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COMMITTEE ON BIOETHICS
COMITE DE BIOETHIQUE
(DH-BIO)

Developments in the field of bioethics in member states and other states
Développements dans le domaine de la bioéthique dans les Etats membres et les autres Etats

Developments in the field of bioethics in international organisations
Développements dans le domaine de la bioéthique dans les organisations internationales

[1] This document contains contributions in their original language. / Ce document contient les contributions dans leur langue d'origine.

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3rd DH-BIO meeting

BELGIUM / BELGIQUE

Modification de la loi du 7 mai 2004 relative aux expérimentations sur la personne humaine, par la loi du 19 mars 2013 portant dispositions diverses en matière de santé. La loi de 2004 inclut une nouvelle définition de « comité d'éthique » reprise de la directive européenne 2001/20/CE du 4 avril 2001. En matière d'expérimentation humaine, on distingue désormais les comités d'éthique avec agrément partiel et complet. Les comités d'éthique hospitaliers et les Comités rattachés à une faculté de médecine ou à la Société scientifique de Médecine générale ou à la Wetenschappelijke Vereniging voor Huisartsgeneeskunde peuvent être des comités d'éthique avec agrément partiel. Pour disposer d'un agrément complet, le comité d'éthique avec agrément partiel doit respecter des conditions supplémentaires. Seuls les Comités d'éthique avec agrément complet peuvent rendre l'avis nécessaire au commencement d'une expérimentation. Cet avis doit être motivé. La procédure d'agrément complet est accordée par le ministre pour un délai renouvelable de 4 ans.

- **Modification de la loi du 19 décembre 2008 relative à l'obtention et à l'utilisation de matériel corporel humain destiné à des applications médicales humaines ou à des fins de recherche scientifique**, par la loi du 19 mars 2013 portant dispositions diverses en matière de santé. Les modifications visent principalement à préciser le cadre légal des biobanques et à offrir la possibilité aux établissements de production de contrôler le matériel corporel humain avec lequel ils effectuent des opérations.

On entend par biobanque, la structure qui, à des fins de recherche scientifique, à l'exception de la recherche avec des applications médicales humaines, obtient, le cas échéant traite, stocke et met à disposition du matériel corporel humain, ainsi que, le cas échéant, les données relatives au matériel corporel humain et au donneur qui y sont liées. Pour être exploitée, une biobanque doit être notifiée auprès de l'Agence fédérale des médicaments et des produits de santé, et ces objectifs et activités doivent recevoir l'avis favorable d'un comité d'éthique avec agrément complet.

DENMARK / DANEMARK

Assisted reproduction

During the winter and spring there has been a significant public debate regarding assisted reproduction. The topics debated have among other things been:

- Using the same donor of semen for siblings when there is a known risk for serious, hereditary diseases
- Reporting and reaction regarding “adverse events” (genetic diseases) from donor to child (in connection to the EC-directive regarding tissues and cells)
- Number of children allowed from one single sperm donor – new binding rules have been introduced instead (formerly there was it was part of a guideline from the Danish Health and Medicines Authority)
- Cases regarding donors of semen who after the donations have discovered a risk of passing on genetic diseases where it has not been possible to track down the families due to the fact that the treatment took place in the 1980’ties where the rules regarding “traceability of tissue” was not in place

Abortions

Recently there has been public debate on the methods used for carrying out late induced abortions, where it has been argued that the use of foetocidium (induction of fetal demise before abortion using intracardiac potassium chloride) should be offered to those seeking abortion in the later stages of a pregnancy. The Danish Council of Ethics has published an opinion on the subject; unfortunately it is not available in English. It may be noted that the council is divided about the subject – approximately one half does not recommendation the use of intracardiac potassium chloride, while approximately the other half recommends that the method may be used depending on the specific case and the a individual assessment made by the doctor and the patient.

Genome testing

Furthermore the National Ethics Council has published a report regarding “genome testing - ethical dilemmas in relation to diagnostics, research and direct-to-consumer testing”. Enclosed you’ll find an executive summary in English. As a result a working group has been established to examine the Danish legislation with in this area.

Genome-Testing.pdf

GERMANY / ALLEMAGNE

Opinions of the German Ethics Council

The German Ethics Council recently submitted an opinion on “The future of genetic testing – from research to clinical applications”, published on 30 April 2013. This document can be found under the following link: http://www.ethikrat.org/publikationen/stellungnahmen/die-zukunft-der-genetischen-diagnostik.

An English version of this opinion is expected to be published on the German Ethics Council’s website.

MONTENEGRO

During last couple of years, Parliament of Montenegro ratified a number of laws in the areas of healthcare and health insurance, which significantly cover the field of bioethics as the domain of competence of DH-Bio. More significant, however, is the fact that these laws are being implemented more and more effectively in practice.

During this year (March-April 2013), activities regarding Montenegro's kidney transplant programme have been resumed within the Clinical Centre of Montenegro, with the help of experts from Zagreb, Croatia. For now, these kidneys are procured from living donors, which is a safeguard of sorts from possible abuse such as organ trafficking. Procedures are conducted as prescribed by the Law on the Removal and Transplantation of Human Body Parts for the Purpose of Medical Treatment.

As for the matter of nuclear transfer, with regard to article 18.2 of Oviedo Convention, this area is regulated by a Constitutional provision, art. 27.2 of Montenegrin Constitution, which states that "any intervention aimed at creating a human being that is genetically identical to another human being, living of dead, shall be prohibited". Furthermore, Law on Infertility Treatment with Assisted Reproductive Technologies forbids the preimplantatory and prenatal diagnostic with the purpose of determining gender, unless when it's needed to prevent birth of a child with severe hereditary diseases.

PORTUGAL

Advanced Directives Law

In July 2012 the Portuguese Parliament approved by unanimity a Law (32/2012) concerning Advanced Directives.

