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Ethical issues form

Proposers are requested to fill in the following table

Does your proposed research raise sensitive ethical issues related to:	Yes	No
Human beings	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Human biological samples	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Personal data (whether identified by name or not)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Genetic information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Animals	<input type="checkbox"/>	<input checked="" type="checkbox"/>

I am required to confirm that the proposed research does not involve:

- any form of human cloning for reproductive purposes;
- any form of human heritable genome editing;
- any form of human embryo research which could involve the creation of embryos for the purpose of research or for the creation of human embryos for reproductive purposes;
- any form of research which could involve the creation of human embryos with the intention of creating a child with the intention of

National Regulations on Ethics and Research in

Romania

România



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by
Dr. Gabriel Raicu

European Commission contacts:
Barbara Rhode, An Baeyens and David Coles
Brussels, 2003

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It can be accessed through the Europa server (<http://europa.eu.int>).

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Foreword

The ethical issues associated to the achievements of scientific and technical progress, especially in knowledge fields situated at the leading edge, have always represented a source of intense debates, sometimes producing most serious crises, covering wide social segments. Romania and, in particular, its Science and Technology community, is fully aware and is fully supporting the more recent efforts at the international scale, to provide a consistent, mutually recognised and viable framework for observing and monitoring the complex domain of ethical problems. According to the 2002 statistical data, the scientific community in Romania accounts for about 23,600 researchers, out of which 8,500 are certified researchers and 5,160 have a PhD degree. The total R&D personnel is of about 37,700. The distribution of researchers by fields indicates a high percentage of researchers in the technical and engineering sciences field, about 60%, **while the life science field stands for a total of about 10%**, including medical and biological, as well as agricultural sciences. The system of public funding for R&D and innovation activities is based on three main instruments:

- **The National Plan for RTD and Innovation**, which is the major instrument for the implementation of S&T policies and includes 14 programmes oriented towards the generation of economic effects for the short/medium term, through projects based on the direct collaboration between research and industry; support for the international integration of the Romanian S&T system. The Plan is co-ordinated by the Ministry of Education, Research and Youth.
- **The Programmes of grants for scientific research**, addressing individual researchers/teams and oriented towards the stimulation of scientific excellence and the formation and development of the scientific career. The Programmes of grants are coordinated by the Ministry of Education, Research and Youth and, respectively, by the Romanian Academy.

- **The Sectoral R&D and Innovation Plans**, a new instrument launched this year, which permits various ministries to develop their own R&D Plans, addressing specific technological development problems, at a more narrow, sectoral or branch level.

All research activities developed in Romania comply with ethics requirements, according to international norms and practice. The national legislation addressing ethical issues includes provisions in strict accordance with the international regulatory framework referring to experiments and research involving persons and personal data, human biological material, including embryos and stem cells, experiments on animals, the use of GMOs. The bodies dealing with ethical issues include the Bioethical Commission by the Ministry of Health and Family, the Bio-safety Commission by the Ministry of Agriculture, as well as ethical Commissions at the level of research institutions. We also mention the recent initiative promoted by the Ministry of Education, Research and Youth, to develop the regulatory framework devoted to ethical issues with a specific "code of ethical and deontological conduct in research, development and innovation". The adoption of the Code, expected for the end of this year, will be followed by the development of detailed procedural regulations specific to various scientific fields. Finally, we wish to express our conviction that the correlation of efforts, at both national and international levels, will lead to concrete and transparent progress in the adequate treatment of ethical issues, both by the scientific and technical community, as well as by society at large.

*Professor Alexandru ATHANASIU
Minister of Education, Research and Youth*

Introduction

The European Commission is committed to ensuring that research funded under the 6th Framework Programme respects ethical principles. What legal requirements do researchers have to respect in European Commission funded research projects?

