet, être donnée par des politiques ou des organes politiques. Or, nous ne sommes pas habilités à susciter la réponse de politiques dans le cadre du CERDP.
4. Nous ne citerons pas les normes européennes applicables en Belgique, puisqu'elles sont connues de l'institution qui nous soumet le questionnaire.

*QUESTIONS 1 et 2 :*

*1. In your country, what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research (outline and overview of the current state of play)?*

*2. Which institutions in your country are responsible for monitoring the ethical aspects of scientific research, i.e. possible danger to humans or the environment, as well as possible scientific misconduct? What procedures are used by these institutions?*

Pour plus de clarté, nous avons identifié quatre domaines de recherche et d'activité scientifiques qui nous paraissent les plus sensibles aux préoccupations éthiques et pour lesquels la demande d'encadrement normatif est, dès lors, la plus évidente. Il s'agit du secteur biomédical, du secteur de l'énergie nucléaire, du secteur du traitement et de la transmission de données et de la biologie végétale (en particulier, la recherche et les applications dans le domaine des OGMs).

Pour chacun des texte normatifs cités, nous indiquerons, dans toute la mesure du possible, les dispositions susceptibles de fournir des éléments de réponse concernant les aspects visés dans la question 2. Il est toutefois évident que les codes, chartes, etc., sont moins attentifs à ces aspects, dans la mesure où ils supposent généralement une adhésion volontaire et, partant, une volonté de les respecter.

Mais avant d'aborder chacun de ces domaines, nous attirons l'attention sur une tentative de synthèse des principes éthiques (menée à bien en juillet 2008), qui avait pour objet d'élaborer un code d'éthique applicable à toutes les disciplines. Il s'agit du *« Code d'éthique de la recherche scientifique en Belgique »* (http://www.belspo.be/belspo/home/publ/pub_ostc/Eth_code/ethcode_fr.pdf), qui résulte d'une initiative commune de l'Académie Royale des Sciences, des Lettres et des Beaux-Arts de Belgique, de l'Académie Royale de Médecine de Belgique, de la *Koninklijke Vlaamse Academie van België voor Wetenschappen en Kunsten* et de la *Koninklijke Academie voor Geneeskunde van België* et qui a été rédigé sous la houlette d'éminents représentants de ces académies, ainsi que du directeur général Coordination et Information du Service Public Fédéral de Programmation « Politique scientifique ».

Ce code se veut à la fois la synthèse des principes qui prévalent dans les différents domaines de la recherche scientifique en Belgique et une référence pour l'élaboration de nouvelles normes dans ces domaines ou pour l'établissement de codes dans des domaines non encore « codifiés ». Il ne reprend pas les lois et réglementations en vigueur, pour le motif que ces lois et réglementations doivent de toute manière être respectées. Il prévoit, d'une manière générale, que les écarts par rapport aux principes et règles qu'il énonce donnent lieu à des avis formulés par des personnes ou institutions qualifiées.

Après cette information préalable, nous nous penchons à présent sur chacun des domaines identifiés plus haut.

### A. Secteur biomédical (bioéthique)

1. *Loi du 7 août 1987 sur les hôpitaux* (http://www.ejustice.just.fgov.be/loi/loi.htm, puis sélectionner « Loi » et « Date promulgation »).

Cette loi crée des « comités locaux d'éthique », aussi dénommés « comités d'éthique biomédicale », qui ont pour mission de donner des avis sur les aspects éthiques de tous les protocoles d'expérimentation. La mission, la composition et le fonctionnement de ces comités sont précisés dans les Annexes, Annexe N1, III (Normes d'organisation), 9°*ter*, de *l'arrêté royal du 23 octobre 1964 portant fixation des normes auxquelles les hôpitaux et leurs services doivent répondre* (http://www.ejustice.just.fgov.be/loi/loi.htm, puis « Arrêté royal » et « Date promulgation »), modifié par l'arrêté royal du 12 août 1994. Concernant ces comités d'éthique, on se reportera également à la loi du 7 mai 2007 relative aux expérimentations sur la personne humaine (*cf.* ci-dessous).

2. *Loi du 7 mai 2004 relative aux expérimentations sur la personne humaine*
(http://www.ejustice.just.fgov.be/loi/loi.htm, puis « Loi » et « Date promulgation »).

Outre qu'elle réglemente ces expérimentations, cette loi élargit le rôle des comités locaux d'éthique et rend leurs décisions contraignantes dans le domaine de l'expérimentation clinique. Elle limite le nombre de comités et accroît, de ce fait, la responsabilité de chacun d'eux. Elle impose par ailleurs la déclaration d'éventuels conflits d'intérêts. (N.B. : Pour le rôle précis joué par les comités d'éthique, *cf.* le chapitre VIII de la loi.) On notera que cette loi prévoit, en son chapitre XII, la possibilité de suspendre ou d'interdire les expérimentations en cas d'infraction et instaure, en son chapitre XIV, un système de contrôle de la conformité des expérimentations avec les bonnes pratiques cliniques et les bonnes pratiques en matière de fabrication des médicaments expérimentaux.

Les principaux **comités d'éthique** s'organisent actuellement en **réseau** et collaborent avec le **« Comité consultatif national de bioéthique »**
(http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Commitees/Bioethics/index.htm)
Le Comité consultatif national de bioéthique est une instance indépendante des autorités publiques, qui a été créée par l'accord de coopération du 15 janvier 1993 signé par l'État fédéral et les Communautés française, flamande et germanophone. Il a pour mission :
- de rendre des avis sur les problèmes soulevés par la recherche et ses applications dans les domaines de la biologie, de la médecine et de la santé ;
- d'informer le public et les autorités sur ces problèmes.

3. *Loi du 11 mai 2003 relative à la recherche sur les embryons in vitro*
(http://www.ejustice.just.fgov.be/loi/loi.htm, puis « Loi » et « Date promulgation »).
On observera que cette loi crée, en son article 7, une « Commission fédérale pour la recherche médicale et scientifique sur les embryons in vitro », dont les missions sont définies à l'article 10, et prévoit des sanctions en ses articles 12, 13 et 14 (dont une sanction pénale pour la personne qui accomplit des actes interdits par la loi même).

4. *Arrêté royal du 6 avril 2010 relatif à la protection des animaux d'expérience*
(http://www.ejustice.just.fgov.be/loi/loi.htm, puis « Arrêté royal » et « Date promulgation »).
Cet arrêté royal crée, en son chapitre II, section 2, une « Commission d'éthique » auprès de chaque laboratoire, ainsi qu'un « Comité déontologique », institué auprès du Service Public Fédéral qui a le bien-être des animaux dans ses attributions.
Ce Comité déontologique formule des avis « relatifs aux expériences sur les animaux » à la demande du ministre ou d'une commission d'éthique. Ces avis peuvent entraîner la suspension ou le retrait, par le ministre, de l'agrément du laboratoire.

5. *Codes, directives et instructions* dans tous les départements de recherche de toutes les universités.

6. Les divers *avis rendus par les commissions et comités visés ci-devant* font également office de directives dans les disciplines qu'ils concernent.

### B. Secteur du traitement et de la transmission de données

1. *Loi du 8 décembre 1992 relative à la protection de la vie privée à l'égard des traitements de données à caractère personnel* (http://www.ejustice.just.fgov.be/loi/loi.htm, puis « Loi » et « Date promulgation).

Cette loi règle tous les aspects du traitement de données à caractère personnel, c'est-à-dire qu'elle réglemente toute opération ou ensemble d'opérations effectuées ou non à l'aide de procédés automatisés et appliquées à des données à caractère personnel, telles que la collecte, l'enregistrement, l'organisation, la conservation, l'adaptation ou la modification, l'extraction, la consultation, l'utilisation, la communication par transmission, la diffusion ou toute autre forme de mise à disposition, le rapprochement ou l'interconnexion, ainsi que le verrouillage, l'effacement ou la destruction de données à caractère personnel.

Elle institue, en son chapitre VII, une « Commission de la protection de la vie privée », qui
- émet des avis sur toute question relative à l'application des principes fondamentaux de la protection de la vie privée à l'égard des traitements de donnes à caractère personnel ;
- examine les plaintes qui lui sont adressées ;
- délivre les autorisations pour le traitement de ces données.

Les *avis* rendus par la commission visée ci-dessus contribuent également à constituer un corpus de règles à respecter.

### C. Secteur de l'énergie nucléaire

Il n'y a pas de loi ou de texte réglementaire belge qui concerne les aspects éthiques de la recherche ou de ses applications dans le domaine de l'énergie nucléaire.

Cependant, le SCK-CEN (*Studiecentrum voor Kernenergie*-Centre d'étude de l'énergie nucléaire), qui est une Fondation d'Utilité Publique (FUP) à statut de droit privé et a pour mission de maintenir un centre d'excellence ayant trait à l'énergie nucléaire et aux radiations ionisantes, a élaboré pour lui-même une *Charte éthique*, qui tend à fonder ses activités de recherche sur une culture de responsabilité à la fois interne et externe et matérialise le principe selon lequel l'ancrage des valeurs éthiques dans la recherche, la culture d'entreprise et la culture de sûreté et de sécurité est la condition essentielle pour une attitude responsable à l'égard du monde extérieur.

Certaines des grandes rubriques de cette charte (« Responsabilité concernant la santé et la sécurité des employés, des sous-traitants et de la société dans son ensemble », « Prévention à l'encontre de l'utilisation militaire ou illicite de la technologie et du savoir-faire nucléaires », « Protection de l'environnement et de la société, ainsi qu'un respect des intérêts des générations futures ») montrent plus particulièrement l'importance accordée à la responsabilité de l'entreprise et de ses employés à l'égard de la société.
On trouvera le texte de cette charte dans un fichier distinct joint à la présente note.

### D. Biologie végétale (OGMs, etc.)

Selon le professeur P. Dujardin (de la Faculté des Sciences agronomiques de Gembloux, *Plant Biology Unit*), il n'y a, *en Belgique*, ni charte, ni code, ni corpus déontologique dans le domaine de la recherche en biologie végétale, ce qui ne signifie cependant pas que rien n'est fait en matière de biosécurité.

Des normes ont, en effet, été fixées en matière de gestion et d'évaluation des risques, et ce, par une implémentation, dans les lois fédérales et décrets régionaux, des diverses directives, décisions, règlements et lignes directrices européens en rapport avec la biosécurité. Les décisions provenant des différentes structures administratives représentatives des différents niveaux institutionnels sont coordonnées grâce à l'existence d'un système commun d'évaluation scientifique de la biosécurité. Dans ce système, tous les aspects scientifiques devant être pris en compte dans le cadre des utilisations d'OGMs et d'organismes pathogènes sont évalués de manière coordonnée et indépendamment des règlementations spécifiques concernées. Ce système commun d'évaluation a été instauré par un Accord de coopération en matière de biosécurité (*cf.* le texte de cet accord : http://www.biosafety.be/COOPAG/COOPAGFR.html).

Pour les normes spécifiques concernant la dissémination volontaire d'OGMs dans l'environnement et la mise sur le marché d'OGMs, l'utilisation confinée d'organismes pathologiques et/ou génétiquement modifiés (y compris la recherche clinique) et la protection des travailleurs exposés à des agents biologiques, nous vous demandons de vous référer directement au site Belgian Biosafety
Server (http://www.biosafety.be/HomePageFR.html).

*QUESTION 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Pour la raison indiquée dans les Observations préliminaires, n° 3 (*cf.* le début de la présente note), nous ne répondrons pas à cette question.

*QUESTION 4: main organisations representing scientific society*

1. Académie royale de Médecine de Belgique :
2. Académie royale des Sciences, des Lettres et des Beaux-Arts de Belgique :
3. Comité d'éthique des Académies royales de Belgique :
http://www.armb.be/avis-code-ethique-recherche.htm
4. Comité consultatif national de Bioéthique :
http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Commitees/Bioethics/index.htm
5. Faculté universitaire des sciences agronomiques de Gembloux, Plant Biology Unit
Biologie végétale
6. Commission de la protection de la vie privée :http://www.privacycommission.be/fr/
7. Commission fédérale pour la recherche médicale et scientifique sur les embryons in vitro : http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Commissions/Embryoinvitro/index.htm
Commission Fédérale pour la recherche médicale et scientifique sur le Embryons in vitro (CFE)

8. Conseil consultatif de biosécurité : http://www.conseil-biosecurite.be/
9. Service de Biosécurité et Biotechnologie :http://www.biosafety.be/SBB/SBB_1.html
10. SCK/CEN (Centre d'Étude de l'Énergie nucléaire) :

Annexe : Charte éthique SCK•CEN

## Bulgaria / *Bulgarie*

Reply provided by the National Assembly (20.06.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific ?*

According to Art. 3 of the **Law of Encouragement of the Scientific Research** "the scientific research activity shall be based on the principles of ethics, transparency, publicity, accessibility and applicability". Art. 56 of the **Law for the Higher Education** stipulates that : "the members of the academic council shall be obliged to observe scientific and professional ethics". With these two general provisions ethics is raised as a major standard in science and related research. The question of ethics is particularly important in areas that directly affect the lives and health of people and animals. Therefore it is conceived that the medical ethics in the theoretical and in the practical aspect is ahead than the ethics in other scientific fields. In the **Law of Health** the regulations of Chapter Seven, Section IV "Medical scientific studies of people. Medical science" (Art. 197 – 208c) have a legal basis in Art. 29, para. 2 of the **Constitution**, where it is stated that "no one shall be subjected to medical, scientific or other experimentation without his voluntary written consent".

*Question 4: main organisations representing scientific society ?*

**Union of Scientists in Bulgaria** is an independent, non-governmental, non-profit, non-political, academic and professional organization of scientists. The main aim of the Union of Scientists in Bulgaria is to assist the advancement of science and higher education in the country, to promote their prestige and contribution to the prosperity of the Republic of Bulgaria./ www.usb-bg.org.

## Croatia / Croatie

Reply provided by the secretariat of the Education, Science and Culture Committee, Croatian Sabor (29.06.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific ?*

According to the Act on Scientific Activity and Higher Education (OG 123/03), scientific research should be based on freedom and autonomy in creativity, scientific ethics and transparency, meaning accessibility to the

public. The act emphasises the importance of higher education institutions being open to society, citizens and the local community as well as their interaction with society and the obligation of universities, polytechnics, colleges and public scientific institutes to develop the social responsibility of students and other members of the academic and scientific community (Article 2).

The Act on Genetically Modified Organisms (OG 70/2005) sets out procedures to be used for dealing with Genetically Modified Organisms (GMOs), and lists protective measures and sanctions including those which might be applied to laboratories. The Government of the Republic of Croatia has established a Council on GMOs (Article 56) composed of 17 members, recommended by relevant bodies, including scientific bodies. The Council gives opinions regarding the social, ethical, technical and technological, as well as scientific aspects, of using GMO. Material from human beings is explicitly excluded from the Act.

The Copyright and Related Rights Act (OG 167/2003) regulates the relationship between the ethics of electronic resources management and the policies and practices regarding issues of information ownership.

Other relevant acts:

- The Act on Animal Protection (OG 135/2006) regulates the use of animals for testing and in other aspects of scientific research.
- Decision on establishing the Bioethical Committee for following the genetically modified organisms (OG 50/00).
- Decision on establishing the National Bioethical Committee for Medicine (OG 35/01)
- Act on Transplanting Parts of Human Body for the Purpose of Medical Treatment (OG 177/04)
- Codex of Ethics in Medicine and Deontology (OG 47/04)
- Ethical Codex of Psychological Activity (OG 13/05)
- Patient Protection Act (OG 169/04)
- Decision on Establishing the Bioethical Committee for following GMO (OG 50/00)
- The Convention for the Protection of Human Rights and Dignity of the Human Being with Regards to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine was ratified by Croatian Parliament (March 1, 2003).

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research ? What procedures are used by these institutions?*

According to Article 112 of the Act on Scientific Activity and Higher Education, the Croatian Parliament appoints the **Committee for Ethics in Science and Higher Education** on the government's recommendation. This committee is composed of nine members who hold office for four years. Their work is based on the **Code of Ethics**. Committee aims to promote the principles and values of ethics in science, higher education, business and public life as well as in the way new technologies are used and environment protection.

The Committee adopts a Code of Ethics which it will use to determine the principles of ethics to be followed in higher education, scientific work, publication of results, relations between scientists, teachers and other participants in the scientific and educational process, conduct and actions connected with competition on the market, and relations with the public and the media. According to their status, higher education institutions, institutes and other scientific organisations are establishing their own **Committees for Ethics** and adopt their Code of Ethics.

When applying for the financial support of the Ministry of Science, a special statement on the importance of respecting ethical rules must be signed by scientists.

Details on the work of the Committee for Ethics in Science and Higher Education can be found on its web site http://www.azvo.hr/en/ethics-committee-in-science-and-higher-education

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Croatia supports the ethical requirements for participation in the EU Framework Programme, bearing in mind that the EC with its commitment to the Science and Society Action Plan gives ethics important role meaning, amongst other things, that the research should not involve (i) research activity aimed at human cloning for reproductive purposes; (ii) research activity intended to modify genetic heritage of human beings which could

make such changes heritable (iii) research activity intended to create human embryos solely for the purpose of research, or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Croatian researchers are encouraged to sign an ethical clause in contracts and to fulfil the ethical requirements. Croatian legislation mentioned in the previous question is presently the basis for fulfilling the ethical rules in research, although it does not specifically cover the areas specified in the request for participation in the FP7.

There are provisions and committees, on university and institutional level, dealing with ethically disputable research. However, the improvement should be made in the implementation of their decisions in the sense of consequences to the researchers who are breaching ethical rules.

*Question 4: main organisations representing scientific society ?*

National Council for Science, University of Zagreb, University of Rijeka, University of Split, University of Osijek, Institute Ivo Pilar, Institute Rudjer Boskovic; Croatian Foundation for Science.

## Cyprus / Chypre

Reply provided by the House of Representatives (08.07.2011)

*Question 1: In your country, what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

The legislative framework mainly consists of the following texts, which can be found in English in this link:
http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/538006E398361B89C22571C9002B25A1?OpenDocument
The Bioethics (establishment and function of the National Committee) Law of 2001 and the Operational Guidelines for the establishment of Ethics Committees in reviewing biomedical research involving human subjects in Cyprus.

The Law ratifying the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 2001.

*Question 2: Which institutions in your country are responsible for monitoring the ethical aspects of scientific research? What procedures are used by these institutions?*

The **National Bioethics Committee** is competent according to legislation for monitoring the ethical aspects of scientific research. The legislation also provides that the competences of the Committee regarding monitoring of ethical and scientific standards for carrying out biomedical research on human subjects can be assigned to Evaluation Committees and this has been put to practice.