In order this law can be fully applied, it had to have been regulated until 6 months later (deadline January 2013), namely to specify if advanced directives a indication or mandatory for health professionals.

The law says that advanced directives "should be respected", expression that some Portuguese bioethicists see as rather ambiguous.

So far, no guidelines specify how should the NHS (at hospitals and health centres levels) and private hospitals announce this law to their patients.

SAN MARIN / SAN MARINO

The National Bioethics Committee of Republic of San Marino has dismissed two documents on issues of particular importance for the Republic of San Marino, as the scientific and bioethical reflection contained in them could be preparatory to a regulatory adjustment:

"The determination of death" (unanimously approved at the plenary session of 21 January 2013): a document that defines the process of death and the criteria for its assessment, with the assumption that bioethics is the absolute protection of human life until the last moments, which must be interpreted to guarantee the original proposal to document, including the use of computer and audio-video-recording, all clinical and instrumental exams required for the definitive pronouncement by the condition of death.

"The bioethical approach to persons with disabilities" (unanimously approved at the plenary session of 25 February 2013): the first document about persons with disability approved by a National Bioethics Committee in little more than six years since the Convention on the Rights of Persons with Disabilities by the General Assembly of the United Nations and for which the Republic of San Marino has received the appreciation of the UN General Secretary, Ban Ki-moon, on the occasion of his visit to the Republic for the inauguration of the Regent Captains on April 1.

Both documents are available at the following address: http://www.sanita.sm/on-line/home/comitato-bioetica/comitato-sammarinese-di-bioetica/documenti-csb.html

Public debate: Before licensing document about disability, the National Bioethics Committee met with the associations of San Marino disabled and received disability data on the population of San Marino. These data have been included as an attachment in the document.
The Committee is going to organize an international conference on disability, supposedly in autumn.

SERBIA / SERBIE

Legislation

The current low about solid organ transplantation in Serbia regulates that diseased persons can be donors of the organs only if they have signed donor card, or if family members confirm they wish to be donors. Anyhow, family members must be informed and confirm that diseased person didn't change his/her opinion after signing donors card. This approach seemed not to be satisfactory for increasing number of demands for organ transplantations (first of all liver and heart) and from that reason change in the low is now on the public debate. New proposition is that every diseased person can be treated as the organ donor. Only persons that during their life have expressed clear wish that they don't want to be donors of organs would be excluded from the donors list.

Public debate/ Ethics Committee

During last year at the Institute for philosophy and social theory in the Belgrade Centre for bioethical studies (**CBS**) was established. Together with Oxford Centre for Neurothics and some Companies they organized international conference "Enhancement: Cognitive, Moral and Mood" in the Belgrade from 14th to 16th May 2013.

SPAIN / ESPAGNE

In December 2012, the Minister for Health, proceeded to the renewal of the members of the Spanish Bioethics Committee.
http://www.comitedebioetica.es/?lang=en_US

SWITZERLAND

Concerning **Developments in the field of bioethics** it might be noteworthy that the Federal Law on Transplantation of 8 October 2004 (TxA) is in part currently being re-examined, too; the draft was handed over to parliament on 8 March 2013. The aim is to provide more clarity about the correct moment when to ask a potential donor's relatives for a donation, to clearly regulate the consent to preparatory activities in the case of potential donors without capacity of discernment and to make sure that living donors do not suffer from any financial disadvantages. Besides, cross-border commuters shall have the same chances to get an organ as inhabitants.

UNITED KINGDOM / ROYAUME UNI

CONSIDERATION OF NEW LAWS TO ALLOW MITOCHONDRIAL TRANSFER IN THE UNITED KINGDOM

In 2009, following a review of the United Kingdom's laws governing assisted reproduction and embryology, a power was placed in the primary legislation, the Human Fertilisation and Embryology Act 1990, as amended, to make new regulations to permit the manipulation of gametes (sperm and eggs) and embryo to allow techniques to replace faulty mitochondria with healthy material to prevent the transfer of a mitochondrial disease from a female carrier to her child. The UK Government of the day gave an assurance to the UK Parliament that such regulations would not be made until the proposed treatment techniques were demonstrated to be effective and safe for patients and offspring.

In 2011, the UK Government was asked to make regulations by researchers. Two techniques were proposed for approval:

- Maternal Spindle Transfer (MST): involves removing the spindle from the mother's egg before it is fertilised by the father's sperm. The spindle is then placed into a donor egg with healthy mitochondria (from which the donor's spindle, and therefore her nuclear DNA, has been removed).

- Pro-nuclear transfer (PNT): involves removing pro-nuclei from an embryo with unhealthy mitochondria immediately after fertilisation. The pro-nuclei, are then transferred into a donated embryo that has had its original pro-nuclei removed.

The UK Health and Science Ministers asked the national fertility regulator, the Human Fertilisation and Embryology Authority (HFEA), to co-ordinate an expert group to consider the science in this area and, particularly, the two proposed treatment techniques. The Group concluded that both techniques had merit but there was insufficient evidence to recommend one technique over the other. The group also considered there was insufficient evidence to guarantee the safety of either technique and recommended a list of further experiments.

While the further experimental work was undertaken, the HFEA, conducted a public consultation exercise that focused on the ethical issues attached to these treatments. The HFEA reported that while these was a strong body of opposition to allowing this procedure in the UK, overall, the view of the public was that the treatment techniques should be allowed but their use should be carefully controlled.

The scientific expert group also reconvened to look at the progress made on the recommended experiments. Again, the Group expressed the view that there remains insufficient research currently available to recommend one particular technique above another. The Group also concluded that, although there was still nothing to indicate that the techniques were unsafe, further research on some specific aspects should be undertaken. The Group also recommended long-term follow up monitoring of any children born as a result of the techniques.

The UK Government is currently considering the findings of the consultation exercise and the scientific review. If it decides that, based on this evidence, it is appropriate to take the next step towards regulations, these will be drafted and published for a further round of public consultation.