The text of the 6th Framework Programme makes reference to the following international texts:

- The Charter of Fundamental Rights of the European Union
- European Union directives
- Convention of the Council of Europe on Human Rights and Biomedicine (1997) and the additional protocol on the Prohibition of Cloning Human Beings (1998)
- UN Convention on the Rights of the Child (1989)
- Universal Declaration on the human genome and human rights adopted by UNESCO (1997)
- Helsinki Declaration

These regulations and texts are all well known and can be consulted on the website http://europa.eu.int/comm/research/science-society/ethics/legislation_en.html.

Apart from such European legislation and international texts, the Specific Programme for research, technological development and demonstration 'Integrating and strengthening the European Research Area' (2002-2006) requires also that "In compliance with the principle of subsidiarity and the diversity of approaches existing in Europe, participants in research projects must conform to current legislation, regulations and ethical rules in the countries where the research will be carried out. In any case, national provisions

apply and no research forbidden in any given Member State will be supported by Community funding in that Member State.⁽¹⁾"

The specific regulation of ethical issues is a matter of subsidiarity. Rooted in the cultural background of the nation state, there are many ethical rules and guidelines in the national legal system that the scientists have to apply when conducting research in a country.

The guide for proposers of the 6th Framework Programme requires applicants to identify whether workpackages contain one or more of the five following ethical issues, namely whether the research work involves

- humans,
- human tissue,
- personal or private data,
- genetic information,
- or animal experimentation.

Detailed information on how these issues are handled has to be given, including the explanation of the applicable national legal background.

Such projects that contain ethical issues may be submitted to an ethical review if they have been shortlisted after the scientific evaluation.

When co-operating in a European research consortium, it is important that researchers from

(1) See Annex 1 (COUNCIL DECISION of 30 September 2002 adopting a specific programme for research, technological development and demonstration: 'Integrating and strengthening the European Research Area 2002-2006).

partner countries have easy access to the national regulations on those five areas, where ethical issues may arise. It is an advantage if researchers not only understand the regulation of their own countries, but also those of potential partners and when they seek to collaborate.

This document is part of a series that aims to make the regulatory situation in the accession and candidate countries more transparent and better accessible to scientists in Europe.

The Romanian text has been written by Dr. Gabriel Raicu and subsequently approved by the Ministry of Education, Research and Youth of Romania. The Commission has been promoting this project and is now dedicating a bilingual publication (original language and English) to the accession and candidate countries in order to facilitate their participation in the 6th Framework Programme. The project has been co-ordinated for the Commission by Alexandra Bitusikova, An Baeyens and David Coles. The responsibility and credit for the contents rest with the author and the Ministry of Education, Research and Youth of Romania.



Barbara Rhode
 Head of Unit "Ethics and Science"
 Research Directorate General

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1. International instruments in Romanian law

According to Art. 11 (International Treaties) of the Romanian Constitution (adopted on 8 December 1991), the Romanian State pledges to fulfil as such and in good faith its obligations as deriving from the treaties it is a party to; and treaties ratified by Parliament, according to the law, are part of national law.

Moreover, the Constitution grants precedence of human rights in its Article 20: Citizens' rights and liberties must be interpreted and enforced in compliance with the Universal Declaration of Human Rights, its covenants and other treaties Romania is a party to. Should there be any inconsistency between the covenants and treaties on fundamental human rights Romania is a party to and internal laws, the international regulations will prevail.

2. National overview

1) Overview of national legal structure

Laws (abbrev. "L." (Lege)) – are enacted by Parliament. They enter into force upon their promulgation by a presidential decree in the "Monitorul Oficial" (abbrev: M.Of.); the official Romanian newspaper for laws. In principle, a Law is published in the "Monitorul Oficial" a few days before the publication of the presidential decree. It may happen that the Law mentions a postponed date on which it will enter into force, if some time is needed for the implementation of the law. An emergency ordinance (abbrev.: "OU" (Ordonanta de Urgenta)) – is emitted by the Government. Upon

its publication in the "Monitorul Oficial", it enters into force. Thereafter, it needs to be ratified by the Parliament and promulgated by a presidential decree in the "Monitorul Oficial". During the ratification process, the Emergency Ordinance can be modified, or rejected. A governmental ordinance (abbrev.: ORDO (Ordonanta)) – is enacted by the Government being empowered by the parliament, which is usually happening during the holiday of Parliament. It enters into force when it is published in the "Monitorul Oficial". Thereafter, it has to be promulgated by a presidential decree in the "Monitorul Oficial". It functions like a law.