Regarding the procedures used, they involve evaluation of applications for scientific researches and clinical trials and approval or disapproval of the proposed procedures. Further, the Committee provides recommendations and issues opinions to any competent person or body in the public, in the private sector as well as to the wider public, on bioethical issues.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Since the Members of the Committee are not appointed as full time members and also because of the fact that there is only minimum administrative support to the work of the Committee, the efficient monitoring of compliance of the approved scientific activities at the stage of their implementation, remains a challenge, even though there are legislative provisions which render the deviation from the approved procedures, a criminal offence. Further, the annual report of the Committee for the year 2009-2010 also notes that there is a need for the establishment of research and deontology committees within hospitals and other medical establishments, so that they facilitate the enhanced understanding and application of bioethical principles and related legislation.

Please note that, since the last expiry of the mandate of the Committee in 2010, the new Committee is yet to be appointed and thus this answer refers mainly to the administrative challenges faced by the Committee.

*Question 4: Could you indicate the main organisations representing scientific society?*

The Ministry of Health, the Institute of Neurology and Genetics, the Bank of Cyprus Oncology Centre and the University of Cyprus.

## Czech Republic / *République tchèque*

Reply provided by the Office of the Chamber of Deputies of the Parliament of the Czech Republic, Division of education and communication (28.06.2011)

*Question 1 : what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

In the Czech legislation, there are no specific provisions concerning sensitive questions of social responsibility in conducting scientific research. Particular research centers and institutions have their own **Commissions on Ethics**[27] or **Ethics Codes**.

Some aspects concerning research on human embryonic stem cells are governed by special legislation.[28]

Czech legislation on research:[29]

- Act No. 341/2005 Coll. on Public Research Institutions
- Act No. 342/2005 Coll. on the Amendments of Some Related Acts in connection with the Adoption of the Act on Public Research Institutions
- Act No. 130/2002 Coll. on State-Funded Research and Development Support and on the Amendment of Some Related Acts (the Act on the Support of Research, Experimental Development and Innovations)
- Government Regulation No. 267/2002 Coll. on the Research and Development Information System
- Act No. 283/1992 Coll. on the Academy of Sciences of the Czech Republic in the wording of Act No. 220/2000 Coll. and Act No. 342/2005 Coll.
- Community Framework for State Aid for Research and Development and Innovation (2006/C 323/01)
- Statute of the Czech Republic Government´s Research and Development Council (Annex to Government Resolution No. 82 + A of 19th January 2005)
- Statute of the Czech Research Foundation (Grant Agency of the Czech Republic) (Annex to Government Resolution No. 770+A of 7th August 2002, in the wording of Government Decree No. 305/2009 and Government Decree No. 1234/2009

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research ? What procedures are used by these institutions?*

Generally, there is no central institution responsible for monitoring the ethical aspects of scientific research in the Czech Republic. Research and Development Council established **Bioethical Commission** (this Commission is dealing with ethical aspects of scientific research).[30]

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

There are no problems with ethical principles when monitoring scientific activities.

*Question 4: main organisations representing scientific society*

[27] For example the Academy of Sciences of the Czech Republic

[28] Law No. 227/2006 Coll., on Research on Human Embryonic Stem Cells and Related Activities, as amended. English version available on: http://www.msmt.cz/vyzkum/act-on-research-on-human-embryonic-stem-cells-and-related-activities-and-on-amendment-to-some-related-acts-2

[29] Available in English on: http://www.cas.cz/veda_a_vyzkum/ or http://www.vyzkum.cz/FrontClanek.aspx?idsekce=15607

[30] http://www.vyzkum.cz/FrontClanek.aspx?idsekce=15908

Research and Development Council (advisory body of the Government of the Czech Republic) - http://www.vyzkum.cz/Default.aspx?lang=en (English)

Ministry of Education, Youth and Sports (the central administrative office responsible for research and development) - http://www.msmt.cz/vyzkum (Czech)

Academy of Sciences of the Czech Republic – http://www.cas.cz/veda_a_vyzkum/index.html (English)

## Estonia / Estonie

Reply provided by the Chancellery of the Riigikogu (09.06.2011)

*Question 1: Estonian regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research.*

**Organisation of Research and Development Act:**
http://www.legaltext.ee/et/andmebaas/tekst.asp?loc=text&dok=X60038K3&keel=en&pg=1&ptyyp=RT&tyyp=X&query=research+and+development
In Estonia Organisation of Research and Development Act principally regulates the sphere of scientific research. However, the Act does not contain sections about ethics.

**Medicinal Products Act:**
http://www.legaltext.ee/et/andmebaas/tekst.asp?loc=text&dok=X90009k2&keel=en&pg=1&ptyyp=RT&tyyp=X&query=ravimiseadus

**Human Genes Research Act:**
http://www.legaltext.ee/et/andmebaas/tekst.asp?loc=text&dok=X50010&keel=en&pg=1&ptyyp=RT&tyyp=X&query=inimgeeni

Human Genes Research Act stipulates work of the special **Ethics Committee** which is related to the processing procedures of the Gene Bank. (The assessment of the Ethics Committee is binding. The case is related to decoding the data.) The Ethics Committee acts pursuant to generally recognised ethical rules and international conventions.

**Personal Data Protection Act:**
http://www.legaltext.ee/et/andmebaas/tekst.asp?loc=text&dok=XXXX041&keel=en&pg=1&ptyyp=RT&tyyp=X&query=isikuandmete

**Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine***:* Convention on Human Rights and Biomedicine, concluded at Oviedo on 4 April 1997 – RT II 2002, 1, 2), and **Additional Protocol** to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, concluded in Paris on 12 January 1998 – RT II 2002. In Estonia: both came into effect on first of June 2002.

Also, the decree of Social Minister stipulates work of the **medical ethics committee** for clinical trials, consisting of scientists and representatives of different fields, which provides evaluation as to the ethics of the conduct of clinical trials of medicinal products with the aim to guarantee the protection of the rights, safety and well-being of trial subjects. The work of a committee is guided by the Act and other relevant legislation, good clinical practice, the Helsinki declaration of the World Medical Association and the statutes of the committee.

**Code of Ethics of Estonian Scientists in English:**
http://www.akadeemia.ee/_repository/File/ALUSDOKUD/Code-ethics.pdf

Estonian Academy of Sciences has created the *Code of Ethics of Estonian Scientists*. The Code is expected to regulate the relations amongst scientists and with the society. It will set benchmarks to help scientists to pass moral judgement over their own activity and that of their fellow scientists. The task of the Code of Ethics is to highlight the moral dimensions of science and the social responsibility of scientists. The problem of individual responsibility of a scientist has gained in significance lately, in view of the occasional inability of societal institutions to keep pace with the dramatic progress of science and technology.

*Question 2: Which institutions in your country are responsible for monitoring the ethical aspects of scientific research, i.e. possible danger to humans or the environment, as well as possible scientific misconduct? What procedures are used by these institutions?*

**Estonian Medical Association Ethics Committee** is engaged in introducing bioethical principles and the problems of medical ethics.

**Tallinn Ethics Committee on Medical Research** is an independent committee of experts that acts at the Institute of Health Development and gives ethical and legal assessments of planned research projects in order to ensure maximum safety for the subjects who participate in research. The objective of the Committee is to ensure the health and fundamental rights of persons who are subjects of research and in its activities the Committee abides by the Convention on Human Rights and Biomedicine of the Council of Europe "Protection of Human Rights and Dignity with regard to the Application of Biology and Medicine" (1997), the Helsinki Declaration of the World Medical Association (1964) and guidelines of good clinical practice. Homepage of the Committee: http://www.tai.ee/?id=1960

**Ethics Review Committee on Human Research of the University of Tartu**[31]. According to the Statute the Committee assesses the ethical aspects of human research in the field of medicine and natural sciences and other human research, if a danger to the physical or mental health of human(s) may occur with conducting the aforementioned research. Homepage of the Committee:
http://www.ut.ee/orb.aw/class=file/action=preview/id=954821/Tartu+%DClikooli+inimuuringute+eetika+komitee+statuut_eng_Dima_puhas.pdf
The **Ministry of Environment** is responsible for allowing genetically modified organisms into the environment, also responsible for marketing of genetically modified organisms and genetically modified products for import from other countries.

There is a committee issuing permits for the tests on animals at the **Ministry of Agriculture.**

Question 3: *What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Answers to this question are given by the Head of the Centre for Ethics of the University of Tartu, prof. **Margit Sutrop** and **Kristi Lõuk**, MA, Centre for Ethics, University of Tartu, Estonia.

Regarding the ethics committee the issue of subsidiary problem needs to be addressed. On the one hand it is expected that research project for instance will follow the requirements of the 7th framework program. On the other hand the approval will be made at local level at regional ethics committee and this will follow the rules of the country, not specifically the rules of the framework program. When the committee approves the application then it will not be later checked how the decision was made or how the research is conducted. This is not specifically the problem in Estonia, but it enables to show the need for more coordination at European level. For instance the need for more discussion at local, cultural level, for instance on the topic that are the guidelines what are there for research in biomedical ethics (with humans) also valid and appropriate for research done with humans in social sciences and humanities? Do social sciences and humanities need special ethics committees? Who are the people in ethics committees? How are they elected or appointed? Who will decide these issues and based on what? Should there be specific guidelines for that? What are the requirements that should be covered in informed consent for? Should there be guidelines for that?

It should be noted that different field in science have different awareness about ethical issues in research. Due to problematic history we can now say that knowledge in biomedical ethics about main issues is good, but we should move towards the understanding that ethics is relevant in all fields of research. From here we research the same issues already addressed earlier that is there need for different guidelines, so that every field has their own or not? Is there need for separate, different ethical review board or not? Should we broaden the competence of the biomedical ethics review boards so that they are able to cover the ethical issues of other fields as well or not? What institutions should have the regulatory power for control?

[31] Ethics Review Committee on Human Research of the University of Tartu:
http://www.ut.ee/orb.aw/class=file/action=preview/id=954821/Tartu+%DClikooli+inimuuringute+eetika+komitee+statuut_eng_Dima_puhas.pdf

Improvement what is needed is to have more special training for researchers, to raise their understanding about ethical issues.

There is a need to establish a committee for handling scientific misconduct. It should be debated by which institution this should be established, should it be the ministry of education and research or by the Estonian Academy of Sciences?

Improvements can be made by having a platform for changing experiences. For instance there are NEC meetings or CDBI has meetings, but this covers mostly biomedical research. Also more meetings at local or regional level would be of help (e.g. Nordic-Baltic).

Last, but not least the European support should be in form by issuing strong requirements that governments should follow. In case there are no strict requirements about what is expected from (national) ethics committee and why they are needed, the state has no initiative to find funding for these institutions and their stuff.

Good overview about ethics in Estonia one can find at the homepage of the Centre for Ethics of the University of Tartu: http://www.eetikakeskus.ut.ee/index.aw/set_lang_id=2;
http://www.ethics.ut.ee/research/regulations

## Finland / Finlande

Reply provided by the research service, Eduskunta – Parliament of Finland (23.06.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

The following legislation concerning research ethics is in effect in Finland:

**Medical Research Act (488/1999)**
- key statute regulating research
- contains provisions on general conditions governing medical research, medical research on persons, clinical trials on medicinal products, and research involving embryos and fetuses, among other things

**Act on the Status and Rights of Patients (785/1992)**
- contains provisions on examination plans and handing over patient documents, among other things

**Act on the Medical Use of Human Organs and Tissues (101/2001)**
- contains provisions on medical research in connection with post-mortem examinations and procedures for using tissue samples for other purposes, among other things

**Act on the Use of Animals for Experimental Purposes (62/2006)**
- contains provisions on requirements for using animals for experimental purposes, supervising authorities, permits and research methods, among other things

**Act on the Openness of Government Activities (621/1999)**
- contains provisions on access to official documents, non-disclosure and the use of documents for scientific research, among other things Personal Data Act (523/1999)
- broad act regarding the processing of personal data
- contains requirements regarding the processing of personal data for research purposes, among other things

**Gene Technology Act (377/1995)**
- contains provisions on the contained use of genetically modified organisms, their deliberate release into the environment and the launch and operation of installations and premises intended for the handling of genetically modified organisms

The National Advisory Board on Research Ethics (see answer 2) has prepared **guidelines on good scientific practice and procedures for handling misconduct and fraud in science**. These guidelines seek to outline good scientific practice and violations of it in multidisciplinary terms. The aim is to promote

good scientific practice and prevent scientific dishonesty in all public organizations conducting research. The guidelines contain procedures for handling alleged violations of good scientific practice. The research community must naturally comply with legislation, which takes precedence over the guidelines.

The guidelines cover all fields of science. The research community is broadly committed to the guidelines, although they are part of a voluntary system. In addition to guidelines on research ethics, different fields of science have their own ethical norms. The Academy of Finland has also published guidelines on research ethics based on those issued by the National Advisory Board on Research Ethics.

You will find the guidelines in English here:
http://www.tenk.fi/en/resposible-conduct-research-guidelines

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research ? What procedures are used by these institutions?*

**Monitoring of ethical considerations (possible danger to humans or the environment)**

*a) Medical research*

The Medical Research Act (488/1999) prescribes that each hospital district with a university providing medical education in its region shall have at least one ethics committee (regional ethics committee). **The regional ethics committee** shall monitor guide and evaluate the handling of matters pertaining to research ethics in its region. Each regional ethics committee consists of a chair and at least six other members. These are appointed by the board of the hospital district.

**The National Committee on Medical Research Ethics**, which operates in connection with the National Supervisory Authority for Welfare and Health, is responsible for delivering an opinion on clinical drug trials. It consists of a chair, a deputy chair and a maximum of 14 other members, who are appointed by the Government for a term of four years.

*b) Animal experiments*

According to the Act on the Use of Animals for Experimental Purposes (62/2006), animal experiments may be carried out only with authorization by **the Animal Experiment Board**. The Animal Experiment Board is responsible for processing applications for authorization to perform animal experiments and granting authorization for such experiments. The Animal Experiment Board is appointed by the Government for a term of five years on the basis of a proposal by the Ministry of Agriculture and Forestry.

*c) Gene technology*

The point of departure in legislation regarding gene technology is that the use of gene technology may involve unknown risks to human health and the environment and that these risks should be minimized. Consequently notification of the use of genetically modified organisms must always be sent to the competent authority, **the Board for Gene Technology**. This board is appointed by the Government for a term of five years on the basis of a proposal by the Ministry of Social Affairs and Health, to which it is linked. The Gene Technology Act (377/1995) prescribes the board's duties

The supervisory authorities referred to in the Gene Technology Act are the National Product Control Agency for Welfare and Health, which supervises the contained use of and, in respect of health issues, the deliberate release into the environment of genetically modified organisms; the Finnish Environment Institute, which supervises the deliberate release into the environment of genetically modified organisms in respect of environmental issues; and the Finnish Plant Production Inspection Centre, which supervises the deliberate release into the environment of genetically modified organisms in the field of agriculture and forestry. If necessary, the Board for Gene Technology determines which supervisory authority is competent in a particular matter regarding the deliberate release into the environment of genetically modified organisms.

The Board for Gene Technology and the supervisory authorities have the right to conduct inspections in order to monitor compliance with the provisions in the Gene Technology Act.

*d) Research in the humanities and social and behavioral sciences*

The National Advisory Board on Research Ethics has prepared **guidelines** on ethical review in the humanities and social and behavioral sciences. Following its recommendation, **ethical committees** have

been established to evaluate research proposals. Ethical committees operate on an organizational or regional basis. Their task is to give a statement on the ethical acceptability of a planned study.

An ethical review examines the plan for collecting data, how the study will be carried out, the information that will be given to subjects and the plan for processing and storing data from the perspective of avoiding risks and harm. The review weighs possible negative impacts or harm to subjects resulting from participation in a study in relation to the potential scientific value of the study. Criteria are always based on accepted ethical principles in the humanities and social and behavioral sciences, i.e. the autonomy of research subjects, avoiding harm, privacy and data protection. The guidelines on ethical review are intended for post-graduate research, since it is the task of thesis supervisors to ensure that thesis work complies with ethical principles.

You will find the guidelines in English here:
http://www.tenk.fi/en/ethical-review-human-sciences

**Monitoring of ethical consideration (possible misconduct or fraud in science)**

**The National Advisory Board on Research Ethics** operates in connection with the Federation of Finnish Learned Societies under the Ministry of Education and Culture. It was established in 1991.

The National Advisory Board on Research Ethics consists of a chair, a deputy chair and eight other members. These are appointed by the Ministry of Education and Culture for a term of three years. The board must include representatives from major scientific fields from the viewpoint of research ethics and key supervising authorities. It meets seven times a year. Its decisions are issued in the form of recommendations that are not legally binding. The board focuses on discussion and information activities in its field and the preparation of general guidelines on research ethics. The research community is responsible for **self-regulation** in applying guidelines within the framework of legislation. The board does not take part in inquiries or investigations or arrange hearings concerning alleged violations of good scientific practice.

The board's guidelines on good scientific practice and procedures for handling misconduct and fraud in science define violations of good research practice as a lack of professional ethics which precludes high quality research. Violations of good scientific practice have been divided into two categories: misconduct in science and fraud in science. Misconduct in science is manifested as gross negligence and irresponsibility especially in the conduct of research (such as careless and hence misleading reporting of research findings and methodology). Fraud in science means deceiving the research community and often decision-makers as well. Manifestations of fraud include fabrication, misrepresentation, plagiarism and misappropriation.

In Finland organizations that conduct scientific research are primarily responsible for promoting good scientific practice and dealing with alleged misconduct and fraud in science. International comparisons have shown that Finland's system functions well and can serve as a model of self-regulation.

**Other national expert bodies**
In addition to the above, Finland has a number of other organizations at the national level that coordinate and promote research ethics, work to standardize practices and monitor the development of science.

**The National Advisory Board on Social Welfare and Health Care Ethics** discusses general principles concerning ethical issues in the field of social welfare and health care and the status of patients and clients. Its tasks are prescribed in the Government Decree on the National Advisory Board on Social Welfare and Health Care Ethics (667/2009). Members must be selected so that they represent the views of service users, service providers, personnel, legal experts and researchers in the social welfare and health care field, as well as society at large. At least four of them must be Members of Parliament.