EMERGING SCIENCE AND BIOETHICS ADVISORY COMMITTEE (ESBAC)

The Emerging Science and Bioethics Advisory Committee (ESBAC) was established as an expert advisory committee in 2012, and is the main UK advisory body on emerging healthcare scientific developments and their ethical, legal, social and economic implications.

ESBAC is sponsored by the Chief Medical Officer (CMO) for the Department of Health (DH), England. Its membership includes representation from all UK Health Departments for whom ESBAC also provides advice. ESBAC also provides a forum to consider and develop coordinated advice across the wider science, health and academic communities to help set priorities in response to new developments.

ESBAC is a multidisciplinary committee with members drawn from the social sciences, humanities, economics, law, industry, science in society, biosciences and biotechnology.

The Committee's full terms of reference are included in ESBAC's Code of Practice at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/120718/ESBAC-Code-of-Practice-updated.pdf

ESBAC held its first open Forum event with stakeholders on 13 May 2013, giving stakeholders the opportunity to comment on the Committee's approach to horizon scanning and its draft proposals to undertake work in three areas:

- The implications of emerging technology in the diagnosis of dementia
- Exploring the use of emerging technologies to optimise treatment
- Governance related issues in the context of the regulation of emerging technologies in healthcare.

(ESBAC Secretariat – esbac@dh.gsi.gov.uk)

UPDATE FROM THE NUFFIELD COUNCIL ON BIOETHICS

FUTURE PROJECTS

Children and clinical research

A new work theme to examine the ethical issues raised by the involvement of children and young people in clinical research will begin in late spring. The central focus of this project will be to consider whether the current regulation systems strike the right balance between promoting the understanding of childhood diseases and ensuring the proper protection of child participants. This Working Party will be Chaired by Professor Bobbie Farsides, Professor of Clinical and Biomedical Ethics at the University of Sussex.

CURRENT PROJECTS

Biological and health information

This project will examine the ethical issues raised by sharing and linking of health and biological data in connection with genomics, health records, database linkage and privacy. The Working Party, chaired by Professor Martin Richards, met in March and again in early May.
http://nuffieldbioethics.org/biological-and-health-data

Novel neurotechnologies: intervening in the brain
This Working Party, chaired by Professor Tom Baldwin, is exploring the ethical, social and legal issues arising from novel neurotechnologies such as deep brain stimulation, brain-computer interfaces (BCI), and neuron replacement therapy. The report is expected to be published on 25 June, a launch seminar and media campaign are planned.
www.nuffieldbioethics.org/neurotechnology

PREVIOUS PROJECTS

Donor conception: ethical aspects of information disclosure
The council published a report on the ethical issues arising in connection with sharing of information amongst families affected by donor conception on 17th April. The launch discussion event was attended by many people directly involved including donor-conceived people, parents, donors and fertility clinicians. The report received media coverage including 11 BBC regional radio interviews, the BMJ, the Independent and the Press Association.
www.nuffieldbioethics.org/donor-conception

Emerging biotechnologies
The Council's report, 'Emerging biotechnologies: technology, choice and the public good' was published on 13th December 2012. The report sets out a 'public ethics' approach for science policy with the aim of maximising the social benefits and democratic accountability of the governance of emerging biotechnologies. The Council has begun a programme of dissemination and follow up meetings, and will hold the first of a series of seminars with key stakeholders on 24th April.
www.nuffieldbioethics.org/emerging-biotechnologies

Mitochondrial donation
The Council's report 'Novel techniques for the prevention of mitochondrial DNA disorders: an ethical review' was published in June 2012. In March 2013 the HFEA announced its advice to the Government on novel treatments that could prevent the transmission of inherited mitochondrial DNA disorders following their public consultation on the issues. Much of the HFEA's advice to Ministers regarding policies and safeguards that would need to be implemented should the techniques be permitted for use in treatment is generally in line with the conclusions of the Council's report, including for example the recommendations that mitochondria donors should not mandatorily be identifiable to resulting children born from their donation, and that follow up studies should be conducted.
www.nuffieldbioethics.org/mitochondrial-dna-disorders

Health Science & Bioethics Division
Department of Health
United Kingdom
May 2013

MEXICO / MEXIQUE

National Bioethics Commission of Mexico

The National Bioethics Commission (CONBIOÉTICA) was established in 1992, and became a deconcentrated agency of the Federal Secretariat of Health in 2005 through a presidential decree, which gave it technical and operational autonomy, and the specific task of promoting a bioethical culture in Mexico through a plural, secular and inclusive perspective, based on the respect for human rights and the protection of all living beings and the environment.

The commission is a national institution, with a plural, inclusive and secular scope, and technical and operational autonomy. It is directed by a council, which is integrated by a president and six members who are designated carefully in order to preserve a balance of different professions, gender and perspectives, with wide recognition in their field of knowledge. Their essential tasks include analyzing and discussing bioethical issues for public debate and expressing their opinions, and also being familiar with different points of view.

During the past few years, the consolidation of the legal framework of CONBIOÉTICA has consolidated its leading and normative roles and performance as a consulting organism for the establishment of public policies, especially in the field of public health, regarding bioethics. Additionally, CONBIOÉTICA participates actively in the National Health Council and the staff meetings of the Secretary of Health.

During these first twenty years of existence, the CONBIOÉTICA has made important achievements regarding its mission, and among these accomplishments we would like to present those that are most relevant as developments in the field of bioethics:

• 20 years as a public institution: strengthening and initiating bonds for collaboration.