2) Ethics committees

▪ National Ethical Commission for the clinical study of drugs

According to Art. 85 of Law 336/2002, which approved the Emergency Ordinance 152/1999 on Medicinal Products for Human Use, a clinical study can be started only after it has been approved by the National Ethical Commission or the institutional ethics committee which will certify that the ethical rules are respected in compliance with the "The Rules for good practice during clinical study" (1). Conform to Art. 76, the Drug's National Agency and Health Ministry elaborate these rules.

The National Ethical Commission (2) for the drug's clinical study functions under the authority of the Romanian Academy of Medical Sciences. The recommended composition of this commission is as follows: 5 physicians, 2 pharmacists, 2 psychologists / sociologists, 1 jurist, 1 layperson, 1 nurse, 1 theologian. A minimum of two Commission's members must be female. ("The Rules for good practice during clinical study", page 12, annex 6 - page 92 and annex 16 - page 105). The President of this National Ethical Commission is Prof. Dr. George Litarczek.

▪ Institutional ethical commissions (for the clinical study of drugs)

Following "The Rules for good practice during a clinical study", the institutional ethics committee functions as a local ethics committee during a clinical study.

▪ Bioethical Commission of Family and Health Ministry (3)

This commission functions under the authority of Family and Health Ministry like the other commissions (Cardiology Commission, Gastroenterology Commission, etc.). The Minister of Health appoints the President and its Members. This Commission has a consultative role. The President of Bioethical Commission of Family and Health Ministry is Prof. Radu PALADE, MD.

3) Competent bodies

▪ Ombudsman Institution

The 'Ombudsman Institution' (4) represents the supervisory authority for the area of the protection of personal data.

▪ National Sanitary Veterinary Agency

This Agency is the supervisory authority, under the Ministry of Agriculture, Alimentation and Forests, for the area of scientific research involving animals.

3. Research involving persons

▪ **Law 336/2002**

First of all, research involving human beings is ruled by the Law 336/2002, which approved Emergency Ordinance 152/1999 on Medicinal Products for Human Use (L nr. 336 publicat in M.Of. nr. 418 din data: 06/17/2002; OU nr. 152 publicat in M.Of. nr. 508 din data: 10/20/99).

According to Art. 84, a clinical study must be based on rigorous, scientific data that will be evaluated by the Drug's National Agency, which will issue an approval for the performance of the clinical study. A clinical study can be started only after it has obtained the approval from the National Ethical Commission for the clinical study of drugs and/or from the institutional ethics committee. "The Rules for good practice during clinical study" defines which type of study needs the approval of the national commission or only, the approval of a local one.

▪ **Law 100/1998 on Health Care Assistance (L nr. 100 publicat in M.Of. nr. 204 din data: 06/01/2001)**

Research on persons is also governed by the Law 100/1998 on Health Care Assistance.

In its Annex 2, Chapter I, Art. 2, the Ministry of Health is allowed to elaborate rules on the registration and the control of drugs and biological products for human use.

In conclusion, the Ministry of Health and Family and Drug's National Agency elaborate the rules - „The Rules for good practice during clinical study". Some of these rules are:

- Any research involving persons is authorised and supervised by the Drug's National Agency and is undergoing an ethical review by the National Ethical Commission (and Institutional (Ethics) Commissions – as local ethics committee).
- Informed consent is compulsory for any research involving persons and must be given in writing and signed by the subject or his/her legal representative.
- For children, there is no mention of a specific age, from which the child would be competent. If a child (or other person unable to consent) is capable to understand the information of the informed consent form, he has to sign too.
- Vulnerable persons could be: students of medicine, pharmacology, dentistry; persons who work in hospitals or medical laboratories, employees of pharmaceutical industry, members of the Army, prisoners, patients suffering from an incurable disease, unemployed people, very poor persons, minority groups, homeless persons, refugees, minors and persons unable to consent.
- Pregnant women can be involved in a clinical study only if the study will be of direct benefit to the group of pregnant women.