**The Cooperation Group for Laboratory Animal Sciences** was established jointly by the Ministry of Education and Culture and the Ministry of Agriculture and Forestry. Its task is:
- to coordinate research and education involving laboratory animals;
- to promote ethical principles in animal experiments and the welfare of laboratory animals;
- to promote education in fields involving animal experiments.

The Cooperation Group for Laboratory Animal Sciences consists of a chair, a deputy chair, a secretary and nine members. These represent researchers and experts employed by universities, research institutes and industry. The cooperation group has three subgroups, which focus on education, ethics and information.

**The Advisory Board on Biotechnology** is a consultative body of experts in issues related to bio- and gene technology. Its key objectives include research ethics, the dissemination of information and public

consultation on matters involving gene technology. According to the Government Decree on Gene Technology (928/2004) its duties are:
- to promote cooperation between authorities, research in the field and operators in the field of biotechnology and in particular gene technology, as well as to organise information and training in the field;
- to monitor and promote international cooperation in biotechnology;
- to monitor in particular the developments and research in gene technology, as well as its health and environmental impacts;
- to promote the taking into account of ethical considerations in gene technology;
- to attend to other duties relating to biotechnology assigned to it by the relevant ministries.

The Advisory Board on Biotechnology is appointed by the Government for a term of three years on the basis of a proposal submitted by the Ministry of Social Affairs and Health. It includes representatives of supervising authorities, key business, consumer and industrial organizations and researchers working in different fields of gene technology.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

According to information obtained from the National Advisory Board on Research

Ethics, problems are linked to cases in which fraud is suspected. Research organizations prefer to avoid this kind of awkward situation and are hesitant to launch an investigation. Another problem concerns the legal security of anyone who reports suspected fraud. A young researcher who suspects that a professor has misused research findings, for example, will think twice before contacting the rector.

According to information supplied by the Ministry of Education and Culture, cases of fraud are relatively rare in Finland. Instruction in research ethics is provided in universities as part of degree work and especially during post-graduate work. This instruction should be compulsory at more universities.

The National Advisory Board on Research Ethics noted that the research ethics control system functions all right in itself, but some activities fall in a grey area. In other words they may not constitute fraud in a strict sense but are scientifically questionable. Ethical guidelines must keep up with the times and be revised when this is necessary.

*Question 4: main organisations representing scientific society*

National Advisory Board on Research Ethics

## France

Réponse préparé par la division de l'office parlementaire des choix scientifiques et technologiques de l'Assemblée nationale (11.7.2011)

*Question 1 : Quelles lois, réglementations et recommandations/directives officielles sont en vigueur dans votre pays concernant les questions clés que sont la responsabilité sociale en matière de conduite de la recherche scientifique et l'éthique de la recherche scientifique ?*

La loi 2011- 814 du 7 juillet 2011 sur la bioéthique en cours d'adoption modifiera à la margelles pratiques décrites.
http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000024323102&dateTexte

On distingue actuellement trois types de recherches : les recherches biomédicales, correspondant à l'ancien cadre de la loi n° 88-1138 du 20 décembre 1988, dite loi « Huriet-Sérusclat » ; les recherches *« visant à évaluer les soins courants »,* issues de la loi n° 2004-806 du 9 août 2004 de santé publique et les recherches non interventionnelles ou observationnelles, introduites par cette même loi.

**1-La loi n° 88-1138 du 20 décembre 1988** relative à la protection des personnes qui se prêtent à des recherches biomédicales, dite loi « Huriet-Sérusclat », affirme la légalité de la recherche, en organisant le dispositif d'encadrement à partir de trois principes généraux : *« Aucune recherche ne peut être effectuée sur l'être humain :*
*– si elle ne se fonde pas sur le dernier état des connaissances scientifiques et sur une expérimentation pré-*

*clinique suffisante ;*
*– si le risque prévisible encouru par les personnes qui se prêtent à la recherche est hors de proportion avec le bénéfice escompté pour ces personnes ou l'intérêt de cette recherche ;*
*– si elle ne vise pas à étendre la connaissance scientifique de l'être humain et les moyens susceptibles d'améliorer sa condition ».* Elle établit en outre une distinction entre les recherches avec ou les recherches sans bénéfice individuel direct (ABID / SBID). Elle vise également à garantir la protection des personnes, en définissant les conditions de leur participation aux recherches, en instaurant un régime déclaratif donnant la possibilité aux autorités compétentes de suspendre des projets jugés non conformes, et en créant les comités consultatifs de protection des personnes en matière de recherche biomédicale (CCPPRB), qui rendent des avis sur les conditions de validité de la recherche.

Ce double impératif – encadrer la recherche et protéger les personnes qui s'y prêtent – constitue le socle du droit français en matière de recherches sur l'être humain.

**Depuis les premières modifications de la loi « Huriet-Sérusclat » par la loi n° 90-86 du 23 janvier 1990 et la loi n° 94-630 du 25 juillet 1994, le dispositif légal applicable aux recherches biomédicales a connu plusieurs adaptations récentes.**

**2- la loi n° 2002-303 du 4 mars 2002** relative aux droits des malades et à la qualité du système de santé, dite loi « Kouchner », a renforcé les règles concernant le recueil du consentement de la personne, ou d'une personne de confiance ou d'un proche lorsque la personne est hors d'état d'exprimer sa volonté.

**3-La loi n° 2004-806 du 9 août 2004 relative à la politique de santé publique a notamment eu pour objet d'assurer la transposition de la directive européenne n° 2001-20-CE du 4 avril 2001 relative au rapprochement des législations applicables aux bonnes pratiques cliniques dans la conduite d'essais de médicaments à usage humain.** Elle a introduit plusieurs innovations importantes par rapport au dispositif de la loi de 1988, parmi lesquelles :

– la suppression de la distinction entre recherche avec bénéfice individuel direct et recherche sans bénéfice individuel direct, remplacée par un examen des projets de recherche fondé essentiellement sur l'évaluation du bénéfice escompté pour la personne ou l'intérêt pour la santé publique au regard du risque prévisible encouru ;

– le remplacement du régime de déclaration par un régime d'autorisation préalable par l'autorité compétente (l'Agence française de sécurité sanitaire des produits de santé – AFSSAPS – pour les recherches portant sur les médicaments et certains produits de cosmétique et d'hygiène corporelle, et le ministère chargé de la santé dans les autres cas) ;

– la transformation des CCPPRB en comités de protection des personnes (CPP), à la composition élargie et aux compétences étendues ;

– le renforcement des conditions de participation des personnes vulnérables aux recherches biomédicales de façon à renforcer leur protection ;

– la création d'une procédure spécifique pour les recherches visant à évaluer les soins courants, définies par un décret n° 2006-477 du 26 avril 2006 comme celles *« dont l'objectif est d'évaluer des actes, combinaisons d'actes ou stratégies médicales de prévention, de diagnostic ou de traitement qui sont de pratique courante, c'est-à-dire faisant l'objet d'un consensus professionnel, dans le respect de leurs indications ».*

La loi n° 2004-801 du 6 août 2004 relative à la bioéthique a mis en place un système de déclaration des collections de produits biologiques au ministère de la recherche et d'avis des CPP sur l'information et le consentement des personnes à l'origine des prélèvements.

La loi n° 2006-450 du 18 avril 2006 de programme sur la recherche a introduit des dispositions portant sur la prise en charge par les caisses d'assurance maladie des médicaments ou produits faisant l'objet d'une recherche biomédicale autorisée.

Enfin, la loi n° 2008-337 du 15 avril 2008 ratifiant l'ordonnance n° 2007-613 du 26 avril 2007 portant diverses dispositions d'adaptation au droit communautaire dans le domaine du médicament a fait de l'AFSSAPS la seule autorité compétente en matière de recherche biomédicale, les compétences jusqu'ici exercées par le ministère de la santé dans ce domaine lui étant transférées.

**Une proposition de loi déposée par le député M Olivier Jardé votée en deuxième lecture par le Sénat et l'Assemblée nationale** est depuis **novembre 2010**, en attente de saisine de la Commission mixte paritaire crée une catégorie unique de recherches sur la personne, assortie de règles communes. La création d'un droit commun de la recherche sur la personne est un signal fort puisqu'elle reconnaît l'intérêt scientifique commun de ces catégories de recherche et fonde leur distinction par rapport aux autres types de recherche sur leur sujet d'étude, l'homme, considéré dans son intégralité.

Visant à encourager la recherche sur l'homme, la proposition de loi accroît également la protection dont celui-ci bénéficie en l'associant plus étroitement au processus de recherche. Les règles d'information et de recueil de consentement ou d'opposition seront précisées pour chaque type de recherche et toutes les recherches devront recevoir l'autorisation préalable d'un comité de protection des personnes.

Le texte propose ensuite de définir les catégories de recherches sur la personne en fonction des risques encourus par les personnes qui s'y prêtent et fait bénéficier chacune d'un encadrement détaillé, gradué en fonction de ces risques.

Enfin, la proposition de loi simplifie un certain nombre de démarches afin d'encourager et de sécuriser la recherche.

Si cette proposition de loi était adoptée, les recherches sur la personne seraient désormais distinguées selon un seul critère, celui de l'intervention. C'est la graduation de ces interventions qui distinguera désormais les différentes catégories de recherche :

-**les recherches interventionnelles** définies par la proposition de loi comme des recherches « *comportant une intervention non justifiée par la prise en charge médicale habituelle de la personne* ». Elles remplaceraient les actuelles recherches biomédicales. Le droit applicable, notamment les règles de consentement (accord écrit) et l'autorisation préalable d'un comité de protection des personnes et de l'autorité compétente, ne change pas.

**-Les recherches « interventionnelles ne comportant que des risques et des contraintes négligeables et ne portant pas sur des médicaments » se substituent aux actuelles recherches « visant à évaluer les soins courants ».** Le champ couvert par cette définition est légèrement plus vaste que l'actuelle puisqu'il fait entrer dans cette catégorie des interventions sans risque : prise de sang ou imagerie non invasive, par exemple

-**Un cadre nouveau pour les recherches non interventionnelles, ou observationnelles** apports majeurs, demandé par la communauté scientifique internationale car la Commission européenne a publié, en mars 2007, une ligne directrice dans le domaine des essais non interventionnels, A, qui est une incitation à réglementer ce domaine adressée aux États membres.

*Question 2 : Quels sont, dans votre pays, les institutions qui sont chargées de contrôler les aspects éthiques de la recherche scientifique ? Quelles procédures utilisent ces institutions ?*

Plusieurs organismes interviennent en France pour assurer un suivi éthique des essais cliniques et plus généralement des nouvelles technologies.

**-Au niveau local, les comités de protection des personnes** (CPP) ont aux termes de la loi du 9 août 2004, leur confie en effet, de facto, un rôle de co-décideur dans l'autorisation des recherches biomédicales.
L'article L.1123-6 du code de la santé publique (introduit par la loi du 9 août 2004) précise ainsi que « *avant de réaliser une recherche biomédicale sur l'être humain, le promoteur est tenu d'en soumettre le projet à l'avis de l'un des comités de protection des personnes compétents pour le lieu où l'investigateur ou, le cas échéant, l'investigateur coordonnateur, exerce son activité* ».
Les CPP disposent de deux collèges un collège scientifique au sein du premier siègent des personnes ayant une qualification et une expérience approfondie en matière de recherche biomédicale, dont au moins deux médecins et une personne qualifiée en raison de sa compétence en matière de bio statistique ou d'épidémiologie ; le second rassemble des représentants des associations de malades et d'usagers du système de santé, un psychologue, un travailleur social et des personnes qualifiées choisies en fonction de leurs compétences en matière juridiques ou en matière d'éthique.

**- Au niveau national *: Le Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé (CCNE)*** *a pour mission de donner des avis sur les problèmes éthiques et les questions de société soulevés par les progrès de la connaissance dans les domaines de la biologie, de la médecine et de la santé. »*

Toutes les missions du CCNE sont inscrites dans la loi de bioéthique du 6 août 2004 (loi n° 2004-800) qui lui confère le statut d'autorité indépendante

Le CCNE peut être saisi par le Président de la République, le président de l'Assemblée nationale, le président du Sénat ou un membre du Gouvernement, ainsi que par un établissement d'enseignement supérieur, un établissement public ou une fondation, reconnue d'utilité publique. Ces établissements ou fondations doivent avoir pour activité principale la recherche, le développement technologique ou la promotion et la protection de la santé. Il peut également se saisir de questions posées par des personnes autres que celles qui sont mentionnées à l'alinéa ci-dessus ou par un ou plusieurs de ses membres.

L'Agence de la biomédecine, la Haute autorité de santé, l'agence française de sécurité sanitaire des produits de santé interviennent également, (voir leur site en français ou anglais). Par ailleurs, les grands organismes de recherche CNRS, INSERM INRA disposent de Comités d'éthique.

*Question 3 : Quels sont, d'après vous, les problèmes qui existent au niveau du fonctionnement du système juridique et institutionnel de votre pays s'agissant de contrôler le respect de l'éthique dans les activités scientifiques ? Quelles améliorations faudrait-il apporter et mettre en œuvre ? Qu'attendez-vous des institutions européennes ?*

Il serait souhaitable qu'il y ait une meilleure coordination entre les différents organismes et qu'à l'échelon européen, on assiste à une harmonisation des procédures et des pratiques.

*Question 4 : Pouvez-vous indiquer les organisations principales qui représentent la communauté scientifique dans votre pays, qui seraient susceptibles de transmettre à la commission de la culture, de la science et de l'éducation leur avis sur cette question?*

Les Académies sont susceptibles de jouer ce rôle : Académie de sciences, Académie nationale de médecine, Académie des technologies, etc.

## Georgia / Géorgie

Reply provided by the Parliament of Georgia (30.06.2011)

In reply to your request on "The Ethics of Science" we would like to inform you that according to the Georgian legislation the only legal formulation dealing with the ethical provisions of scientific research is the following statement of article 6 of the Law on National Scientific Academy of Georgia: g) The General Meeting of the National Scientific Academy of Georgia considers the scientific ethical issues.

There are no other legal definitions and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research in Georgia.

## Germany / *Allemagne*

Reply provided by Bundestag, Germany (1.8.2011)

*Question 1: Laws concerning ethical aspects of scientific research*

1. Research on humans
2. Research on animals
3. Handling of human biological material

Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz - AMG)
Medicinal Products Act (The Drug Law)
http://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html

Gesetz über genetische Untersuchungen bei Menschen (Gendiagnostikgesetz - GenDG) (in round terms: law on gene diagnostics)
http://www.gesetze-im-internet.de/gendg/BJNR252900009.html

Gesetz über Medizinprodukte (Medizinproduktegesetz - MPG) (in round terms: Medical Products Act)
http://www.gesetze-im-internet.de/mpg/BJNR196300994.html

Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz - ESchG) (in round terms: Embryo Protection Act)
http://www.gesetze-im-internet.de/eschg/BJNR027460990.html

Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen (Stammzellgesetz - StZG) (in round terms: Law on stem cells)
http://www.gesetze-im-internet.de/stzg/BJNR227700002.html

Tierschutzgesetz (in round terms: Animal Protection Act)
http://bundesrecht.juris.de/tierschg/BJNR012770972.html

Gesetz über die Spende, Entnahme und Übertragung von Organen und Geweben (Transplantationsgesetz - TPG) (in round terms: law on transplantation)
http://bundesrecht.juris.de/tpg/BJNR263100997.html

Gesetz zur Einrichtung des Deutschen Ethikrats (Ethikratgesetz - EthRG) (in round terms: Ethics Commission Act)
http://www.gesetze-im-internet.de/ethrg/BJNR138500007.html

*Question 2: Institutions responsible for monitoring the ethical aspects of scientific research:*

Biomedical scientific projects concerning humans (p. e. research based on surveys, research with human cell material or direct medical tests on humans, research with personalized data) have to be approved prior to their beginning by an ethical committee which is build up by federal state law (16 federal states in Germany). The Committees evaluate scientific quality, the juridical acceptance and the ethical tenability of the project.

Since 2004 the approval of an Ethics Committee is obligatory before clinical trials with the aim of drug approval can be commenced. In other areas of biomedical research the vote of the Ethics Committee is not obligatory but generally recommended.

The Ethics Committees for the Evaluation of biomedical research projects are installed directly at the site of the medical faculties, at the universities and at the federal chambers of physicians. The federal states of Berlin, Bremen and Sachsen-Anhalt have installed their Ethic Committees for clinical trials for drug approval within the federal administration.

The detailed regulation about composition, competence, by-laws, procedures etc. of the Ethic Committees vary and are regulated by federal state law. In general the Ethics Committees are built up from members of different disciplines especially experts for ethics and theology on the one hand and medical and scientific experts on the other hand.

By 27th of December 2007 the German government made a report for the German Bundestag about the experiences with the current system of diverse Ethics Committees. Subsequent to this report the system is approved and no major changes were recommended. The full report is available under:
http://www.bundesaerztekammer.de/downloads/StellKlinPruef20070511.pdf

An overview about the Ethics Committees for approval of projects in the area of biomedical research can be found here: http://www.ak-med-ethik-komm.de/index.html

Subsequent to the German law on stem cells (Stammzellgesetz) each project dealing with experiments on human embryonic stem cells has to be approved by a central Ethics Committee which has been installed at the Robert Koch Institute. Four experts of ethics or theology and five experts of biology and medicine are nominated into the Committee following to §8 of the law. The government decides on the nomination for a period of three years.