For this 20th anniversary, during march 2012 the CONBIOÉTICA hosted an important event where many activities took place: the inauguration of the new seat; the first exhibition of the former chairmen of CONBIOÉTICA; the issue of a commemorative postal stamp; a bioethics book expo; the edition of a commemorative lottery ticket from the National Lottery; and the exhibition 'Bioethics and social responsibility'. Also during these events, the seventh national meeting of local bioethics commissions took place, and we also celebrated the 10th anniversary of the international award Manuel Velasco Suarez for excellence in bioethics, a joint effort between the Pan-American Health and Education Foundation (PAHEF), the Pan-American Health Organization (PAHO) and CONBIOÉTICA as part of the Secretariat of Health.

Also, during these celebrations, CONBIOÉTICA signed two very collaboration agreements with the National Autonomous University of Mexico (UNAM) and the National Council for Science and Technology (CONACyT).

These agreements are meant to establish the foundations and mechanisms of the collaboration between the institutions involved, and therefore carry out specific actions that may contribute to the improvement, development and encouragement of the academic activities, research and dissemination of bioethics, and also to begin designing mechanisms to strengthen bioethics and ethics in science, technology and research.

Additionally, the commission has managed to formally establish other alliances with institutions such as the General Hospital of Mexico (Dr. Eduardo Liceaga), the National Academia of Medicine of Mexico, and the Council for Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA), in order to engage joint activities regarding bioethics. It also maintains a close relationship with its peers worldwide, such as the Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé of France; the Commission de l'éthique en science et en technologie (CEST), from Quebec, Canada; and of course UNESCO in order to address the different issues that bioethics care for, and to strengthen the development of this discipline not only in Mexico, but all over the world, participating in

their forums and working groups.

This gives us not only more presence, but an opportunity to join efforts in order to better achieve our institutional mission, and gives us a strengthened position to generate new strategies and projects, especially regarding young population, through the Program of Youth and Bioethics that the CONBIOÉTICA has already started to operate.

• A new seat for bioethics in Mexico

Since January 2012, CONBIOÉTICA has been designated to a new seat, which has encouraged its job with more adequate facilities and working space, especially since the Centre of Bioethical Knowledge (CECOBE) that is mainly the area in charge of communication with the public and gathering information was given a proper space for public consultation and equipment for virtual and long distance communication.

The proposal for the new building was designed and developed under bioethical standards, such as easy access to people with disabilities according to federal regulations and environmentally friendly use of energy, among others.

In order to encourage research, education and public debate on bioethics, this project will be complemented with a seminar unit, which has already been approved and in process of being built successfully, and which will be used for the development of human resources and academic and diffusion activities, and also as a special space designated to host national and international events on bioethics.

• National and international reference on bioethics.

CONBIOÉTICA is a reference of actions in Mexico regarding bioethics, not only as a normative and consulting multidisciplinary organism as established by law, but also because of its governing nature on bioethics in the country, which is why it has been entrusted with the task of formulating and expressing technical opinions and pronouncements regarding legislation and public policies in bioethics from the executive, legislative and judicial branches, either federal or local.

Also, CONBIOÉTICA has been encouraging the proper integration of the bioethics infrastructure throughout the country, which is integrated by the local bioethics commissions, which are collective organisms that promote the foundations and the application of the existing regulations in bioethics and also foster public debate around bioethical issues in the local scene, especially regarding healthcare, medical research and the protection of the environment, but also Research Ethics Committees and Clinical Bioethics Committees, which are now by law forced to comply with the guidelines, regulations and policies established by the National Bioethics Commission.

On this matter, CONBIOÉTICA supported the reformation of the General Health Act, in order to establish as mandatory the existence of clinical bioethics committees and research ethics committees in every healthcare and research institution in Mexico. CONBIOÉTICA issued regulations regarding the registration and integration of these committees, which have been published through an agreement from the Secretary of Health, strengthening its normative function.

The National Bioethics Commission, and generally the institutions that form the national bioethics infrastructure in the country, are an important support for the protection of human rights and dignity, because of their leading role in the decisions and management of bioethical issues, especially those immersed in the context of healthcare and research, both from the individual and collective point of view. Its performance has influence on the improvement of life quality, which results in direct benefits for the whole population.

On the other hand, the presence of CONBIOÉTICA in the international scene has consolidated this institution as an important actor not only in local or regional forums, but in the worldwide bioethics field. The commission enjoys enough prestige and international recognition, which is why it will be able

to communicate with consulting organisms from different countries, especially in the American region, as a result of the meeting hosted by CONBIOÉTICA during 2011, which summoned the representatives of consulting bodies of 10 countries of the American region. Also, during the ninth Global Summit of National Ethics Committees, which took place in Carthage, Tunisia, in 2012, CONBIOÉTICA presided the international working group of research ethics. The commission is constantly collaborating with the main international organizations and institutions on bioethics as well, such as: the Ethics and Health Division, WHO; Global Summit of National Ethics Committees, WHO; Committee on Bioethics (DH-BIO), Council of Europe; International Bioethics Committees UNESCO and its Ethics Division; Latin American and Caribbean Federation of Bioethics Institutions (FELAIBE); European Commission's International Dialogue on Bioethics (BEPA); Nuffield Council on Bioethics, United Kingdom; and the International Association of Bioethics (IAB).

As a result of this, the CONBIOÉTICA has been designated as host of the 10th Global Summit of National Ethics/Bioethics Committees, which is brought by the Permanent Secretariat of the World Health Organization, and the 12th World Congress of Bioethics of the International Bioethics Association. Both events are to take place in 2014.

These events are of the utmost relevance in the international bioethics scene, and are considered to be trendsetters in the development of this field and the generation of new perspectives and debates, which is why 2014 will be the Year of Bioethics in Mexico.