4. Research involving human biological material (blood, organs, tissues, cells, dna)

The Law 2/1998 on Removal and Transplantation of Human Tissue and Organs (see summary below, annex 1) (L nr. 2 publicat in M.Of. nr. 008 din data: 01/13/98) is not covering the area of research involving the use of human biological materials.

Mention must be made about the Law 4/1995 on blood donation, therapeutic utilisation of human blood (L nr. 4 publicat in M.Of. nr. 009 din data: 01/18/95). According to Art. 28, scientifically research on transfusion is authorised and supervised by the National Institute of Haematological Transfusion of Bucharest and the National Commission of Transfusion.

5. Research involving human embryos and embryonic stem cells

Following Art.18., point 2 of the Law 17/2001 related to the ratification of the Convention on human rights and biomedicine and the Additional Protocol on Prohibition of Human Cloning (L nr. 17 publicat in M.Of. nr. 103 din data: 02/28/2001), the creation of human embryos for research purposes is prohibited.

Conform to the Additional Protocol on Prohibition of Human Cloning (Law 17/2001), the human cloning is prohibited in Art. 1, point 1 of the same law.

However, there is no regulation existing with regard to IVF, research on embryos or embryonic stem cells.

6. Personal data

The protection of personal data is regulated by the Law 667/2001 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (L nr. 677 publicat in M.Of. nr. 790 din data: 12/12/2001).

The Law establishes the 'Ombudsman Institution' as supervisory authority, which is functioning under the authority of the Parliament. Many paragraphs of the Law 667/2001 are a very close copy from the wordings of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

'Personal data' is defined as: "Art.3 – (a) any information relating to an identified or identifiable natural person; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity;

...

Art. 7 – (1) It is prohibited for the processing of personal data revealing racial or ethnic origin, political opinions, religious beliefs, philosophical beliefs or others similar, trade-union membership, and the processing of data concerning health or sex life.

(2) Paragraph 1 is not applied where:

(a) the data subject has given his explicit consent to the processing of those data;

- (b) processing is necessary for the purposes of carrying out the obligations and specific rights of the controller in the field of employment law, (...);
- (c) processing is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent;
- (d) processing is carried out in the course of its legitimate activities with appropriate guarantees by a foundation, association or any other non-profit-seeking body with a political, philosophical, religious or trade-union aim and on condition that the processing relates solely to the members of the body or to persons who have regular contact with it in connection with its purposes and that the data is not disclosed to a third party without the consent of the data subjects;
- (e) the processing relates to data, which is manifestly made public by the data subject;
- (f) the processing is necessary for the establishment, exercise or defence of legal claims;
- (g) the processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy."

7. Genetic information

In Romania, there is no specific law on human genetics.

8. Research involving animals

Research involving animals is regulated by the Law 471/2002, which approves the Governmental Ordinance 37/2002 on the Protection of animals used for scientific or other experimental purposes (L nr. 471 publicat in M.Of. nr. 535 din data: 07/23/2002 and ORDO nr. 37 publicat in M.Of. nr. 095 din data: 02/02/2002).

This law specifies the animals that can be used for scientific or other experimental purposes (1. Mouse - *Mus musculus*; 2. Rat - *Rattus norvegicus*; 3. Guinean Pig - *Cavia porcellus*; 4. Golden Hamster - *Mesocricetus auratus*; 5. Rabbit - *Oryctolagus cuniculus*; 6. Nonhuman Primates; 7. Dog - *Canis familiaris*; 8. Cat - *Felis catus*; 9. Quail - *Coturnix coturnix*).