*Question 4: Main organisations representing scientific society in Germany*

Max-Planck-Gesellschaft http://www.mpg.de/de
Hinweise und Regeln der Max-Planck-Gesellschaft zum verantwortlichen Umgang mit Forschungsfreiheit und Forschungsrisiken (References and rules of the Max Planck Society on responsible care with the freedom of research and risks of research)
http://www.mpg.de/200127/Regeln_Forschungsfreiheit.pdf

Deutsche Forschungsgemeinschaft – Verhaltenscodex: Arbeit mit hochpathogenen Mikroorganismen und Toxinen (Deutsche Forschungsgemeinschaft – Code of Conduct: Work with highly pathogenic microorganisms and toxines)
http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2008/codex_dualuse_0804.pdf

Helmholtz-Gemeinschaft Deutscher Forschungszentren http://www.helmholtz.de/
Leibniz-Gemeinschaft http://www.leibniz-gemeinschaft.de/
Deutsche Forschungsgemeinschaft http://www.dfg.de/index.jsp

Fraunhofer-Gesellschaft http://www.fraunhofer.de/
Arbeitsgemeinschaft industrieller Forschungsvereinigungen e.V. (AiF)
http://www.aif.de/home.html
Deutsche Referenzzentrum für Ethik in den Biowissenschaften (DRZE)
http://www.drze.de/
Institut für Wissenschaft und Ethik (IWE)
http://www.iwe.uni-bonn.de/deutsch/index_mo14.html

## Greece / *Grèce*

Reply provided by the Greek Parliament (23.06.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

Greece has a detailed legislation regarding social responsibility and ethics in scientific research, particularly in the broad area of life sciences and medicine. Relevant provisions exist for

a) Research in humans (clinical trials), as governed by
- The Oviedo Convention on Human Rights and Biomedicine (Act 2619/1998, art. 15 – 17),
- Act 3418/2005 "Code on Medical Ethics" (art. 24 – 27)
- Directives 2001/20/EC (ministerial decision ΥΑ ΔΥΓ 3/89292/2003), 2005/28/EC (ministerial decision ΔΥΓ 3 α/79602/2007)

b) Research in human embryos, as governed by
- the Oviedo Convention on Human Rights and Biomedicine (Act 2619/1998, art. 18)
- Acts 3089/2002 (art. 1459 C.C.) and 3305/2005 (art. 11, 12)

c) Research in vertebrate animals, as governed by
- Act 2015/1992
- Presidential Decree 160/1991 (Directive 86/609/EC)

The Hellenic National Bioethics Commission (HNBC) has issued a number of recommendations concerning the above topics[32] and a special opinion on the "Research Ethics in the Biological Sciences"[33].

Below you may find all legal texts that are of relevance to bioethics. We have included few non-binding documents, such as Declarations, that we consider them to be important texts of reference. Texts are grouped into thematic categories –Biomedicine, Transplantations, Assisted Reproduction, Cloning, Patents, Animals in Research, Biodiversity - permitting a user-friendly navigation of the site (http://www.bioethics.gr/category.php?category_id=68).

*Question 2: Which institutions in your country are responsible for monitoring the ethical aspects of scientific research, i.e. possible danger to humans or the environment, as well as possible scientific misconduct? What procedures are used by these institutions?*

There are special institutions responsible for monitoring the ethical aspects of research. In particular:
1. For research in humans, the **National Ethics Committee for Clinical Trials**
2. For research in embryos, the **National Authority for Medically Assisted Reproduction**
3. For research in animals, the district veterinary services and the **Central Direction of Protection of Animal Production** (Ministry of Rural Development and Food)

All these institutions are entitled to *approve* research protocols and to *monitor* their implementation. *No research can be performed in these areas, without such a previous official approval.*

[32] See: http://www.bioethics.gr/media/pdf/recommendations/recom_clinical_trials_en.pdf
http://www.bioethics.gr/media/pdf/recommendations/recs_opinion_en.pdf
http://www.bioethics.gr/media/pdf/recommendations/recom_stem_cells_eng.pdf
http://www.bioethics.gr/media/pdf/recommendations/animals_recom_english.pdf
[33] See: http://www.bioethics.gr/media/pdf/recommendations/reseth-opin-en.pdf
http://www.bioethics.gr/media/pdf/recommendations/research_ethics_code.pdf
http://www.bioethics.gr/media/pdf/recommendations/guide.pdf

The HNBC is responsible to provide specific information and guidance (if asked) to these institutions.

Two other bodies are investigating the ethical, social and legal aspects of Science:

**National Bioethics Commission** (http://www.bioethics.gr/index.php?category_id=3)

The Commission is composed of nine (9) members, distinguished scientists, appointed by the Prime minister for a term of five years. The Commission is an independent advisory body of experts addressed to public authorities either by its own initiative or upon request. Its mission is to highlight the interaction of life sciences and contemporary social values. More particularly the Commission :
(a) investigates the ethical, social and legal aspects that arise from scientific advances in biology, biotechnology, medicine and genetics,
(b) outlines, in collaboration with the respective ministries, proposals of general policy and provides specific recommendations on related issues,
(c) collaborates with international organizations and related bodies and represents Greece to international fora, and
(d) informs the public on issues related to biotechnological advances and the impact of their applications promoting public awareness and dialogue.

The Commission has also the responsibility to co-ordinate other relevant committees at a national level. More details can be found in the Commission's founding law (see attached files, Law No 2667/1998) and the rules of procedure (see attached files). The General Secretariat of the Government supports the Commission on a financial and administrative level.

**Parliamentary Special Permanent Committee on Research and Technology**
Parliamentary Special Committee on Research and Technology is a committee provided by the Standing Orders of the Greek Parliament. It is instituted at the onset of every Regular Session of the Parliament to study national affairs or issues of general interest that emerge from technology development and scientific research. It consists of 17 Members of Parliament representing all the parliamentary groups in the House. Its task covers any matter within the sphere of the technology development so as to give advice on strategy on technological field. It also monitors matters related to bioethics, as recent advancements in science increases the concern that scientific progress is not always acceptable from an ethical point of view. Benchmarks, ethical principles and standards have to be established to guide scientific progress and the Committee could set the ethical criteria on which legislation or other regulations about the ethics of science should be based.

It is a regular member of EPTA Network (European Parliamentary Technology Assessment).The scientific support of its work is undertaken by the Directorate of Studies of the Hellenic Parliament. Several scientists and researcher fellows participate to the discussion meetings of the committee in order to present their point of view on such matters.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

There are two major problems in this respect:

A) Scientists and research personnel do not receive special education or training on research ethics, therefore they are not sufficiently aware of relevant requirements

B) Research Ethics Committees (RECs) are very rare in local universities, hospitals or other research units. An approval from the local scientific committee, covering ethics and legal issues as well, usually is considered as sufficient, even in very sensitive protocols. The status of the few existing RECs usually is not in conformity with the internationally accepted standards.

The European institutions could insist on the establishment of RECs according to these standards (even by encouraging the enactment of a relevant national law). A good motive for this may be a detailed ethics report that should always be asked from the local research teams, in case they apply for European funding.

*Question 4: main organisations representing scientific society*

Such organizations are, in particular
a) The HNBC (http://www.bioethics.gr/index.php?category_id=3)
b) The General Secretary of Research and Technology (Ministry of Education)
(http://www.gsrt.gr/default.asp?V_LANG_ID=2)

c) The National Ethics Committee for Clinical Trials (http://www.eof.gr/web/guest)
d)The National Authority for Medically Assisted Reproduction (http://www.iya.gr/index.cfm/doc/1/cat/2)

## Hungary / *Hongrie*

Reply provided by the Information Service for MPs, Library of the Hungarian Parliament (22.06.2011)

**Questions:**

- Ethics of scientific research,
- institutions responsible for monitoring the ethical aspects of scientific research,
- the main organisations representing scientific society.

**Answers:**

In Hungary we do have code of ethic of science research called the **Science Ethics Code of the Hungarian Academy of Sciences** (*accepted in May 2010*), see below:
http://mta.hu/data/cikk/12/68/86/cikk_126886/etikai_kodex_angol_.pdf

**The Committee on the Ethics of Science** of the Hungarian Academy of Sciences is the body carrying out the ethical examination.

An Aggregate of Academy Law XL of 1994 as Amended in 2009 with the updated Statutes of the Hungarian Academy of Sciences, and the Academy's Updated Procedures in English see here:
http://mta.hu/articles/statutes-105251__3591

The address of the Hungarian Academy of Sciences webpage in English: http://mta.hu/english/

## Iceland / *Islande*

Reply provided by the information service of Althingi (28.06.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

There is a number of acts and regulations relating to ethics of science, esp. medical research and operations:

Patients' Rights Acts No. 74/1997. The Regulation on Scientific Research in the Biomedical Sector No. 286/2008 was laid down in accordance with article 29 of that Act.

Biobanks Act No. 110/2000
Act on Artificial Fertilisation and use Human Gametes and Embryos for Stem-Cell Research No. 55/1996
Act on the Protection of Privacy as regards the Processing of Personal Data No. 77/2000

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research ? What procedures are used by these institutions?*

This is described in the Regulation on Scientific Research in the Biomedical Sector No. 286/2008, article 6, Permission to carry out biomedical research projects:

"A scientific research project in the field of biomedicine shall not be permitted without prior evaluation of possible risk on the one hand, and benefits on the other. In that evaluation, however, the interest of the individual shall invariably outweigh scientific or societal interests."

No scientific research project in the biomedical field may be carried out without the approval of the **National Bioethics Committee** or an ethics committee under art. 4. [there is an ethics committee at each of the two largest hospitals in Iceland].

Studies which require the participation of children, or members of vulnerable social groups, shall be evaluated with especial care, as these groups are entitled to special protection. Such studies may involve,

for instance, adults who, due to mental disability, disease or other factors are incapable of granting consent. Such individuals shall be involved in decision-making as far as possible. Child subjects shall be involved in decision-making in so far as their development permits and without exception if they are aged 12 years or older.

The National Bioethics Committee may issue further rules on participation in research by children and members of vulnerable groups.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

The population of Iceland is relatively small, around 320.000 persons. The small community can create problems due to relations of many kinds, with colleagues, friends, family, etc.

Neither this author nor any other staff members of the Parliament are qualified to estimate the functions of the system of scientific research in Iceland or what improvements should be implemented. Knowledge of this matter is sought to experts in scientific institutions in the country. The question on expectations from European institutions (run by the Council of Europe?) can be directed to those associations and institutions listed under 4.

*Question 4: main organisations representing scientific society*

Associations
The Union of University Teachers, the University of Iceland fh@hi.is
The Union of University Teachers, University of Akureyri hjordis@unak.is
The Icelandic Medical Association, Ethics Council lis@lis.is

Institutions
The Icelandic Centre for Research (supports research, research studies, technical development and innovation in Iceland) rannis@rannis.is

The National Bioethics Committee visindasidanefnd@vsn.stjr.is
The Minister of Welfare appoints the chair of the committee that consists of seven members. It shall be ensured that the committee includes individuals with expertise in the fields of biomedical science, ethics of research, human rights and social science.

## Italy / Italie

Reply provided by the Chamber of Deputies in cooperation with the National Bioethics Committee (16.06.2011)

*Question 1: What are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

The **Italian Constitution** provides that: "the Republic guarantees the freedom of the arts and sciences" (Art. 33). Accordingly, scientific research, both public and private, is free. Moreover, the Italian Constitution promotes the development of culture and of scientific and technical research (Art. 9). Freedom of scientific research is a general principle that can't find unjustified limitations in the Italian jurisdiction.

It is noteworthy in this connection that the guiding criteria underlying the recent reorganization of non state-controlled research entities operating under the supervision of the Ministry of Education, the University and Research1 (cf: Enabling Law 165/2007; Legislative Decree 213/2009) include recognition of the statutory autonomy pursuant to art. 33 of the Constitution accompanied by an explicit reference to the need to safeguard independence and free research activity within the framework of the specific mission and objectives of each entity as periodically laid down by the Government in the National Research Programme. Nor the ethical pluralism characterising the actual debate can deny such a general principle.

In some cases the legislator found that specific regulation was needed in order to protect

1 The Italian Space Agency (ASI); the National Research Council (CNR); the Trieste Scientific and

Technological Research Area; the Italian Institute of Germanic Studies; the National Higher Mathematics Institute (INDAM); the National Astrophysics Institute (INAF); the National Institute of Nuclear Physics (INFN); the National Institute of Geophysics and Volcanology (INGV); the National Institute of Oceanography and Experimental Geophysics (OGS); the National Weather Institute (INRIM); the "Enrico Fermi" Study and Research Centre; the "Anton Dohrn" Zoological Station.

2 Art.1 of Law 165/2009 provides for the recognition of the entities' statutory autonomy in full respect of article 33, paragraph six, of the Constitution and consistent with the principles embodied in the European Researchers' Charter annexed to recommendation no. 2005/251/EC of the European Commission of 11 March 2005. The purpose is to safeguard their independence and free research activity aimed at the advancement of knowledge, without prejudice to the Government's responsibility regarding the indication of the mission and the specific objectives of each entity within the framework of the National Research Programme and the strategic objectives set by the European Union.

3 The National Research Programme (PNR), within the meaning of Legislative Decree 204/1998, is the principal research planning and coordination instrument. The Programme is of three years' duration and is updated annually. For the three years 2011-2013 the PNR earmarks 1.8 billion euro for the performance of 14 priority (or "flagship") projects. The Programme has to receive the definitive approval of the Council of Ministers. human beings/persons in specific existential situations which are considered of high sensibility consistently with the Italian Constitution values.

The Laws and regulations concerning key sensitive questions of social responsibility in conducting scientific research, as well as ethics of scientific research in Italy are the following:

1) Voluntary termination of pregnancy.
It is regulated by Law No. 194 of May 22, 1978 – *Provisions on the social protection of motherhood and the voluntary termination of pregnancy*. According to such legislation, once a year the Italian Minister of Health submits to the Parliament a report dealing with the implementation of the mentioned law.

2) Medically-Assisted Reproduction (MAR)
It is regulated by Law No. 40 of February 19, 2004 – *Provisions on medically-assisted reproduction*. A number of *Guidelines* enacted by Istituto Superiore di Sanità (National Institute of
Health) integrate the legislation every three years thereby outlining procedures and techniques relevant to medically-assisted reproduction.

3) Testing on human embryos
Law No. 40/2004 recalled above, bans through article 13 all kinds of medical research conducted on embryos. However, in the absence of alternative procedures, clinical research may be carried out only in the interest of the health and development of the embryo and with therapeutic and diagnostic aims. Pre-implantation diagnosis was deemed permissible according to several rulings (see Court of Cagliari, September 22, 2007; Court of Florence, December 17, 2007; Ruling
No. 398 by the Regional Administrative Court of Lazio; Court of Bologna, June 29, 2009 and Court of Salerno, January 9, 2010).

4) Surrogate Motherhood.
It is prohibited under the previously recalled Law No. 40/2004, article 12, section 6.

5) Palliative care
It is regulated by Law No. 38 of March 15, 2010 – *Provisions aimed at granting access to palliative care treatment and pain therapy*.

6) Euthanasia
It is forbidden under articles 575 (*homicide*), 579 (*killing on demand*) and 580 (*Assistance or instigation of suicide*) of the Italian Criminal Law.

7) Informed consent or the refusal of medical treatment
A debate on a draft law is currently underway in Parliament, concerning matters related to an informed consent to medical action, and the disclosure of early statements of intent.The principle of informed consent, according to which no-one shall be subjected without or *a fortiori* against his or her deliberate consent to medical action was fully upheld by our case-law, which relied both on the transnational and national law. In particular, the latter was inspired by the Constitution that recognizes the inalienable rights of the individual (article 2), personal freedom (article 13) and the right to health as a fundamental human right (article 32).

8) Clinical Trial.
Italy has been limited to transposing the European directives with the following enactments:
- Decree-Law 211/2003 – *Transposition of directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*;
- Decree-Law 200/2007 – *Transposition of directive 2005/28/EC laying down principles for good clinical practice as regards investigational medicinal products for human use*, *as well as the requirements for authorisation of the manufacturing or importation of such products.*

In addition, to complement the legislation, the Ministerial Decree of May 12, 2006 points out – *Minimum requirements for the establishment, organization and functioning of ethics Committees for clinical trials of medicines.*

9) Organ transplantations
In general: The matter shall be governed by Law No. 91 of April 10, 1999 – *Provisions relating to the removal and transplantation of organs and tissues* and is complemented by the Decree of the Minister of Health, dated April 8, 2000 – *Provisions relating to the removal and transplantation of organs and tissues which implements prescribing rules for the expression of willingness to donate one's organs for transplantation purposes*. Especially:
- for kidney transplantation: Law No.458 of June 26, 1967;
- for partial liver transplantation: Law No.483 of December 16, 1999;
- for bone marrow donation: Law No.107 of May 4, 1990; Law No. 52 of March 6, 2001:
- for corneal transplantation: Law No.301 of August 12, 1993.

10) Use of human embryonic material
Article 13 of Law 40/2004 forbids the use of embryonic material as well as its medical experimentation. Experimentation is allowed for adult and umbilical cord stem cells: Law No. 219 of October 21, 2005 – *New regulation on the activities related to the transfusion and national manufacturing of blood products.* Broadly speaking, the use of human biological material is also subject to other legislation:
- Law No. 78 of February 22, 2006 – *Converted into law, setting forth amendments to the Decree-Law No. 3 of January 10, 2006 which implements directive 98/44/EC on the legal protection of biotechnological inventions*;
- Decree-Law No. 191 of November 6, 2007 – *Implementation of directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*.

11) Conscientious objection.
It is a right that the Italian law does not address in a single piece of legislation whereas it is claimed in a number of laws: Law 194/78 (*Provisions on the social protection of motherhood and the voluntary termination of pregnancy)*, article 9; Law 40/2004, (*Provisions on medically-assisted reproduction*), article 16 and Law 413/93 (*Standards on conscientious objection to animal testing*).

*Question 2: Which institutions in your country are responsible for monitoring the ethical aspects of scientific research, i.e. possible danger to humans or the environment, as well as possible scientific misconduct? What procedures are used by these institutions?*

The **National Bioethics Committee (NBC)** was established by a decree signed by the President of the Council of Ministers on 28 March 1990 with the task of expressing opinions, and also for the purpose of preparing legislative acts, to address the ethical and legal problems that may arise as a result of the progress in scientific research and technological applications on life. The Committee formulates opinions and motions, which are published on the website following approval. The NBC establishes and maintains relations at European and International levels.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Problems concerning aspects of scientific activities from the standpoint of ethical correctness may be found in the parliamentary debates about recent laws affected by these topics. See, e.g. recently, "Provisions aimed at granting access to palliative care treatment and pain therapy." (A.C. 624, then law n. 38, 15 march 2010) - Chamber of deputies - general debate - Sitting n. 213, 14 september 2009); Senate: bills on informed consent or the refusal of anticipate willing in health treatment ( A.S. 10), sittings N. 175 (afternoon) 18 march 2009, N. 176 (morning), 19 march 2009, N. 177 (afternoon), 19 march 2009; Chamber of Deputies: bills on

informed consent or the refusal of anticipate willing in health treatment (A.C. 2350, sittings: N. 444, 7 march 2011: Camera.it - Lavori - Resoconti Assemblea – Dettaglio resoconto; N. 446, 9 March 2011: Camera.it - Lavori - Resoconti Assemblea – Dettaglio resoconto.

On Medically-Assisted Reproduction (MAR) - Law 19 february 2004, n. 40 - see the debate in the Senate N. 462 (afternoon), 24 september 2003, N. 463 (morning), 25 september 2003, N. 467 (morning), 1 october 2003.