• An institution with scientific and technologic development recognition nationwide

In 2011, CONBIOÉTICA became a part of the National Registry of Scientific and Technological Institutions and Enterprises (RENIECyT), which helps to identify the institutions that carry out activities related to research, and scientific and technological development in Mexico. This registration allows the participation in federal incentive and support programs in order to undertake new tasks and projects. As a result of this, CONBIOÉTICA has received public resources in order to strengthen the Centre of Bioethical Knowledge, with the establishment of a virtual library and a telebioethics system. As a first strategy in order to make the most out of this new project, in 2012 the CECOBE has started an annual videoconference cycle, where many renowned experts in the bioethics field have given lectures that can be viewed online by the general public, and can also be taken into account as part of the permanent training that public servers must fulfill on an annual basis.

Also, CONBIOÉTICA has encouraged and given orientation to several institutions that are interested or that already have programs or courses on bioethics, and is currently working on developing a certified course for members of research ethics committees and clinical bioethics committees with the University Program on Bioethics of the UNAM. This course contains elements from the UNESCO´s Bioethics Core Curriculum.

Likewise, the CONBIOÉTICA collaborated with the Autonomous Technological Institute of Mexico (ITAM) in the development of a "Bioethics and Law" course that will take place during August 2013.

In April 2013, the National Academy of Medicine of Mexico created a seat of honor for bioethics. An expert bioethicist, who will give a perspective to the different matters and dilemmas that may arise during the sessions of the Academy will occupy this seat. The creation of this seat represents the important role that bioethics plays in Mexico's healthcare system.

• Center of Bioethical Knowledge: closer to the public.

The Centre of Bioethical Knowledge (CECOBE) started to operate as part of the main activities of CONBIOÉTICA. Its function is to collaborate in order to increase the impact on the promotion of bioethics culture specifically through two synergic actions: the searching, gathering and updating of specialized information in the field of bioethics (physical and virtual library), and the development of a dissemination program regarding the main topics of this discipline, and of course of the advances and perspectives of the commission.

The library offers free information services to the general population and also students, specialists, academics and researchers in bioethics, through printed and digital publications, and diverse

databases which are completely avant-garde nationwide and worldwide. With this, CECOBE pretends to become one of the most complete and specialized information centers in the field of bioethics. As for the dissemination strategies, we can mention many books, pamphlets, posters and publications of many sorts, as well as the development of a social communication and education program about the main topics in bioethics through different communication media. Until today, CECOBE has formalized numerous collaboration and exchange agreements with several libraries and information centers, which increases its possibilities to offer services of the utmost quality.

The new perspective for CECOBE is telebioethics and virtual library, a project that is being enhanced with public resources with the purpose of reaching the public and also be able to generate new strategies in order to encourage research, teaching, and public debate around bioethics, through the advantages that the new technologies on information and communication can offer in order to become an avant-garde institution with the most updated and affordable information available regarding bioethics, and other relevant topics, such as human rights, public health, environmental aspects, and ethics.

European Commission / Commission européenne

On March 22, 2011, the President of the European Commission had requested the European Group on Ethics in Science and New Technologies to issue an Opinion on the ethical implications of Information and Communication Technology, **ICT**.
Following the Competiveness Council on the Euratom Programme, the Commission also asked the European Group on Ethics in Science and New Technologies to contribute to the debate on a sustainable energy mix in Europe by issuing an Opinion on the ethical impact of **Energy** choices.
In 2013, having issued the above Opinions and in accordance with the request from the President of the European Commission, the European Group on Ethics in Science and New Technologies will develop its Opinion on **Surveillance and Security** technologies.

The European Group on Ethics in Science and New Technologies (EGE) is an independent advisory body with a status defined in several EC legal documents (e.g. EC/98/44).

The developments and actions to implement the above Commission goals included: *(reverse chronological order)*

On the **21st-22nd of May 2013**, the EGE held its 27th meeting in Brussels. The EGE met with a number of guest speakers and worked on developing its Opinion on Surveillance and Security Technologies.

On **18 April 2013**, the President and the Vice-President of the EGE met with President Barroso.

On the **16th-17th of April 2013**, the EGE held its 26th meeting in Brussels. The EGE notably met with a number of guest speakers and had an exchange of views with the Information and Privacy Commissioner of Ontario, Dr. Ann Cavoukian. The meeting was largely dedicated to the work on its Opinion on Surveillance and Security Technologies.

The semi-annual meeting of the European Commission's **Inter-Service Group on Ethics and EU Policies** took place on **March 21st**, topics addressed included ICT governance and security, drones, dual use research of concern, Horizon 2020, ESPAS, and energy policy. 15 European Commission services confirmed their participation and their attendance to the

meeting (ECFIN; INFSO; SANCO; COMP; ENTR; SG; RTD; MARE; COMM; EEAS; TRADE; HOME; EAC; JRC; ENER; JUST; ENV; BEPA).

On the **19th-20th of March 2013**, the EGE met in Brussels. During the two-day event, a number of guest speakers from different European Commission services presented their inputs on the state of play and ethical implications of security and surveillance technologies.

On the **26th-27th of February 2013**, the President of the EGE participated in an inter-institutional symposium on energy (*Benefits and limitations of nuclear fission for a low carbon economy*) organized by the European Commission's Directorate-General for Research and Innovation following a request by the Council. All participants welcomed the EGE Opinion and indeed the initiative of President Barroso to provide the energy mix debate with a proper and balanced analysis of the ethical, legal and social implications of such a complex policy sector.

On the **19th-20th of February 2013**, the EGE held its 24th meeting in Brussels. The Group worked on the scoping and development of its future **Opinion on Surveillance and Security Technologies**.

On the **15th -16th of January 2013**, the EGE held its monthly meeting in Brussels. On **January 16**, the Group adopted its **Opinion No 27: An ethical framework for assessing research, production and use of energy**. The Opinion has been transmitted to President Barroso and will be presented at the *European Commission Symposium on Nuclear Fission Research for a Low Carbon Economy*, taking place between the 26th -27th of February 2013 in Brussels. In its Opinion, the EGE proposed an *integrated ethics approach* for the research, production and use of energy in the EU seeking for an *equilibrium* between four criteria - access rights, security of supply, safety, and sustainability - in the light of social, environmental and economic concerns.