According to the above-mentioned law, the principles of replacement, reduction and pain's limitation must be respected. The law is also defining the role of the National Sanitary Veterinary Agency that supervises the activity in this domain of research. The National Sanitary Veterinary Agency functions under the authority of Ministry of Agriculture, Alimentation and Forests.

Annex 1

Summary (5) of the Law 2/1998 on Removal and Transplantation of Human Tissue and Organs

The Law on the Removal and Transplantation of Human Tissue and Organs was adopted by the Parliament in January 1998. It contains 5 chapters and 9 annexes.

Chapter I contains general stipulations.

Transplantation can be done for therapeutic purposes. The following concepts are defined: removal, transplant, donor and receiver. Also the commercialisation of human tissue and organs is prohibited, the condition of consent is defined, physical or moral constraint are prohibited and the role of the Transplant of Human Tissue and Organs Commission is detailed; the non-observance of confidentiality and the advertising for donation are prohibited.

Chapter II refers to the removal: removal is only allowed for therapeutic purposes, after clinical and laboratory tests were taken and only if it does not

affect the donor's life. The donor's informed consent must be obtained; the consent may be withdrawn. The removal from donors who are incapable of giving their consent (underage donor or without discernment) is prohibited, except in the case of bone marrow transplantation from a minor to his brother or sister, under certain conditions. Removal from dead persons can be performed only after brain death has occurred and if the family, relatives or legal representatives have consented hereto.

Chapter III refers to transplant, to the consent of receiver or of his legal representative.

Chapter IV contains penalties for violation of this law.

Chapter V contains transitory and final stipulations (in which type of centres the removal and the transplant are effectuated, who supports the cost of medical investigations, hospitalisation, medication, intervention, etc.). The law also contains annexes: standard declaration forms for living donors, dead donors, post-mortem donors, receivers, and diagnosis criteria of brain death's confirmation.

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- (1) "The Rules for good practice during clinical study", Drug's National Agency, Editura Medicala, Bucharest, Romania, ISBN 973-39-0407-4, Romanian version
 - (2) Contact address: Ms. Pharmacist Magdalena Badulescu, President of Drug's National Agency, Agentia Nationala a Medicamentului, 48, Av. Sanatescu str., Sect.1, 71324 Bucharest, Romania, Tel. + 40 21 224 11 02 or 224 17 10; Fax + 40 21 224 34 97.
 - (3) Contact address: Prof. Dr. Radu Palade, President of Bioethical Commission of Health and Family Ministry, Spitalul Clinic Universitar, Splaiul Independentei, Nr. 169, Sectia Chirurgie I, Bucharest, Romania, Tel. + 40 21 637 21 90 / 560

- (4) Contact address: Mr. Prof. Dr. Ioan Muraru, Ombudsman, Avocatul Poporului, 3-5, Iancu de Hunedoara Blvd., 70000 S1 ;Bucharest, Romania, Tel: + 40 21 231 50 01, Fax: + 40 21 231 50 00, E-mail: avp@avp.ro, Homepage: www.avp.ro
- (5) Raluca Parvu, - fragment from the article "The transplant: Ethical and Legal Problems" published in "Bioethics in Romania - Themes and Dilemmas", edited by CEPES (European Centre for Higher Education) - UNESCO Office in Bucharest, 1999 (Raluca Parvu, MD, MA, philosopher, at the present PhD student at Surrey University, UK)

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Gabriel Raicu, M.D., M.A.

Medical Doctor at the University Emergency Hospital of Bucharest; graduated from the Faculty of General Medicine of Bucharest (2000); Master of Arts in "The management of medical and social welfare services", Faculty of Sociology and Social Welfare Services, University of Bucharest (2003); founding member (1996), vice-president (1997-1998) and president (1999-2001) of "Constantin Maximilian" Bioethics Group of Medical Students Society of Bucharest

gabrielraicu@yahoo.com



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