The European Institutions do not seem to be expected to unify ethical principles in scientific research. They could facilitate the cooperation between national institutions in ethical issues related to scientific and technological progress, and to suggest topics for reflection. The European Institutions could also make an activity of monitoring and reporting on questions of social responsibility in conducting scientific research, as well as on the ethics of scientific research.

*Question 4: main organisations representing scientific society*

In Italy many organisations represent scientific society. We can mention:
1) Ministry for University and Scientific Research (Ministero dell'Università e della Ricerca MIUR);
2) National Council for Research (Consiglio Nazionale delle Ricerche- CNR);
3) National Academy of Sciences (Accademia Nazionale delle Scienze).

## Latvia / *Lettonie*

Reply provided by LATVIJAS REPUBLIKAS SAEIMA (20.05.2011)

In reply to your request please see attached **Law on Scientific Activity and Scientist's Code of Ethics.**

More information concerning scientific research in Latvia is available on the website of Ministry of Education and Science Republic of Latvia www.izm.gov.lv
Latvian Council of Science www.lzp.gov.lv
Latvian Academy of Science www.lza.lv

## Lithuania / *Lituanie*

Reply provided by the parliamentary research department, Office of the Seimas (27.06.2011)

Higher education and research in the Republic of Lithuania and their supervision is regulated by the ***Law on Higher Education and Research***[34] which is in force from 22 December 2009.

Pursuant to the *Law* academic ethics is one of the principles of research. The *Law* provides for the institution of supervisor of academic ethics and procedures. However, the institution does not function yet as the draft resolution of setting up of the institution and on the regulations of the institution is currently under consideration in the Seimas (Parliament).

According to the *Law* the academic community[35] in every research or higher education institution acts in compliance with the **code of academic ethics**, which is prepared and approved by higher education and research institution in accordance with the recommendations of the national supervisor of academic ethics and procedures (Article 53). Practically all the academic communities have their own codes of academic ethics and their ethics commissions in spite of the fact that the institution of supervisor of academic ethics and procedures does not exist.

The provisions applicable to the national Supervisor of academic ethics and procedures are stipulated in the Article 18 of the Law:

According to the Law the activities of state research institutes are externally evaluated every six years,

[34] http://www3.lrs.lt/pls/inter/dokpaieska.showdoc_l?p_id=366717
[35] The academic community consists of students, the teaching staff, the research staff, other researchers, and professors emeritus of higher education and research institutions.

involving experts from foreign states. The evaluation comprises all fields of activities including implementation of the requirements of academic ethics and procedures (Article 43).

The *Research Council of Lithuania* acts in compliance with its ***Regulations***[36].

Protection of human rights and dignity in the field of health care is performed by the *Lithuanian Bioethics Committee*[37] (LBEC). LBEC was established at the end of 1995 following the ***Law on the Lithuanian Health Care System***[38]. LBEC takes responsibility inter alia for ethical issues of biomedical research and exercises supervision of biomedical research under permissions given by the Committee (Articles 55, 80) . The legal basis for the activities of the LBEC consists of some number of **national laws and international legal documents** (see translations[39]). The Committee functions in line with the **Regulations** approved by the Ministry of Health.

Pursuant to the *Law on Higher Education and Research* the ***Supervisor of academic ethics and procedures*** (see 1.) shall be appointed by the Seimas on the recommendation of the *Research Council of Lithuania*. *The Lithuanian Research Council* is an advisory body of the Seimas and the Government for research, studies and research development policy. The Council functions in line with its own Regulations[40].

For the meantime, by its Decision[41] of 4 April, 2011, the Research Council of Lithuania approved composition of the ***Academic Ethics Commission*** which consists of 6 academic persons. The Council instructed the Commission to consider plagiarism or other academic dishonesty cases according to Commission's Rules of Procedure.

All the academic communities have their own ethics commissions which monitor activities of academic communities in compliance with their codes of academic ethics.

***The Lithuanian Bioethics Committee*** **(**LBEC) has been appointed by the Minister of Health. It consists of 17 members, half of them medical professionals and the rest non-medical specialists (lawyer, ethicist, philosopher, psychologist, theologian etc.). Appointment is based on expertise and experience in the field of biomedical ethics. The chairman was elected by majority vote during the first meeting of the committee. LBEC has its own budget to support a small administrative staff and cover the expenses of its main activities. LBEC meets almost every month on an *ad hoc* basis. For more detailed information, see the website[42].

The main organisations representing scientific society in Lithuania :
The Research Council of Lithuania: info@lmt.lt , www.lmt.lt
The Lithuanian Bioethics Committee: lbek@sam.lt , http://bioetika.sam.lt/index.php?-1664506446

## Republic of Moldova / *République de Moldova*

Reply provided by Information and Analysis Department, Parliament of Moldova (24.05.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

In our country the legislative norms to regulate this domain are as follows:

- Code on Science and Innovation of the Republic of Moldova No.259-XV from 15 July 2004
- Regulation on the operation of specialized scientific councils and confer scientific degrees and scientific titles and scientific education in the Republic of Moldova from 25 November 2004
- Regulation of activity of the specialized assessment of the science and innovation organizations from 24 February 2005
- Regulations on recognition and equivalence of documents of high scientific and scientific-teaching qualifications obtained abroad

[36] http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=379790
[37] http://bioetika.sam.lt/index.php?-1876243809
[38] http://www3.lrs.lt/pls/inter/dokpaieska.showdoc_l?p_id=82095
[39] http://bioetika.sam.lt/index.php?-1170655261
[40] http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=379790
[41] http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_bin?p_id=396461
[42] http://bioetika.sam.lt/index.php?1975608885

➢ Commission Recommendation of 11 march 2005 on the European Charter for Researchers and on Code of Conduct for the Recruitment of Researchers

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research ? What procedures are used by these institutions?*

***a)*** **National Council on Accreditation and Attestation**, with the status of legal person, is the central governmental institution in the evaluation and accreditation of the organizations in the field of science and innovation, and the attestation of scientific and scientific-highly qualified teachers. National Council acts in accordance with the Constitution, the Code on Science and Innovation of the Republic of Moldova and other acts of the Republic of Moldova, Presidential decrees, decisions and orders of the Government, with international treaties to which the Republic Moldova is a party. Link: http://www.cnaa.md/attestation-commission/

**Attestation Committee**
Attestation of scientific and scientific-pedagogical personnel of higher qualification is exercised by the Committee on attestation of scientific and scientific-pedagogical personnel (hereinafter – the Committee on attestation). Members of the Committee on attestation are nominated for no more than one term among men of science whose competence and high professionalism in science and technology are recognized. Link: http://www.cnaa.md/accreditation-commission/

**Accreditation Committee**
Evaluation and accreditation of organizations in the field of science and innovations are exercised by the Committee on accreditation of organizations in the field of science and innovations (hereinafter - the Committee on accreditation). Committee on accreditation functions on the basis of Regulations on accreditation of organizations in the field of science and innovations presented in Appendix 1 of the Code of the Republic of Moldova on science and innovations.
Link: http://www.cnaa.md/institutions/

**b) Academy of Sciences of Moldova**
Academy of Sciences of Moldova (A. S. M.), the only public institution of national interest in science and innovation, is the plenipotentiary coordinator of scientific and innovation activity - as the country's highest scientific advisor of the public authorities of Moldova. It has an autonomous status and functions according to the principles of self-administration. The Academy of Science operates in accordance with the Constitution of the Republic of Moldova, the Code on Science and Innovation, Partnership Agreement with the Government, norms of legislative acts and other regulations.

According to the Law on the Academy of Sciences No. 1181 from 27.07.2000, Chapter V The structure of the Academy of Sciences Article 14 Institutions of the Academy of Sciences
(1) The Academy of Sciences comprises research institutions and development centers, the Central Scientific Library, Archives, a Publishing House and other production units that ensure the work of the Academy of Sciences. Academy of Sciences' Institutions can act as legal persons in accordance with regulations approved by the General Assembly.
(2) To optimize the management of scientific research, the institutions will elect a board of directors who operate in the framework of their internal Regulations.

**c) Ministry of Education and Youth**
**d) Ministry of Health**
**e) Ministry of Agriculture and Food Industry**
**f) Ministry of Internal Affairs**
**g) Ministry of Culture and Tourism**

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

According to the Article 121 of the Code on Science and Innovation of the Republic of Moldova No.259-XV from 15 July 2004, Scientific and technological information organizations are defined as:

1) Organizations of information science and technology centres are subdivisions of scientific, business and specialized organizations and their departments, funds and scientific libraries, scientific-technical and other legal entities with any type of property and legal form of organization, whose object is to provide beneficiaries with information science technology.

(2) The structure and functions of scientific information and technological organizations under public law are determined by the Academy of Sciences, jointly with relevant central bodies.
(3) The structure and functions of scientific and technological intelligence organizations of private law are established in accordance with the laws in force.

*Question 4: main organisations representing scientific society*

According to the Code on Science and Innovation of the Republic of Moldova No.259-XV from 15 July 2004, Chapter IX, article 131, legal status of organizations in the field of science and innovation,

(1) Depending on their status as scientific, and social organization, science and innovation organizations fall into the following types: a) research and development institute with branches; b) undertaking research, c) undertaking innovation, d) science centre, e) innovation centre, f) scientific station, g) independent scientific laboratory, h) institution of higher education and its science and innovation structures, i) association in science and innovation domain, science and technology, science and education clusters, j) Scientific foundation, k) innovation foundation, l) financial institution to support science and innovation activity, m) science-technology park, Innovation Incubator and Techno-polis, n) science museum, o) Scientific Library, p) scientific archive, q) scientific publishing house, r) other organizations in science and innovation.

(2) The structure of the public organization of science and innovation, elaborated in accordance with the strategic directions of science and innovation, is proposed by the Director, reviewed and approved by the **Scientific Council** and confirmed by the **Supreme Council** in coordination, where appropriate, with the central specialized body.

According to the Code on Science and Innovation of the Republic of Moldova No.259-XV from 15 July 2004, Chapter VII protection of intellectual property and information insurance Section 1, Article 106,
(1) The State Agency for Intellectual Property (hereinafter - State Agency) has the responsibility to organize and carry out the legal protection of intellectual property as well as industrial property, copyright and related rights in the Republic of Moldova has the status of State enterprise and operates on principles of self-management and self-financing.

## Montenegro / Monténégro

Reply provided by the Parliament of the Republic of Montenegro (24.06.2011)

*Question 1: what are the laws, regulations and official recommendations/ guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

Respect of ethical standards in conducting science in Montenegro is prescribed by:

- the Constitution of Montenegro;
- the Law on Scientific - Research Activities, and
- the Ethical Code of Science and Research Institutions.

**The Constitution of Montenegro (Official Gazette of Montenegro, 01/07)**

Chapter “Biomedicine” Article 27 stipulates that:

- the man’s right and dignity of human beings are guaranteed regarding the application of biology and medicine;
- each intervention directed towards creation of human being that is genetically identical with other alive or dead human being is forbidden;
- it is prohibited to carry out medical and other experiments on human beings without his/her consent.

Chapter “Freedom of creation” Article 76 stipulates that:

- the freedom of scientific, cultural and artistic creation shall be guaranteed;
- the freedom to publish scientific and artistic works, scientific discoveries and technical innovations shall be guaranteed.

**Law on Scientific – Research Activities (Official Gazette of Montenegro, 80/19)**

Article 3 provides that:

Scientific - research activity is an activity of public interest, and performance of scientific research is free and available to all domestic and foreign individuals and legal entities.

Article 4 paragraph 1 item 6 provides that:
Scientific - research activities are based upon the principle of: "freedom and autonomy of scientific creativity, which needs to be independent, morally and intellectually, from every political authority and economic power and which is performed with respect of ethical standards and principles of scientific truth and critical thinking".

Article 4 paragraph 1 item 7 provides that:
Scientific - research activities are based upon the principle of: "ethics and responsibility of researchers who carry out scientific - research activities for the consequences of their work".

Article 4 paragraph 1 item 10 provides that:
Scientific-research activities are based upon the principle of: "protection of personality and dignity of researchers who carry out scientific and research work".

**Code of Academic Ethics at the University of Montenegro** is adopted by the University Senate in 2004.

The Preamble of the Code item 5 lays down that: "tradition of the University is based upon results which are achieved through scientific objectivity and moral credibility, and contributes to overall mission in academic community and society as a whole".

Chapter I - *Professional Responsibility*, in items 1, 2, 6, 8, 12 and 13 the following principles are provided:

- Freedom of research and teaching process are the primary values of the University;
- Duty of academic staff is to respect ethical standards, principles of scientific truth and critical attitude and to protect reputation of the University through their work, acting and behaviour;
- Research and teaching activity at the University must be morally and intellectually independent from any other political authority and economic power;
- Duty of academic staff is to protect freedom of scientific - research and teaching work and to protect honour of their profession and they shall not abuse the authority of their profession for the purpose of personal or political interests;
- When a member of academic staff believes that he/she is requested to act opposite to his/her ethical principles or personal scientific and intellectual beliefs or consciousness, his/her duty is to initiate discussion about that topic;
- Academic staff are free to develop their original method of research and their own style of teaching.

Chapter III - *Responsibility toward Colleagues*, items 2 and 4, establishes the obligation of academic staff to foster culture of argumentative dialogue through their scientific works, public acting and mutual relations, as well as to respect individual and professional dignity of young colleagues and to take care of their teaching and scientific development.

Chapter V - *Social Mission,* item 2 stipulates that non-teaching activities of academic staff must not have a negative influence on the quality of teaching and scientific work.

In the last Chapter VI – *Application*, item 4 stipulates that the Court of Honour provides for responsibilities and declares measures for violation of ethical standards.

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research ? What procedures are used by these institutions?*

Article 7 of the Law on Scientific – Research Activity provides that:
Scientific-research activity is realized by: Montenegrin Academy of Sciences and Arts, scientific-research institutions, higher education institutions and other physical and legal entities, in accordance with the law.

Article 11 paragraph 1 and 2 provides that:
Scientific research work is carried out through a scientific research program and project;
Scientific research program and project is led by a leader of scientific research program and project;
Scientific-research institution as a bearer of the research, as well as a leader of the research project, are responsible for monitoring the ethical aspects of scientific research, possible danger to humans and the environment, and possible scientific misconduct. So is the expertise body in the institution, Council for Scientific Research Activities, which, according to the Article 39 paragraph 3 item 2 "analyses, evaluates and adopts reports on implementation of programs and projects".

Besides that, scientific-research institutions, through codes of ethics, more closely regulate monitoring the ethical aspects of scientific research (as mentioned in the #1 answer).

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Thus far, the functioning of Montenegrin legal and institutional system to monitor scientific activities from the standpoint of ethical correctness has not been raised as an issue.

The legislative framework that handles scientific monitoring activities from the standpoint of ethical correctness, in our opinion, is in line with the legal rules that handle this issue in modern science.

Normative improvement in handling this issue is contained in the new Law on Scientific-Research Activities, adopted at the session of the Parliament of Montenegro on 22 December 2010, and in compliance with the Acquis Communautaire: TFEU (Treaty on the Functioning of the EU) - the last consolidated Lisbon Treaty, Part three, Policy and internal actions of the Union, Title XIX, Scientific research, technological development and space, article 179-188.

Since Article 4 paragraph 1 item 4 of the Law provides that scientific-research activities are based upon the principle of "integration into European Research Area and Framework Programs of the European Union for research activities and other international programs", monitoring scientific activities from the standpoint of ethical correctness is done in accordance with legal rules of the EU.

*Question 4: main organisations representing scientific society*

The Ministry of Education and Sports along with the following scientific-research institutions: Montenegrin Academy of Sciences and Arts, The State University of Montenegro, University „Mediteran" and University „Donja Gorica", could provide the Committee on Education, Science, Culture and Sports with their views on the ethics of ecience issues.

## The Netherlands / Pays-Bas

Reply provided by the House of Representatives (Tweede Kamer der Staten-General)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research as well as the ethics of scientific research?*

There are the following regulations on the ethics of scientific research in general (in Dutch):

**Regulation of the National Committee on Scientic Integrity** (Reglement Landelijk Orgaan Wetenschappelijke Integriteit)
http://www.knaw.nl/Content/Internet_KNAW/thematisch/bestanden/lowi_6349-reglement.pdf
Regulation of the National Committee on Scientic Integrity about the procedure concerning complaints about violations of scientific integrity.

**Dutch code on Science Conduct** (Nederlandse gedragscode Wetenschapsbeoefening)
http://www.vsnu.nl/Media-item/Nederlandse-Gedragscode-Wetenschapsbeoefening.htm
Code of the Association of Universities (Vereniging van Universiteiten – VSNU) on the principles of scientific education and research: care, reliability, controllability, impartiality, independence.

**Code on Conflict of Interests** (Gedragscode belangenverstrengeling)
http://www.nwo.nl/files.nsf/pages/NWOP_6CYFSB/$file/Gedragscode%20belangenverstrengeling%20vormgever.pdf
Code of the Dutch Organization for Scientific Research (Nederlandse Organisatie voor Wetenschappelijk Onderzoek – NWO on confidentiality and conflicts on interests.

**Code on the use of Personal Data in Scientific Research** (Gedragscode voor gebruik van persoonsgegevens in wetenschappelijk onderzoek)
http://www.vsnu.nl/Media-item/Gedragscode-voor-gebruik-van-persoonsgegevens-in-wetenschappelijk-

onderzoek.htm
Code of the Association of Universities on the protection of privacy using personal data in scientific research.

Listed here are a number of bills concerning sensitive ethical questions (the complete text of the bills – in Dutch – you can find in the attachment under 'Embryowet'. The Embryo Bill is also attached in English).

**Embryo Bill**
This bill prohibits the use of embryos for human cloning, the creation of human-animal combinations and the use of sex selection techniques. Other uses such as for healing the sick or the welfare of infertile couples are permitted under certain conditions.

**Bill on medical-scientific research** (Wet medisch-wetenschappelijk onderzoek -WMO)
This bill protects human subjects in medical research following the Nuremberg Code, the Declaration of Helsinki and the Good Clinical Practice guidelines of the CIOMS (Council for Medical Organizations of Medical Sciences). Medical ethics review committees or in specific cases the Central Committee on Research Involving Human Subjects (Centrale Commissie Mensgebonden Onderzoek - CCMO) ensure the protection of human subjects involved in medical research.

**Decree on Stem cell Therapy** (Planningsregeling Stamceltransplantatie)
This decree allows stem cell therapy only in the context of medical research in a number of institutions.