On the **11th-12th of December 2012**, the EGE held its 22nd meeting in Brussels. The Group worked on the finalization of the Opinion 27.

On **the 20th-21st of November 2012**, the EGE held its monthly meeting in Brussels aimed to finalize the Opinion on the ethics of the energy mix. During this session, the EGE has also **adopted its position on the proposal for a regulation of the European Parliament and the Council on Clinical Trials**.

The EGE position has since been appreciatively acknowledged and drawn upon in the inter-institutional process of refinement of the Clinical Trials regulation.
The developments in that regard can be found here: http://ec.europa.eu/health/human-use/clinical-trials/
(this European Commission web-site directs to all documents and to further tools such as http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2012/0192%28COD%29 enabling to follow the proposal in the different steps of the procedure).

On **the 19th of November 2012**, the EGE held its Rapporteurs' Meeting in Brussels. Discussions centered around the finalization of the EGE Opinion on the ethics of energy mix in Europe.

On the **4th-5th of October 2012**, the European Group on Ethics together with the EU NEC Forum, gathering the Chairs of the **EU 27 National Ethics Councils,** met in Nicosia, Cyprus. The conjoint event was organized by the Bureau of European Policy Advisers (BEPA) and the Research Directorate General (RTD), in collaboration with the **Cypriote Council Rotation Presidency**. The meeting touched upon: the Horizon 2020 Programme, the function of NEC forums as dialogue platforms on science within the EU, the adopted EGE Opinion 26 on Ethics and ICT as well as the forthcoming EGE Opinion 27 on Ethics of the Energy Mix in Europe. In the afternoon of the 4th and 5th of October, the EGE held its working meeting in parallel to the NEC Forum meeting.

On the **3rd of October 2012**, **the European Group on Ethics** met **the Cyprus National Bioethics Committee** in Nicosia for a bilateral meeting. The afternoon session comprised an EGE working group meeting.

On the **18th of September 2012**, the EGE Secretariat organized an **open Roundtable on Ethical Aspects of the Energy Mix in Europe** (100 participants). The Roundtable was aimed at promoting a transparent dialogue between relevant stakeholders. Among participants, the EGE Secretariat welcomed members of the scientific community, industry, civil society, policy makers, media and the general public.

On the **19th of September 2012**, the EGE Secretariat held its 17th meeting in Brussels. On **16th-17th of July 2012**, the EGE Secretariat organized a rapporteurs' meeting in Rome, Italy. On **the 18th-20th of June 2012**, under the auspices of the **Danish EU Council Rotation Presidency**, the EGE, the Danish National Ethics Committee, **the International Dialogue on**

Bioethics (clustering the Chairs of G20 NECs and the Forum of the EU 27 NECs) met in a three day event which took place in Copenhagen.

On the **18th of June 2012**, the EGE had its working meeting on its approaching Opinion on Ethics of the Energy Mix. The members worked on the structure of the current Opinion.

On the **19th of June 2012**, the fourth meeting of the European Commission ***International Dialogue on Bioethics (IDB)*** took place; an event organized by the European Commission under the auspice of the Danish rotation Council Presidency. Invited participants included members of the EGE, the Chairs of 15 non-EU NECs, and the Chairs of the EU 27 NECs and CH, NO, Croatia, Serbia (**46 Countries**). The non-European countries represented this year included: Argentina, Canada, China, Egypt, India, Indonesia, Japan, Mexico, The Philippines, Russia, South Africa, and COPAB (Pan-African Bioethics Congress). Representatives of the bioethics sector within UNESCO, WHO, and COHRED also held a speech. The topic discussed this year was '**The Governance of Large Research and Medical Databases in Clinical and Research Multi-Centre Trials**', as proposed by the Chief Scientific Adviser - Prof. Anne Glover.

On **the 20th of June 2012**, the EGE and the Danish NEC organized a bilateral meeting, focusing on the previous Danish Opinions on climate change and food security and the Danish debate on renewable energy.

On **15th-16th of May**, the EGE Group held its 14th meeting in Brussels. The **16th ISG meeting** took place in **May 31st**, topics addressed include, ICT governance, Horizon 2020, revision of EC/2001/20; ESPAS, Inter-institutional debate on energy mix etc. 15 Commission services confirmed their participation and their attendance to the meeting (INFSO; REA; SANCO; COMP; ENTR; SG; RTD; MARE; COMM; EEAS; TRADE; HOME; EAC; JRC; ENER; BEPA, JUST, ENV). On **17th-18th of April**, the EGE Group held its 13th meeting in Brussels.

On 20th-21st of March, the EGE Group started working on its new **Opinion on Ethics of Energy** requested by **President Barroso** on the 19th of December 2011. The Opinion will contribute to the debate on a sustainable energy mix in Europe by studying the ethical impact of research on different energy sources on human well-being. The EGE also had a meeting with **Vice-President Neelie Kroes** in order to discuss the content of its ***Opinion 26: Ethics of***

Information and Communication Technologies. Vice-President Kroes welcomed the EGE Opinion and underlined that the Commission will now take inspiration from the proposed recommendations to further foster societal and ethical consideration in the construction of the European Digital Society. On **21st- 22nd February**, **the EGE Group adopted its 'Opinion 26: Ethics of Information and Communication Technologies'**.

On **18th-19th January 2012**, the EGE held its 10th meeting in Brussels. The Group worked on the finalization of the Opinion on ICT.

WHO / OMS

Current and future activities in the field of Bioethics

Tuberculosis prevention, care and control

Ethics of tuberculosis prevention, care and control remains a focus area of work for the team. After the publication of the WHO Guidance on Ethics of TB (http://whqlibdoc.who.int/publications/2010/9789241500531_eng.pdf) end of 2010, the document has by now been translated into the six official WHO languages and been widely distributed. A series of implementation activities have been organized in 2012 at regional and country level, including in Austin (USA) and Kuala Lumpur (Malaysia).

Plans

- Development of a checklist for national TB programmes
- Development of an online course addressing the ethical issues of TB prevention, care and control.
- Publication of several WHO TB guidelines which include Ethics chapters (for ex. On MDR-TB, TB screening etc.)

Ethics in public health crises in disasters

Following the recommendations of an expert meeting, WHO has been developing a training course on ethical issues to address in public health crises and disasters. A virtual working group has been constituted, which is currently finalizing the draft of the course. Expected publication: end 2013.

HIV/AIDS

The use of antiretrovirals (ARVs) for treatment and for prevention of HIV is a dynamic and rapidly evolving field. Important new evidence has emerged demonstrating the benefit of earlier initiation of ART for the HIV-positive individual to prevent onward transmission to their HIV-negative partner and oral as well as topical antiretroviral pre-exposure prophylaxis (PrEP) for the HIV-negative individual to prevent HIV acquisition. The fact that ARVs cannot only be used for treatment, but also for prevention, poses ethical dilemmas in terms of priority-setting and fair allocation of resources. These ethical questions are being addressed in a joint WHO/UNAIDS project.

In November 2012, WHO/UNAIDS jointly organized a Consultation on Ethical Issues in the Strategic Use of Antiretrovirals. Key outcomes of the meeting are:

Countries must work towards the progressive realization of their High Level Meeting commitments with regard to scaling up ART, intensifying HIV prevention and eliminating stigma and discrimination. Treatment scale-up toward universal access should continue concurrent to the engagement of stakeholders to fairly identify marginalised and high risk populations who are in urgent need of novel HIV prevention interventions. The strategic use of ARVs for prevention purposes in both HIV-positive and HIV-negative persons offers unique opportunities to revitalize prevention, through expanding prevention options, especially for certain vulnerable and marginalized groups with specific needs, and to strengthen combination prevention approaches. Decisions about when and how to implement ARV-based prevention interventions need to be addressed in a manner that meets ethical principles and human rights considerations, both in substance and in process, along with technical and programmatic considerations. The selection of policy options and the strategic allocation of resources for ARV-based interventions for treatment and prevention should be done at the national and local levels, through a fair and transparent process, with the full engagement of relevant stakeholders, including people living with HIV and groups most likely to be vulnerable to and exposed to HIV. There are no simple answers, and different countries will make different decisions based on their own context.

Tools and resources should be made available by international organizations and development partners to facilitate and support the process of decision-making and build the capacity of all those involved.

Vaccine proposal

WHO is currently planning to develop ethical guidance for vaccine R&D and delivery, as a comprehensive ethical framework on vaccines is still lacking at international level. Various national and international organizations have developed general regulations and ethical guidelines advocating for the rights of subjects of medical research. Many issues that arise in vaccine research are quite specific to the field. In addition, in the specific area of vaccines and immunization, many of the key ethical issues relate not to research but implementation and ongoing practice. What is required at this juncture is a strong, comprehensive platform of ethical guidelines. Expected publication date: 2015.

International Clinical Trial Registry Platform

Promotion of clinical trial registration is an ethical requirement and a key component of clinical trial oversight. Following the adoption of a resolution by the World Health Assembly in 2006, the International Clinical Trial Registry Platform (ICTRP) was established to promote transparency in health research activities. It includes now more than 220,000 records of clinical trials and collects data from 15 data providers globally. The WHO network of Primary Registries has virtual monthly meetings, two national registries are in the process to become WHO primary registries and will be evaluated in 2013. More information is available in http://www.who.int/ictrp/en/index.html

Pan African Clinical Trial Alliance

The Ethics and Health team works in close collaboration with the WHO vaccine department to strengthen the oversight of clinical trials in Africa. Following the survey conducted in 2011 in five sub Saharan African countries, a three year project has been initiated to ensure the implementation of harmonized and coordinated procedures of clinical trial oversight in Africa.

Standards for Research Ethics Committees

After the publication of WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants (see http://www.who.int/ethics/publications/en/), WHO is now developing indicators which could facilitate the monitoring of Research Ethics Committees by Member States. An expert meeting jointly organized with the Joint Center of Bioethics at the University of Toronto will take place in July 2013 to validate these indicators.

On line course on research ethics

An online research ethics training course for WHO staff (Headquarters and Regional Offices) has been launched recently; the open access will be considered in a near future.

Expert consultation on the use of placebo controlled vaccine trials

In January 2012, WHO organized an expert consultation to make recommendations for the implementation of existing international guidance about the ethical use of placebo in the specific context of vaccine trials, when a vaccine already exists. The meeting report will be published in April 2013, it will include recommendations concerning issues to be addressed by the ethics review of protocols and suggestions concerning procedures to be followed.

H5N1 and dual-use research

H5N1 avian influenza is an infectious disease of birds that can be spread to people, but is difficult to transmit from person to person. Researchers have succeeded in creating H5N1 viruses that are more transmissible in mammals than those that occur naturally. This has raised concerns about the risks and safety of such research and WHO was asked to convene an international consultation on 26-28 February 2013. How to balance scientific

freedom with concerns for public health security poses various ethical dilemmas. These broader issues of so-called “dual-use” research in the life sciences will be addressed in a follow-up project.

Global Network of WHO Collaborating Centers for Bioethics

Formally established in 2008, the Global Network of WHO’s Collaborating Centers (CCs) for Bioethics currently has 5 designated member institutions, who have agreed on a joint workplan in the area of public health ethics, clinical ethics and research ethics. Further CCs are to be designated in the near future. The 4th meeting of the network was hosted by Columbia University, New York, 14-15 June 2012. Current focus areas of the network are a Q&A on ethics and health, and the areas of vaccines and surveillance.