Two **decrees on modified organisms and genetically modified organisms** - based on the EU regulations on genetically modified organisms (Besluit gemodificeerde organismen milieubeheer en Regeling genetisch gemodificeerde organismen)

**Animal Testing**
There are many laws and regulations dealing in some way with animal testing. The Animal Experiments Committee (Dierexperimentencommissie), a special ethics committee, reviews each test beforehand, the Food Authority (Voedsel- en Warenautoriteit) verifies the implementation. It is forbidden to use great apes such as chimpanzees and gorillas for animal testing. The testing of makeup on animals is also prohibited. The revised EU directive on animal testing is largely consistent with all current Dutch policy on animal testing
The main law and regulation are the Bill on Animal Testing (Wet op Dierproeven) and the Decree of Animal Testing (Dierproevenregeling).
There is also a code on the openness about animal testing by the KNAW, the VSNU and the Dutch Federation of University Medical Centra (Nederlandse Federatie van Universitair Medische Centra – NFU). http://www.vsnu.nl/Media-item/Code-openheid-dierproeven.htm

Question 2: *Which institutions are responsible for monitoring the ethical aspects of scienticic research? What procedures are used by these institutions?*

**National Committee for Scientific Integrity** (Landelijk Orgaan Wetenschappelijke Integriteit -LOWI)
This committee advises the Executive Boards of the Dutch universities, the boards of the university medical centers, the board of Sanquin Foundation and the boards of the NWO and KNAW regarding complaints about violations of academic integrity. The NCSI deals only with complaints when the institution where the breach had taken place, has made a decision. The NCSI can advice the board of an institution on request before the board decides on a complaint (procedure found in the Regulation of the of NCSI – see above)

**Royal Dutch Academy of Sciences** (Koninklijk Nederlandse Academie van Wetenschappen -KNAW)
This organization advises the government and is the organization of a number of scientific institutes. The Commission Science, Ethics and Integrity of the KNAW (Commissie Wetenschap, Ethiek en integriteit – WEI) advises about ethical issues and integrity. It discusses ethical issues (often topical, practical issues), international ethical issues and the forming of opinion about these. Codes of conduct for scientific integrity are an important issue for the committee. This work includes the coordination of various scientific conduct between Europe and the rest of the world. The committee also advises on the introduction and enforcement of these codes.

**Rathenau Institute**
Independent organization that deals with issues at the interface of science, technology and society and informs politics about it. By technology assessment the Rathenau Institute makes clear what the meaning (opportunities and risks) is of technological and scientific developments for people and society.

**Centre for Society and Genomics**
The CSG deals with the ethical questions about genomics. Some 50 researchers from universities and institutions ensure the implementation of the CSG program. In each project the dialogue between researchers and societal or industrial parties starts at an early stage.

Question 3: *What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have form European institutions?*

We refer you to the organisations listed at question 4.

Question 4: *Could you indicate the main organisations representing scientific society?*

National Committee Science, Ethics and Integrity (Commissie Wetenschap, Ethiek en Integriteit) of the Royal Dutch Academy of Sciences (KNAW): http://www.knaw.nl/smartsite.dws?id=27183&ch=DEF&lang=NL
National Committee for Scientific Integrity (Landelijk Orgaan Wetenschappelijke Integriteit – LOWI) http://www.knaw.nl/Pages/DEF/28/514.bGFuZz1OTA.html
Rathenau Institute http://www.rathenauinstituut.nl/
Association of Universities http://www.vsnu.nl/Dutch Organisation for Scientific Research http://www.nwo.nl/
Centre for Society and Genomics http://www.society-genomics.nl/home.html\

## Norway / Norvège

Reply provided by the Norwegian Parliamentary Research Service, Stortinget (29.06.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

***Law on Ethics and Integrity in Research***
In Norway, the Law on Ethics and Integrity in Research[43] (the Research Ethics Act) entered into force in July 2007. The Act seeks to ensure that research carried out by public and private institutions is conducted in accordance with recognised ethical standards.

The act states that national research ethics committees that collectively cover all disciplines shall be established. The committees are all appointed by the Norwegian Ministry of Education and Research and funded by The Research Council of Norway.

**The Act on Medical and Health Research**
In July 2009 The Act on Medical and Health Research[44] (the Health Research Act), entered into force in Norway. The purpose of the Act is to promote good and ethically sound medical and health research. The Act applies to all medical and health research on human beings, human biological material or personal health data. Such research also includes pilot studies and experimental treatments.

The act covers requirements concerning organisation and execution of medical and health research, consent from participants in medical and health research, research involving people, research biobanks and research involving human biological material, research using personal health data, transparency and right of access to the research and supervision. The Ministry of Health and Care Services has developed both regulations (June 2009) and guidelines (July 2010) to the Law on Medical and Health Research. The aim of the guidelines is to provide an overview of key issues and problems related to medical and health research.

**Other laws**
In addition there are a wide range of laws which might be relevant[45] depending on the area of research, such

[43] Act of 30 June 2006 No. 56 on Etichs and Integrety in Research. For an unofficial translation to English. see http://www.ub.uio.no/ujur/ulovdata/lov-20060630-056-eng.pdf
[44] Act of 20 June 2008 No. 44: Act on medical and health research (the Health Research Act), For an translation to English, see http://www.ub.uio.no/ujur/ulovdata/lov-20080620-044-eng.pdf
[45]There is an overview of the most important of these laws (in Norwegian) on the web-site of the National Committees of Research Etichs, see http://www.etikkom.no/no/Forskningsetikk/God-forskningspraksis/Lover/ and http://helseforskning.etikkom.no/ikbViewer/page/reglerogrutiner/loverogregler?p_dim=34770&lan=2&_ikbLanguageCode=n

as:

- The Act relating to Medicines etc

Act of 4 December 1992, no 132 relating to medicines etc

- The Personal Data Act

Act of 14 April 2000 no. 31 relating to the processing of personal data

- The Personal Health Data Filing System Act

Act of 18 May 2001 on personal health data filing systems and the processing of personal health data

- The Patients' Rights Act

Act relating to patients' rights and amendments by Act of 22 December 2006, no 99

- The Freedom of Information Act

Act of 19 May 2006 relating to the rights of public access to documents held by public authorities and public undertakings

- The Cultural Heritage Act

Act of 9 June 1978 No.50 Concerning the Cultural Heritage

- The Biotechnology Act

Act of 5 December 2003 No. 100 relating to the application of biotechnology in human medicine, etc

- The Gene Technology Act

Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms, etc

- The Animals Welfare Act

Act of 19 June 2009 Concerning the welfare of animals

In addition there are international conventions and declarations which are covering different areas relevant for research ethics.

**Guidelines for research ethics**

National research ethics committees shall serve as advisory bodies on research ethics. They have expertise in relevant research disciplines, ethics and law. One of the responsibilities of the National Committees for Research Ethics is to develop guidelines for research ethics. The most essential guidance are:

- A checklist for Research Ethics (2009) which provides an overview of the most important ethical issues to clarify on any research project.
- Guidelines for research ethics in science and technology (PDF) (2008)
- Guidelines for research ethics in the social sciences, law and the humanities (2006)
- Several guidelines regarding research ethics in medical and health, for instance Guidelines for the inclusion of women in medical research and Guidelines for payment to participant in medical and health research projects .

The committees also publish reports on different principal matters regarding research etichs, like Risk and Uncertainty - as a Research Ethics Challenge (2009). A list of all publications by the National Research Committees is available at etikkom.no.[46] The committees also identifies good research practice in the area

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research ? What procedures are used by these institutions?*

In Norway there is a national system for research ethics that consists of the national committees on research ethics, included the national commission of investigation of misconduct, and the regional committees for medical research. However, the research institutes and universities have the primary responsibility for preventing and handling allegations concerning research misconduct, and they have also established local research committees.

There are seven **regional committees for medical and health research** (REK) in Norway. According to the law on Ethics and Integrity in Research all research projects in Norway that involve experiments on human subjects shall be submitted to one of the regional committees for medical and health research for approval. Research projects conducted outside Norway shall be submitted to the committee for approval if the research is being carried out by a researcher employed by a Norwegian employer or if a substantial portion of the funding comes from Norway.

**The Norwegian Board of Health Supervision** oversees medical and health research and the management

[46] Only in Norwegian http://etikkom.no/no/Forskningsetikk/Etiske-retningslinjer/, but the once translated to English are available at http://www.etikkom.no/en/In-English/Publications/

of research biobanks pursuant to the Act on Medical and Health Research.[47] It has the right to issue orders concerning correction and discontinuation. If research projects or research biobanks are being run in a way that can have harmful consequences for research participants or others, or in some other way are unfortunate or unsound, the Norwegian Board of Health Supervision can order that the matter must be rectified. If the Norwegian Board of Health Supervision deems it necessary, it may order that the research project is discontinued or the research biobank is closed.

**The Norwegian Data Inspectorate** oversees use of personal health data pursuant to the Act on Medical and Health Research. The Inspectorate's has right to issue orders concerning correction and discontinuation.[48]

**The National Committee for Medical and Health Research Ethics**
The National Committee for Medical and Health Research Ethics (NEM)[49] was set up in 1990 by the Norwegian Ministry of Education and Research. It is an advisory and appealing body for the regional committees for medical research ethics. The regional committees evaluate all concrete medical research projects, while NEM gives its opinion on issues that are more a matter of principle. Biannual meetings attended by the chairs and secretaries of all the councils deal with issues on which the committees need to collaborate. Furthermore, all members of NEM and the regional committees attend a two-day joint meeting in the autumn, for professional replenishment and discussion.

The work of the medical research ethics committees is based on international conventions such as the Declaration of Helsinki and the Uniform Requirements for Manuscripts Submitted to Biomedical Journals by International Committee of Medical Journal Editors.

**The National Committee for Research Ethics in the Sciences and Technology**
The National Committee for Research Ethics in the Sciences and Technology (NENT)[50] is an independent body which, based on values shared by the general public, shall act as a national watch-post, inform and advise upon research ethics within the relevant fields of research. It was established in 1990. The area of responsibility for the committee is research ethics within science and technology, industrial, agricultural and fisheries research, including those areas of biotechnology and gene technology not covered by medicine.
NENT works at policy level by setting guidelines and general statements and meeting. The Committee also deals with individual research projects.

**The National Committee for Research Ethics in the Social Sciences and the Humanities**
The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH)[51] has been in existence since 1990. NESH works at policy level by setting guidelines and general statements and meeting. The Committee also deals with individual research projects. The Committee uses the guidelines actively when giving its opinion on specific research projects. It also happens that researchers, wanting to safeguard ethical considerations in their research projects, ask NESH for an evaluation. In 2010 the National Committees on Research Ethics run a seminar on research ethics for every university in Norway.

**The National Commission for the Investigation of Scientific Misconduct**[52]
The Law on Ethics and Integrity in Research introduced a new body to investigate research misconduct in 2007; The National Commission for the Investigation of Scientific Misconduct (Granskingsutvalget).

The remit of the National Commission is to assess allegations of serious research misconduct and issue a statement on whether any scientific misconduct has occurred or not. The commission covers all research fields and deals with research carried out by Norwegian research institutions, private or public. It can also investigate cases abroad, if the research has been carried out by researchers employed by a Norwegian institution or if a substantial part of the funding stems from Norway.

Research institutions may redirect an investigation to the Commission if, for example, a case is deemed particularly complicated, has received considerable public attention or due to possible conflicts of interest. The Commission may also decide to investigate a case under authority of the law on misconduct at its own initiative. The law defines scientific misconduct as "falsification, fabrication, plagiarism and other serious

[47] **§ 46.** The authority of the Norwegian Board of Health Supervision
[48] http://www.ub.uio.no/ujur/ulovdata/lov-20080620-044-eng.pdf § 46 and § 52
[49] http://www.etikkom.no/en/In-English/Committee-for-Medical-and-Health-Research/
[50] http://www.etikkom.no/en/In-English/Committee-for-Research-Ethics-in-Science-and-Technology/
[51] http://www.etikkom.no/en/In-English/Committee-for-Research-Ethics-in-the-Social-Sciences-and-the-Humanit
[52] http://www.etikkom.no/en/In-English/Scientific-Misconduct/

breaches of good scientific practice that have been committed willfully or through gross negligence when planning, carrying out or reporting on research".

**The National Committee for Research Ethics on Human Remains**[53] was set up 2008 by the Norwegian Ministry of Education and Research after proposals from the National Committee for Medical and Health Research Ethics (NEM) and the University of Oslo.

The committee evaluates the ethical aspects of research where the source material consists of human remains which are in public museums and collections, or which will be found in future archeological and other surveys. Scientists intending to use human remains in their research are advised to present their projects to the committee for ethical evaluation.

**The Norwegian Advisory Board on Ethical Aspects of Patenting** was established in 2004. The Board is to be the advisory for the Norwegian Industrial Property Office ("Patentstyret") in cases where there is doubt whether the Norwegian Patent Law's clause (§ 1b) that forbids patents on inventions that run counter to "common morality and public order" applies.

Other national institutions dealing with ethics of scientific research are the following (according to a list on the website of the Committees of National Research Ethics):

**The Norwegian Biotechnology Advisory Board**[54] is an independent body consisting of 21 members appointed by the Norwegian government. Each member has a background and/or education which makes him/her competent to discuss questions regarding modern biotechnology. The main tasks of the Norwegian Biotechnology Advisory Board is to evaluate the social and ethical consequences of modern biotechnology and to discuss usage which promotes sustainable development.

**The Data Protection Agency**[55] is an independent administrative body under the Ministry of Government Administration and Reform and is to ensure enforcement of the Personal Data Act of 2000. The purpose of this Act is to protect persons from violation of their right to privacy through the processing of personal data.

**Norwegian Social Science Data Services (NSD)**[56] is one of the largest archives for research data of its kind and provides data to researchers and students in Norway and abroad. Additionally, NSD is a resource centre, which assists researchers with regard to data gathering, data analysis, and issues of methodology, privacy and research ethics. The main objective is to improve possibilities and working conditions for empirical research that is primarily dependent on the access to data.

NSD is the Privacy Ombudsman for all the Norwegian universities, university colleges and several hospitals and research institutes. The ombudsman scheme implies that the requirement for obtaining licenses from the Data Protection Agency for a greater part of research projects are replaced by a notification requirement where NSD is the last instance for reviewing applications for licenses. **Council for Animal Ethics**[57] is an independent advisory body appointed by the Ministry of Agriculture and Food in collaboration with the Ministry of Fisheries and Coastal Affairs. The council for animal ethics are to stay informed and evaluate fundamental ethical aspects of all types of animal husbandry and utilisation of animals, including relations to wild animals, assess the use of direct and indirect biotechnological principals on animals and consider ethical aspects of modern breeding and animal husbandry, including conservation of genetic diversity and considerations for biological resources in the wild.

**The Norwegian Board of Technology**[58] is the consultative office for technology assessment which shall work in the interface of technology and society, and contribute to further a human- and environmentally friendly technological development. The Board explores societal impacts and options of technology and science; stimulates public debate on technology; and advises the Norwegian Parliament (Stortinget) and other governmental bodies on technological issues. The Board furthermore monitors international technological trends and methods for technology assessment.

There are also other public agencies like the Committee for Animal Experimentation which is to ensures that

[53] http://www.etikkom.no/en/In-English/Human-Remains/
[54] http://www.bion.no/english/
[55] http://www.datatilsynet.no/templates/Page____194.aspx
[56] http://www.nsd.uib.no/nsd/english/index.html
[57] http://www.radetfordyreetikk.no/translations-to-english/
[58] http://www.teknologiradet.no/FullStory.aspx?m=5

the animal welfare for laboratory animals is at an acceptable level. The committee makes decisions on individual cases and matters of principle nature, is engaged in consulting, performs inspections and have the authority to approve projects with animals.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Until the Law on Medical and Health Research entered into force in Norway in July 2009 system was described as unnecessary fragmented, complex and unavailable because health and medical research was regulated in about 25 laws (in addition to international laws and professional standards). In addition there were a number of different authorities, partly with overlapping authority, which were to enforce and monitor the different rules and regulations. The intensions of the new superior law for medical research was to promote, improve and simplify medical and health research. It was also to coordinate and simplify the process of approval of experiments on human subjects all research projects, because according to the new law each project should now be submitted to one of the regional committees for medical and health research for approval. As far as we are aware, this new system has not been evaluated.

In 2006 the national research ethics committees in Norway was evaluated by an external Evaluation Committee on the initiative of the Research Council of Norway. It resulted in a new law on Ethics and Integrity in Research which made a legal basis for the existing system of national committees for ethical research and the regional committees and confirmed their independence. In addition the law on Ethics and Integrity in Research introduced a new body to investigate research misconduct.

Since 2007 the Committee of Misconduct has received 24 complaints on research projects, and approx. half of them have been considered. In five cases the conclusion has been deviation from the ethical guidelines, all because of plagiarism of data or results.[59] Only on a very few cases there have been a "pure" investigation of falsification, fabrication, plagiarism, and one of the challenges for the committee has been to distinguish scientific misconduct from professional or personal conflicts in research projects. The Law on Ethics and Integrity in Research[60] entered into force in July 2007, and the national system of research ethics has not been evaluated after this.

**The Norwegian Advisory Board on Ethical Aspects of Patenting**[61] was established in 2004. By autumn 2010 the advises of the Board was only once required. In view of the paucity of cases sent to the Board, the Board wrote a report on the ethics of patenting (2008), where it suggested that the mandate of the Board be changed so that it could take a more pro-active role and include a closer collaboration with the Norwegian Industrial Property Office, as well as a role in public debate. In the light of this report, efforts are currently underway to improve the modus operandi of the Board.

*Question 4: main organisations representing scientific society*

The national committees for research ethics have a common secretariat located in the centre of Oslo, and can be contacted through the email address post@etikkom.no.

Contact information to each committee:[62]

The National Committee for Medical and Health Research Ethics (NEM).
The National Committee for Research Ethics in the Social Sciences and the Humanities
The National Committee for Research Ethics in Science and Technology (NENT).
The National Commission for the Investigation of Scientific Misconduct
The Norwegian Advisory Board on Ethical Aspects of Patenting is an advisory committee for the Norwegian Patent Office and not for the general public. However, everyone interested in the ethics of patenting can contact the board at (+47) 23 31 83 04.

[59] http://www.forskning.no/artikler/2011/mai/287275
[60] http://www.etikkom.no/en/In-English/Scientific-Misconduct/
[61] http://www.etikkom.no/en/In-English/Patent-Board/
[62] http://www.etikkom.no/en/In-English/Contact-Information/

## Poland / *Pologne*

Reply provided by the Bureau of Research, Polish Sejm (30.06.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

There are statutory and constitutional provisions concerning scientific trials. Art. 39 of the Constitution guaranties that: "No one shall be subjected to scientific experimentation, including medical experimentation, without his voluntary consent." This provision excludes non-therapeutical experiments on persons not able to individual consent to research (resolution of the Constitutional Tribunal from 17.03.1993**,** act call W 16/92, OTK 1993, nr 1, poz. 16). Art. 73 of the Constitution states that: "The freedom of artistic creation and scientific research as well as dissemination of the fruits thereof, the freedom to teach and to enjoy the products of culture, shall be ensured to everyone."

Art. 27 of the Act of 6 June 1997 r. Criminal Code expressly excludes criminal responsibility for conducting scientific experiment, if:

a) expected benefit has significant scientific, medical or economic merit and the expectation of the achievement of the aim of the experiment is justified by the current scientific knowledge,

b) volunteer consented to research after having been provided with necessary information about benefits and probability of negative results and right of the person concerned to withdrawal at any time is secured.

Statutory standards of medical experiments are also listed by the Act of 5 December 1996 on Physician's and Dentist's Professions (*Journal of Laws from 2008*, No. 136, Item 857, with amendments). The Act establishes conditions of valid scientific experiment in art. 21-29 requiring *inter alia* independent multidisciplinary review of ethical acceptability of any trial.

An Act on Pharmaceutical Law from 6.09.2001 (Dziennik Ustaw z 2001 r. Nr 126 poz. 1381, with amendments) provides specific regulation on drug testing (art. 37-37al).
There are also binding professional codes of medical ethics prohibiting controversial practices (*inter alia* research cloning).

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research? What procedures are used by these institutions?*

Minister of Health approves any medical trial after independent examination of its scientific merit and after taking into account multidisciplinary review of its ethical acceptability.
Under general provisions of criminal law public prosecutors are also empowered to review any trail.

*Question 3: What problem do you see in the functioning of your country's legal and institutional systems to monitor scientific activities from the standpoint of ethical correctness?*

Effectiveness of the governmental review is restricted by cuts in public spending.

*Question 4: Could you indicate the main organisations representing scientific society in your country ?*

1. Polish Academy of Arts and Sciences in Kraków.
2. Polish Academy of Science in Warszawa.

## Portugal

Reply provided by the Directorate of Documentation, Information and Communication Services, Legislative and Parliamentary Information Division, Assembly of the Republic, Portugal (30.06.2011)

As an introductory note, we inform that is not possible to answer directly to your questions one by one. So, we give a general answer to them.

**National Ethics Council for the Life Sciences**

An Ethics Council is a privileged place for the reflection on the ethical issues raised by the progress of science in its various domains. To reflect, give advice, recommend and promote reflection in society in general are some of its essential competences. Portugal was one of the first European countries to feel the need for a bioethics committee at national level, having founded the "*Conselho Nacional de Ética para as Ciências da Vida*" (CNECV) [National Ethics Council for the Life Sciences][63] by Law no. 14/90, of 9th June. In May 29th 2009, Law n.º 24/2009[64] (available only in Portuguese) has been enacted. The Council's fourth and current term of office began on 4th September, 2003.

The Council has been involved in issuing opinions on current ethical themes, organising and participating in national and international events, striving to fulfil its responsibilities and to stimulate the bioethics debate at all levels of society**.**

The National Council of Ethics for the Life Sciences (CNECV) is an independent body created in 1990 by Law no. 14/90 of the 9th of June for the purpose of "analysing systematically the moral problems which arise out of scientific progress in the fields of biology, medicine or general health care".

The CNECV defines itself as national, independent, pluralist and consultative. National, because its opinions are addressed to all citizens and its very purpose is to promote public reflection on the issues it analyses. Independent, because its members do not represent any particular entity, social group or professional group. Members participate in the Council and its debates according to their own conscience. Pluralist, owing to its transdisciplinar composition, in terms of the members' backgrounds (both from science and the humanities), each bringing its own language, methods and ways of thinking to the quest for a common reflection. Consultative, because, when it issues its opinions or work documents, it binds neither the entities that request them nor any other body.

We may affirm that the CNECV is, deliberately, a body without formal power, which makes its authority, depend on how its pronouncements are received by and influence the opinion of decision-makers and the public.

Bioethics debates wide-ranging issues. Hence, diverse entities are entitled to request opinions from the CNECV - the President of the Republic, Parliament, members of Government, entities entitled to member status, public or private centres practising techniques connected in some way to the fields of biology, medicine or health care - and the Council may issue pronouncements on diverse themes.

Bioethical reflection turns essentially on the greater good of mankind, on how technological advances may best serve human needs, wishes and dignity. Bioethics proposes the kind of citizenship in which all people see themselves as "citizens of the world", respecting divergence and harmonizing different visions.
And, despite the different methods of analysis, the different lines of thought and the diverse reflection structures, the path to follow must be always that of pluralism, tolerance, participation and constructive dialogue.

The members of the council are nominated by the Prime Minister; Minister of Health; Minister of Justice; Minister of Education; Minister of Science and Higher Education; Minister of Youth Affairs; The Bar Association; Commission on Equality and Women's Rights; The Medical Association; The Biologists Association; Lisbon Academy of Sciences; Foundation for Science and Technology; National Council of Legal Medicine; Assembly of the Republic; National organisations representing activities connected with bioethics and Portuguese Council of University Rectors.

Corresponding to the prominence of the CNECV in the arena dedicated to reflection in the field of Bioethics, in the last years a significant number of requests for opinions were addressed to the Council, to which it responded in accordance with its competences, availability and the urgency of the requests. In its web site are available the 2007 and 2008 Activity Reports.[65]

Another example is the opinion of the CNECV[66] on the bill concerning advance health care directives.

[63] http://www.cnecv.pt/?locale=en
[64] http://www.cnecv.pt/legislacao.php
[65] http://www.cnecv.pt/relatorios.php?locale=en
[66] http://www.cnecv.pt/admin/files/data/docs/1299758893_Parecer%2059%20CNECV%202010%20EN.pdf

**Parliamentary committees**

At parliamentary level, the Committee on Education and Science studies these issues as part of its sphere of competence within the Parliament. Thus, on its role as legislator and representative of the people, it discusses and votes (article by article) laws on these matters, receives and deals with petitions on science, hears ministers and other political office holders, as well as experts on the domain of science.

Another committee involved on ethical issues is the Health Committee. In the last legislature (2009-2011) approved the new act on advance health care directives ("living will").
In its website[67] it's possible to see the process of discussion and approval of the matter (available only in Portuguese).

**Legislation**

Law n.º 32/2006, issued on 26th July 2006 (in Portuguese) regulates medically assisted procreation (MAP).

Law n.º 12/2009, issued on March 26th 2009 (in Portuguese), regulates the standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components, transposing Directives 2004/23/EC, 2006/17/EC and 2006/87/EC.

Two legislatures ago, two Bills (in Portuguese) concerning the legal framework on the use of stem cells for research purposes and its therapeutic applications were presented before the Parliament. The legislative process on the initiatives was not completed and the initiatives fell as the Legislature ended.

In the last legislature, some Bills (in Portuguese) concerning the legal framework on the "living will". The legislative process on the initiatives was not completed and the initiatives fell as the Legislature ended.

**Another entities**

Conselho Nacional de Procriação Medicamente Assistida ("*National Council on Medically Assisted Reproduction*")[68].
This organization updates the scientific information on MAR and techniques covered by this legislation. As, establishes the conditions under which the centres should be allowed where are executed the techniques of MAR, as well as the centres where gametes or embryos are preserved.

FCT ("***Science and Technology Foundation***")
The '*Fundação para a Ciência e a Tecnologia'* (FCT)[69] started its operations in August 1997.
The mission of FCT consists in continuously promoting the advancement of scientific and technological knowledge in Portugal, exploring opportunities that become available in any scientific or technological domain to attain the highest international standards in the creation of knowledge, and to stimulate their diffusion and contribution to improve education, health, environment, and the quality of life and well being of the general public. In its structure there is a Scientific Council for Life and Health Sciences.[70]

IGC ("***Gulbenkian Institute of Science***")
The Instituto Gulbenkian de Ciência (IGC) was founded and is supported by the Fundação Calouste Gulbenkian (FCG) to carry on biomedical research and education. The IGC operates as a "host institution", offering excellent facilities and services to foreign and Portuguese research groups or individual scientists, in particular to young post-doctoral fellows who are expected to develop their projects and form their groups in complete autonomy. In its structure there is an Ethics committee.

**Institute of Bioethics of** Portuguese Catholic University (UCP)
**Ethics Science and Society[71] (Institute of Bioethics)** Portuguese Catholic University (UCP).

Some guidelines:
Ethical guidance on the use of human embryonic and foetal tissue transplantation: Conclusions;
Cloning and stem cell technology: a cross-way between ethics and science.

[67] http://arnet/sites/XILEG/COM/10CS/GTDICITV/Paginas/default.aspx
[68] http://www.cnpma.org.pt/subnav_links.aspx
[69] http://alfa.fct.mctes.pt/index.phtml.en
[70] http://alfa.fct.mctes.pt/conselhos_cientificos/vida_saude
[71] http://www.porto.ucp.pt/site/custom/template/ucptplminisite.asp?SSPAGEID=3192&lang=2&artigoID=2099

For more detailed information, we suggest that you contact the CNECV.

## Romania / *Roumanie*

Reply provided by the Directorate for legal documents and studies, Camera of Deputies (23.05.2011)

***The National Authority for Scientific Research (NASR)***[72], set-up in 2005, represents in Romania the Government's specialized body with the mission to formulate, apply, coordinate, monitor and evaluate R&D and innovation policies, in accordance with the Government Strategy and Programme.

In the framework of Romania's accession to the EU and of the reconsideration of research and technological development as strategic priorities of the Government, the National Authority for Scientific Research has the complex mission to ensure the harmonisation of national RDI policies with the current orientations in the field at European level and to ensure the conditions for a rapid and efficient integration of our country in the European Research Area.

The main action lines of the National Authority for Scientific Research, pursued in order to fulfil its mission and to achieve its R&D and innovation policies and objectives, are the following:

- elaboration, launching, financing and monitoring national R&D and innovation programmes;
- development of a stimulating framework for R&D and innovation activities, in accordance with principles, criteria and procedures applied at EU level;
- development of specific measures for the European and international integration of R&D and innovation activities.

According to *Law no. 206/2004 regarding scientific research, technological development and innovation conduct,* a ***National Ethics Council***[73] was established *(MECT Order no 400/*22 February 2007*).*

The Romanian National Research Ethics Council is a national body with an independent status within the Government offices. Administratively, the Council is affiliated with the National Authority for Scientific Research. The Council is an advisory board to the Romanian Government on ethical issues raised by scientific and technological advances in research activities and monitoring the application of the moral and professional code in research activities.

The Order no.400 established the procedures governing appointments, composition and function of the National Research Ethics Council. The National Research Ethics Council (NREC) is composed of 11 members with different competencies. They are nominated for a period of four years which is only renewable once. The Council has 3 Commissions for:
a) socio-humanistic sciences;
b) life sciences;
c) technical sciences.
Each Commission has nine members. Matters for consideration are referred to a Commission in written form and resolutions are adopted by a majority vote.

The National Research Ethics Council has the following tasks:
-to make, if necessary by exercising its faculty to access the required information in the existing national operating centres;
- to express opinions and suggest solutions, also for the purpose of preparing legislative acts, to address the ethical and legal problems that may emerge as a result of the progress of research;
- to promote the drawing up of codes of conduct for practitioners operating in the various research sectors concerned and to encourage proper provision of information.

The **Academy of Romanian Scientists (ARS)**[74] is the continuator and the only legatee of the Academy of Romanian Science (1936-1948) and of the Association of Romanian Scientists established on HCM nr.1012/1956 which has changed her name from the Association of Romanian Scientists into that of Academy of Romanian Scientists in 1996 (Court Decision of October 3, 1996, issued by Sector 1 Court Bucharest, File 231/P.J./1996). In 2007, *Law no. 31 regarding organization and operation of ARS* was passed together with Governmental Decision no. 64, published in Monitorul Oficial no. 457 / July 6, 2007,

[72] http://www.ancs.ro
[73] www.mct.ro
[74] http://www.aos.ro

approving the ARS Status. The Academy of Romanian Scientists is an institution of public interest, self-governed with juridical personality of public right.

## Russian Federation / *Fédération de Russie*

Reply provided by the Analytical Department, the Council of Federation of the Federal Assembly of the Russian Federation (25.05.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

Matters of social responsibility of scientific researches and scientific ethics are considered in the following legal acts:
- Federal law №127-FZ of August 23, 1996 «On science and state scientific-technical policy»;
- Federal law №54-FZ of May 20, 2002 «On temporary ban for human cloning»;
- Federal law №614-FZ of April 12, 2010 «On circulation of medicine preparations» (in part of carrying out expertise of medicine preparations and ethical expertise);
- Resolution №785 of Government of the Russian Federation of November 19, 2007 «On Russian Academy of Science»;
- Resolution №353 of Government of the Russian Federation of May 6, 2008 «On Russian Academy of Medical Science»;
- Resolution №74 of Government of the Russian Federation of January 30, 2002 «On confirmation of the single register of scientific degrees and ranks and condition of order of sentencing scientific degrees».

Question 2: *Which institutions in your country are responsible for monitoring the ethical aspects of scientific research, i.e. possible danger to humans or the environment, as well as possible scientific misconduct? What procedures are used by these institutions?*

There is Council on ethics at the Ministry of health and social development of the Russian Federation, expert body in structure of this ministry.

Since 1998 works Commission of the Russian Academy of Science on struggle with pseudo-science and with falsification of scientific data. Commission has status of public organization, it publishes bulletin in support of science. Also Academy can create temporary commissions for expertise of certain scientific projects and inventions.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Among main problems connected with scientific ethics are:
- precedents of violating copyright and intellectual right, plagiarism;
- spreading of anti- and pseudo-scientific theories, including their reproducing in mass-media;
- situations when pseudo-scientists and pseudo-inventors try to get budget financial support and lobby for their projects, attempts of cheating, patenting and promotion deliberately pseudo-scientific inventions;
- situations when appear handbooks and manuals with pseudo-scientific content.

*Question 4: main organisations representing scientific society*

Commission of the Russian Academy of Science on struggle with pseudo-science and with falsification of scientific data

## Slovak Republic / *République slovaque*

Reply provided by the Parliamentary Institute, Department for analyses, education and parliamentary research, Office of the National Council of the Slovak Republic (15.7.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

Legal regulation concerning scientific research in the Slovak Republic :

Bill nr. 172/2005 on organization of the state support for scientific research and development.

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research? What procedures are used by these institutions?*

Main responsible organisation is Ministry of Education, Science, Research and Sport.
https://www.vedatechnika.sk/SK/Stranky/default2.aspx
Central information portal for science and research (part of the Ministry)
https://www.vedatechnika.sk/SK/Stranky/default2.aspx

---

Slovak Research and Development Agency (SRDA) is the research and development grant agency in the Slovak Republic. It was established by the Act No.172/2005 in July 2005 and it is a successor of the previous agency functioning since 2001. SRDA is the instrument for distribution of public finances for research and development on the competitive basis in Slovakia. SRDA is responsible for research and development promotion in all research fields, including international research cooperation. http://www.apvv.sk/agentura

Under SRDA there is Ethical commission which comments on cases of suspected scientific dishonesty, scientific fraud, as well as other cases of unethical behavior of scientists and researchers in relation with research and development projects, give advice on ethics of science, research and professional ethics of a scientist and researchers, as well as medical ethics, medical ethics and bioethics for the complainants or project leaders (see):

http://www.apvv.sk/buxus/docs/agentura/ine-dokumenty/statut-etickej-komisie-20070322.pdf

Special approach is to single out scientific disciplines e.g. bioethics

In Slovakia, bioethics is in the process of establishment of their foundations. Expression of the practical application of ethics in professional fields of medicine and health was the establishment of the Central Ethics Committee Ministry of Health to advise the Minister of Health, in the 1990. In addition to her work exists ethics committees in some hospitals, which focus on the control of scientific research.

In 1991 was in Slovakia-based Institute of Medical Ethics and Bioethics, which since 1994 issues the journal Medical Ethics and Bioethics. In 2004, launched the Center for Bioethics, information and documents located in Bratislava and has responsibility for countries of the Central Europe.

The Slovak Republic in this area has built a certain position - in 2005 became a member of the Intergovernmental Committee on Bioethics and UNESCO Director-General appointed Professor in COMESA. RNDr. Martha Kollárova, MD., Vice-rector for research and development activities and graduate studies at Comenius University, founder and Chairman of the Slovak Committee for Bioethics at the Slovak Commission for UNESCO.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

We advise to consult this question directly with the Slovak Academy of science http://www.sav.sk/

*Question 4: main organisations representing scientific society*

Slovak Academy of sciences http://www.sav.sk/
Ethical codex of the Slovak Academy of sciences (Slovak language)
http://www.sav.sk/uploads/d0060847495/eticky_kodex_sav.pdf

and the Ethical commission of SRDA http://www.apvv.sk/agentura
http://www.apvv.sk/buxus/docs/agentura/ine-dokumenty/statut-etickej-komisie-20070322.pdf

## Slovenia / Slovénie

Reply provided by the Research and Documentation Division, National Assembly (24.06.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

**The Research and Development Act** (hereinafter referred to as "the Act") defines principles and objectives, and regulates the method of implementing the policy of research and development activity which is financed by the state budget and other sources (European programmes and funds, local communities and economy). The Act also lays down the organisation of research and development activity, as well as the conditions for conducting it (Article 1 of the Act).

In accordance with the Act, researchers (persons conducting research and development activity) shall be granted the autonomy of research. Research and development activity is based on the **principles of ethics and responsibility** for achieving objectives laid down in the Research and Innovation Strategy of Slovenia and in budget memorandums, with respect for social, environmental and sustainable aspects of social development, on the principle of competitiveness, quality, efficiency and openness, as well as on mutual interest cooperation and integration in the national and international environment (Article 2 of the Act).

The **Research Infrastructure Development Plan 2011-2020** also contains the role and importance of ethics as it is committed to respect for the existing ethical principles.

Ethics in research and of researchers is also mentioned in the **Resolution on the National Research and Development Programme 2011-2020** adopted by the National Assembly at its session of 24 May 2011: *Increased embedding of research and innovation into social environment and settlement of fundamental social problems and questions, together with the difficulty of assessing the impact of research and development activity on people's lives and on environment,* ***create the increasing need for the ethical awareness of researchers****.* ***At the same time, the research profession requires great integrity and keen sense of responsibility*** *as the researchers, particularly in small environments like Slovenia, find themselves in situations which could be seen as a conflict of interests or which could harm the reputation of a research institution and the research profession in general* (the Resolution on the National Research and Development Programme 2011-2020).

See also answer no. 2 on international documents (the National Medical Ethics Committee).

*Question 2: Which institutions in your country are responsible for monitoring the ethical aspects of scientific research ? What procedures are used by these institutions?*

In Slovenia, the **National Medical Ethics Committee**, which is an independent body, and the **Ethical Commission for the Experiments on Animals** at the Ministry of Agriculture, Forestry and Food deal with the issue of ethics in research.

The **National Medical Ethics Committee** has long tradition and is one of the oldest national ethics committees in the world. Moreover, it contributed its share to the formulation of the European ethical standards for biomedical research on human beings, including the Oviedo Convention on Human Rights concerning biomedicine and the Additional Protocol to the Convention on Human Rights and Biomedicine concerning biomedical research. These are legal and ethical instruments with the force of law, ratified by Slovenia among the first and directly applicable in practice with regard to the ethics of research on human beings. Slovenia has certain special aspects regulated by individual laws, such as researches on human embryos, handling with human cells and tissues etc. Furthermore, it regularly follows the development of ethics in biomedicine and further cooperates in the elaboration of international standards, such as guidelines

for ethical evaluation of researches (quoted from the Resolution on the National Research and Development Programme 2011-2020).

For more detail on how the National Medical Ethics Committee works, see the website: http://www.kme-nmec.si/.

**The Ethical Commission for the Experiments on Animals** acts in accordance with the Rules on the Ethical Commission for the experiments on animals, laying down the composition, tasks, competence and manner of work of the Ethical Commission. It has nine members: the Chair, the Deputy Chair and seven members. It is appointed by the Minister of Agriculture, Forestry and Food in the agreement with the Minister of Science and Technology, the Minister of the Environment and Spatial Planning, and the Minister of Education and Sport from renowned experts of the veterinary, medical, biologic, pharmaceutical and zootechnical professions. The Commission's mandate lasts four years.

The Ethical Commission delivers opinions and positions on individual ethical issues within its competence - to the VARS, as well as to science and research organisations or other institutions, particularly when so required. The VARS may request the Ethical Commission to deliver an opinion on a certain issue within the time limit determined by the VARS (more: The Rules on the Ethical Commission for the experiments on animals).

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Ethical control over researches is partly open in other areas, for example in social sciences, where rights of people engaged in researches could be violated. Due to the rapid development of science and the use of its achievements, a need for ethical assessment of all scientific projects as a condition for the beginning of work is becoming increasingly significant. The same also applies to areas in which the probability of direct violations of human right and ethical norms appears to be low. A possibility of the so-called double use of achievements should also be taken into account. This can mean unforeseeable misuse (production of new weapons or means for criminal or terrorist activities, unacceptable activities for the benefit of an individual and society). In line with the tendencies in the developed world, it will be reasonable to examine ethical control over publishing which should not affect the freedom of science and the freedom to disseminate scientific results. However, it will be necessary to supplement the legislation and legal regulation in accordance with development across the world. Besides, it will be necessary to adopt codes of moral integrity and good practice in science, serving as a basis for the formulation of such codes in all scientific institutions (quoted from the Resolution on the National Research and Development Programme 2011-2020).

As the primary objective, the Resolution indicates the provision of a high level of ethics of researches at their work and outwards. In order to assess the ethics of research, new independent sectoral commissions for research ethics are needed outside the biomedical sphere. It is necessary to prepare systemic and institutional arrangements to discuss ethical issues in science in all important areas, following the example of the EU Member States. The national code of ethics and integrity, and practice in science should be adopted, serving as a basis for codes of individual research institutions. Furthermore, it is necessary to establish the Court of Honour for the field of science (the Resolution on the National Research and Development Programme 2011-2020).

At this point, I would also like to mention the role of higher education (universities). Higher education is particularly emphasized in the **Resolution on National Programme of Higher Education** 2011-2020 adopted on 24 May 2011. Higher education has significant influence on social development and ethical relations, itself encompassing an important part of population in the decisive phase in the formation of personality. Universities are therefore considered as ethical instances ensuring that the ethical aspect is taken into account in the pedagogic and research processes. Due to the increasing role of knowledge in the society, the need for higher education ethics is growing, demanded also through altered technical and economic conditions in which higher education operates. It is expected from a person with higher education to be able to ethically assess and actively promote humanity in the society. In this sense it is necessary to improve study programmes and formulate codes of ethics for organisations of higher education (the Resolution on National Programme of Higher Education).

The Resolution therefore provides for an important measure, namely the formulation of codes of ethics for institutions of higher education, from 2012 onwards. Institutions of higher education will adopt their own codes of ethics reflected in all areas of work of institutions of higher education. Furthermore, they will be

transferred into the education process, thus influencing the ethical awareness and behaviour of students and graduates (the Resolution on National programme of higher education).

*Question 4. main organisations representing scientific society*

Please see the previous replies.

## Spain / *Espagne*

Reply provided by the Spanish Senate (06.07.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

In Spain, the laws, regulations and official guidelines concerning the ethics of scientific research are as follows:
Law 14/2007, of 3 July, on biomedical research (BOE No. 159 of 04/07/2007) (Sections: 12, 37 - 39 and 77 - 81)

Law 29/2006, of 26 July, on guarantees and rational use of sanitary drugs and products**.** (BOE No. 178 of 27/07/2006) (Section 60.6)

Royal Decree 223/2004, of 6 February, regulating the clinical trials with drugs. (BOE 33 of 07/02/2004) (Chapter III)

At present the new Law on Science is being processed, which contemplates the creation of a National Committee on Research Ethics, as a benched, independent and consultative body, on matters related with professional ethics of scientific and technical research. The current situation of the draft law: Senate. Passed with amendments on 4 May 2011.

BOCG_D_09_37_242 (Official Gazette of the Cortes Generales). Date: 25-MAR-2011. Wording sent by the Congres of Deputies.
BOCG_D_09_51_344 Date:15-APR-2011. Amendments
BOCG_D_09_57_377 Date:04-MAY-2011. Dissenting opinions
BOCG_D_09_57_381 Date:04-MAY-2011. The Committee's opinion
BOCG_D_09_57_382 Date:04-MAY-2011. Report of the Speech

*Question 2: Which institutions in your country are responsible for monitoring the ethical aspects of scientific research ? What procedures are used by these institutions?*

In Spain, the institutions responsible for monitoring the ethical aspects of scientific research are:
Committees on Research Ethics

- Ethics Committees on Clinical Research
- Bioethics Committee of Spain
- Committees on Assistance Ethics

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

We have no data on this matter.

*Question 4: Could you indicate the main organisations representing scientific society ?*

Among the main organisations representing scientific society in Spain, which could provide their views on these issues are the following:

Bioethics Committee of Spain

Coordination Centre of Ethics Committees on Clinical Research
Ethics Committees on Clinical Research accredited in Spain
Health Institute Carlos III

Should this be of interest to you, please find enclosed the following article: Spanish regulations on Ethics Committees and the novelties introduced by the new Law on Biomedical Research. Itziar Lecuona. In: Revista de Bioética y Derecho (Magazine on Bioethics and Law) Nº. 11, September 2007."

## Sweden / Suède

Reply provided by the Swedish Riksdag (27.06.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

Examples of such laws in Sweden are the Act concerning the Ethical Review of Research involving Humans (2003:460) (the Ethical Review Act), the Personal Data Act (1998:204), and the Medicinal Products Act (1992:859). These laws and more information are available at www.epn.se, www.datainspektionen.se , and www.mpa.se. See also http://www.eurecnet.org/index.html (European Network of Research Ethics Committees). Parts of the Higher Education Ordinance also regulate or establish the responsibility of the universities regarding the investigation of accusations of fraud in research.

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research ? What procedures are used by these institutions?*

Both the Central Ethical Review Board (CERB, monitoring of compliance with the Ethical Review Act) and the Regional Ethical Review Boards, the Data Inspection Board (handling of personal data/the Personal Data Act), and the Medical Products Agency (clinical trials of medicinal products/the Medicinal Products Act). The universities/higher education institutions bear responsibility for fraud in research, and the National Agency for Higher Education supervises the universities. The CERB is responsible for investigating fraud in research. The CERB is required to submit a statement at the request of a university or institute of higher education. For more information, see www.epn.se.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Firstly, in contrast to many other countries, Sweden does not have a comprehensive system for investigation and scrutiny of scientific misconduct and fraud - Sweden is probably worst in Scandinavia in this area.

Secondly, the question of representation has not been investigated, and this appears to cause lawyers insurmountable problems. This is one of the reasons why Sweden, although it has signed the Oviedo Convention, has not ratified it. However, several other countries have been able to solve this problem.

Thirdly, among the values that have to be protected are the privacy of individuals and groups and the right to privacy itself. the balance between these values and various research interests, which have been given particular attention recently in connection with the debate on micro databases, are among issues of continuous interest in the debate on the ethics of research.

*Question 4: main organisations representing scientific society*

The particular universities themselves, the National Agency for Higher Education and the National Science Council.

## Switzerland / Suisse

Reply provided by the Federal Assembly (24.06.2011)

*Question 1: what are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

**Laws:**
Article constitutionnel sur la recherche sur l'être humain (Cst. 118b):
http://www.admin.ch/ch/e/rs/101/a118b.html
Loi sur la recherche :
http://www.admin.ch/ch/f/rs/c420_1.html : (Siehe Art. 9 Abs. 1b und Art. 11a)
Loi sur le génie génétique :
http://www.admin.ch/ch/f/rs/c814_91.html
Loi relative à la recherche sur les cellules souches :
http://www.admin.ch/ch/e/rs/c810_31.html
Ordonnance du 4 décembre 2000 sur la Commission nationale d'éthique dans le domaine de la médecine humaine (OCNE) : http://www.admin.ch/ch/f/rs/c810_113.html
09.079 Loi sur la recherche sur l'être humain. (Nouvelle loi en délibération au Parlement) :
http://www.parlament.ch/d/suche/seiten/geschaefte.aspx?gesch_id=20090079

**Guidelines :**
http://www.samw.ch/en/News/News.html : dort unter Ethik diverse Richtlinien
http://www.akademien-schweiz.ch/en/index/Portrait/Kommissionen-AG/Ethikkommission-fuer-Tierversuche.html : Ethical Principles and Guidelines for Experiments on Animals. The Ethics Committee for Animal Experiments is an advisory body of the Swiss Academies of Arts and Sciences.
http://www.akademien-schweiz.ch/en/index/Portrait/Kommissionen-AG/Wissenschaftliche-Integritaet.html:
Another advisory body of the Swiss Academies of Art and Sciences on questions related to scientific integrity
http://www.efbs.admin.ch/en/index.html : The SECB, a permanent federal advisory committee, advises the Federal Council and the federal agencies on the drafting of laws, ordinances, guidelines and recommendations
The Federal Ethics Committee on Non-Human Biotechnology : http://www.ekah.ch/en/index.html
Centre d'évaluation des choix technologiques : http://www.ta-swiss.ch/en/

*Question 2: Which institutions are responsible for monitoring the ethical aspects of scientific research? What procedures are used by these institutions?*

Académie suisse des sciences : http://www.akademien-schweiz.ch/en/index/Portrait/Kommissionen-AG/Wissenschaftliche-Integritaet.html
Commission nationale d'éthique pour la médecine humaine :
http://www.bag.admin.ch/nek-cne/index.html?lang=fr
The Federal Ethics Committee on Non-Human Biotechnology : http://www.ekah.ch/en/index.html
Fonds national suisse de la recherche scientifique :
http://www.snf.ch/F/actuel/Dossiers/Pages/integrite-scientifique.aspx

Swiss agency for the authorization and supervision of therapeutic products. We fulfill our legal mandate and work with partner authorities on a national and international basis:
http://www.swissmedic.ch/index.html?lang=en
Commissions suisses d'éthique de la recherche clinique :
http://www.swissethics.ch/index_f.html

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

Une problématique concerne certainement le fédéralisme suisse : Par exemple, les projets de recherche sur l'être humain sont actuellement – et seront, selon le projet de loi sur la recherche sur l'être humain – soumis à des commissions cantonales d'éthique. Ceci peut amener à des procédures compliquées, potentiellement incohérents d'un canton à l'autre et peut créer, auprès des chercheurs, le sentiment d'être exposé à un certain arbitraire au niveau des décisions finalement prises. La modeste harmonisation prévue par le projet de loi ainsi que les démarches déjà entreprises dans ce sens par Swissethics permettront probablement d'y remédier en partie.
Comme vous l'avez constaté sur l'ensemble des réponses, l'ensemble du domaine est assez bien réglementé.

Dans le cadre des accords bilatéraux, la Suisse participe activement aux programmes de recherche de l'Union européenne.

*Question 4: the main organisations representing scientific society*

Conseil suisse de la science et de la technologie : http://www.swtr.ch/index.php?lang=en
Fond national de la recherche scientifique : http://www.snf.ch/E/Pages/default.aspx
Académie suisse des sciences : http://www.akademien-schweiz.ch/en/index/Aktuell/News.html

## "The former Yugoslav Republic of Macedonia" / « *L'ex-République yougoslave de Macédoine* »

Reply provided by the Ministry of Education and Science, Department of Science and Technological Development (22.06.2011)

In accordance with the Constitution of the Republic of Macedonia, the state is obliged to encourage and support scientific-research activity and technological development. The Ministry of Education and Science has responsibilities for the organization, financing, development and promotion of scientific research, technological development and innovations, technical culture, informatics and information systems, as well as international cooperation in these fields.

The major goal of the Macedonian R&D policy is to provide competitiveness of the Macedonian science compared with the European R&D. Based on the undertaken obligations to set the national legislation in accordance with the EU legislation we have amended the Law on Scientific-Research Activity and the Law on Technological Development.

The Law on Scientific-Research Activity increases the competencies of the Council for Scientific-Research Activity, appointed by the Minister. The Council is in charge of the overall scientific policy and development of regulations to cover the scientific area. Also, it is obliged to define the priority areas and programs for the Scientific-Research activity.

Further, a new approach in the management of the database on scientific-research programs and projects (both national and international) was introduced in order to create quality records.

The Programmes for Scientific-Research Activity, technological development and technical culture of the Ministry of Education and Science provide grant funding for project-based research to research organizations, universities, and to individual scientists. It also encourages the mobility of scientists for bilateral research projects. There are three budget lines that support the following Programmes: Programme for Scientific-Research Activity, Programme for Technological Development and Programme for Technical Culture. The Programme for Scientific-Research Activity finances both the national and international projects and the Programme of the Public Scientific Institutes. The line from the Programme for Technological Development supports the academia – business research collaboration through grants. All grants are awarded through competitive calls.

In the second half of 2010 the most important development in the R&D policy is that the Ministry of Education and Science has started with preparation of new separate R&D policy. The country is for the first time in the process of adoption of separate national R&D policy that should determinate the strategic directions of R&D in Macedonia and create a base for developing additional measures and action plans which are in line with the EU R&D goals. The preparation of this document is in its final stage.

The Ministry of Education and Science has also made changes to the Law for Higher Education regarding the R&D activities performed by the higher education sector. According to the new legislation the Public Universities are obliged to allocate 40% from the students' tuition fee in fundamental and applied research, modernization of the infrastructure for scientific research, training and improvement of the scientific researchers and for investments and maintenance.

Protagonists of the Macedonian R&D activities are following entities:

- Universities (state and private);
- Macedonian Academy of Sciences and Arts;
- Public Scientific Institutes;
- Research & Development Units in the industrial sector;
- Innovation centers;
- Technology parks and transfer centers;

- Individual researchers

Macedonian Academy of Sciences and Arts is an important scientific organization, the goal of which is to stimulate development of the sciences and arts. It is regulated by the separate Law and financed from the national budget, but apart from the budget dedicated for Science.

Protagonists of the Macedonian R&D activities can establish Boards of ethics and promote their own ethical Codex's in compliance with their regulations.

## United Kingdom / Royaume-Uni

Reply provided by the House of Commons (27.06.2011)

*Question 1: What are the laws, regulations and official recommendations/guidelines concerning key sensitive questions of social responsibility in conducting scientific research, as well as the ethics of scientific research?*

In the UK there is no overall legal approach to scientific ethics.[75] Instead, many individual measures are in place to prevent unethical scientific research. These range from education programmes in universities to codes of conduct in specific scientific fields.[76] Specific regulations apply to research in particularly sensitive areas such as animal and human testing.

The Government, predominantly through its Office for Science and the Chief Scientific Adviser, seeks to promote good scientific practices across society. For example, it promotes the Universal Ethical Code for Scientists.

*Question 2: Which institutions in your country are responsible for monitoring the ethical aspects of scientific research? What procedures are used by these institutions?*

The governance arrangements that apply to research are complex and vary depending on the type of research, the participants involved, how it is funded and where in the UK it is undertaken. A description of the institutions and governance arrangements involved in medical and social research can be found here: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4122427.pdf

These are due to be reformed (see below).

The UK Parliament, through its committees, also plays an important role in scrutinising the ethical aspects of research. The House of Commons Science and Technology Committee and the House of Lords Science and Technology Committee are two committees involved in this work, but other committees also touch on this issue when relevant. An important example of parliamentary scrutiny of scientific ethics occurred last year in relation to stolen emails from the Climatic Research Unit.

*Question 3: What problems do you see in the functioning of your country's legal and institutional system to monitor scientific activities from the standpoint of ethical correctness? What improvements are needed and do you consider should be implemented? What expectations do you have from European institutions?*

It is recognised that the current regulatory controls, including ethical regulations, for health research in the UK are overly bureaucratic. As a result the Government plans to introduce a single system for approvals as part of a new Health Research Regulatory Agency. The new agency aims to streamline regulation, improve the cost effectiveness of clinical trials and speed up research.

More information about the problems, and what the Government plans to do about them, can be found here: http://www.acmedsci.ac.uk/p47prid88.html

[75] http://www.parliament.uk/documents/post/postpn340.pdf
[76] http://www.parliament.uk/documents/post/postpn340.pdf

*Question 4: Could you indicate the main organisations representing scientific society?*

1. The Royal Society
2. The Government Office for Science, and the Government's Chief Scientific Adviser
3. The Academy of Medical Sciences
4. Research Councils UK
5. The General Medical Council