Collaboration with NGOs

The Ethics and health unit provides advice to Council of International Organizations of Medical Sciences (CIOMS) for the review of guidelines on biomedical research;
The unit also contributed to the consultation organized by the World Medical Association (WMA) for the review of the Declaration of Helsinki.

Exhibition 10th anniversary

At the occasion of the 10th anniversary of the creation of a dedicated Ethics and health team at the World Health Organization, an exhibition entitled “Global Health Ethics” was developed and will be displayed at WHO. While ethical aspects have always been an integral part of WHO programmes since the establishment of the organization in 1948, the Ethics and Health Initiative was formed in 2002 to serve as the focal point for the examination of ethical issues raised by activities carried out across the Organization – at headquarters, as well as regional and country offices. Given the very broad nature of the topic, the exhibit concentrates on some of the key issues related to ethics and health from a historical perspective, and illustrates the diversity of ethical challenges in medicine, public health and health research today. It also hopes to stimulate questions in the minds of visitors and to foster debate on ethics in global health more broadly.

European Science Foundation / Fondation Européenne de la Science

In the new European Science Foundation (ESF) structure, five smaller Scientific Review Groups (SRGs) now replace the previous Standing Committees which were disbanded at the end of 2012. See more at: http://www.esf.org/hosting-experts/scientific-review-groups.html

We present in this report the developments at the ESF in the Scientific Review Groups for the:

- Biomedical Sciences (SRG-MED, formerly Standing Committee for the European Medical Research Councils EMRC)
- Humanities (SRG-HUM, formerly Standing Committee for the Humanities SCH)
- Social Sciences (SRG-SOC, formerly Standing Committee for the Social Sciences SCSS)
- Life, Earth and Environmental Sciences (SRG-LEE, formerly Standing Committee for the Life, Earth and Environmental Sciences LESC)

SRG-MED:

The Scientific Review Group for the Biomedical Sciences (SRG-MED) covers the following fields:

- Ageing
- Bioethics
- Biomedical basic research including functional genomics, lipidomics, glycomics, signalling pathways
- Clinical trials
- Gastro-intestinal health, food and nutrition
- Human stem cell research and regenerative medicine
- Infectious diseases and antimicrobial resistance
- Imaging techniques
- Mental health
- Musculo-skeletal diseases
- Nanomedicine
- Neurological disorders
- Nursing
- Oncology
- Personalised medicine
- Rare diseases
- Reproductive health
- Veterinary medicine

The SRG-MED is also interested in topics of general interest such as health research classification systems, open access and research using animals.

More information:

- **SRG-MED activities**: http://www.esf.org/hosting-experts/scientific-review-groups/biomedical-sciences/activities.html
- **SRG-MED publications**: http://www.esf.org/hosting-experts/scientific-review-groups/biomedical-sciences/publications.html
- **SRG-MED press releases**: http://www.esf.org/hosting-experts/scientific-review-groups/biomedical-sciences/news.html

SRG-HUM:

The Scientific Review Group for the Humanities (SRG-HUM) supports the principle of curiosity-driven, fundamental research in **traditional core disciplines** of the Humanities, such as:

- Anthropology, Ethnology and Folklore
- Archaeology
- Art and Art History
- Classical Studies
- Cognitive Science
- History
- History and Philosophy of Science

- Literature
- Linguistics
- Music and Musicology
- Oriental and African Studies
- Pedagogical and Educational Research
- Philosophy
- Psychology
- Religion and Theology

SRG-HUM is engaged in newly-structured, **broad fields of study**, such as:

- Area studies (African, American, Asian, Australasian, European studies)
- Media Studies
- Gender Studies
- Heritage Studies
- Digital Humanities

SRG-HUM is contributing to the development of emerging, **trans-disciplinary research areas**, such as:

- Complexity Research
- Cognitive Science
- Development, Environmental and Landscape Studies
- Health and Welfare Research
- Migration Studies
- Studies into Culture and Technology
- Human-Computer Interaction

More information:

- **SRG-HUM activities:** http://www.esf.org/hosting-experts/scientific-review-groups/humanities/strategic-activities.html
- **SRG-HUM publications:** http://www.esf.org/hosting-experts/scientific-review-groups/humanities/publications.html
- **SRG-HUM press releases**: http://www.esf.org/hosting-experts/scientific-review-groups/humanities/news.html

SRG-SOC:

The social sciences study the possibilities and constraints that surround human activity, the ones that open spaces, and erect limits around human creativity. Therefore they **examine and explain human beings** on different levels, from neural foundations to individual behaviour, group processes and the functioning of entire societies.

Naturally, the social sciences benefit from the insights gained through **related disciplines** such as the human, life and medical sciences. These areas of convergence allow for a fuller understanding of the diverse facets of the social science enterprise, and range from literary, philosophical and historical inputs on the one hand, to biological and medical ones, including human biology, on the other. At the same time, almost all (medical, life and human) scientific problems have aspects that require the participation of social sciences in their thorough examination.

The Scientific Review Group for the Social Sciences (SRG-SOC) at ESF covers the following fields:

- psychology and the cognitive sciences
- pedagogic and education research
- social anthropology
- sociology
- gender studies
- economics
- business and administrative sciences
- geography
- demography
- environmental sciences
- law
- political sciences
- communication sciences
- international relations
- social statistics and informatics

More information:

- **SRG-SOC activities**: http://www.esf.org/hosting-experts/scientific-review-groups/social-sciences/activities.html
- **SRG-SOC publications**: http://www.esf.org/hosting-experts/scientific-review-groups/social-sciences/publications.html
- **SRG-SOC press releases**: http://www.esf.org/hosting-experts/scientific-review-groups/social-sciences/news.html

SRG-LEE:

The Scientific Review Group for the Life, Earth and Environmental Sciences (SRG-LEE) covers the following fields:

- Molecular Biosciences
- Microbiology
- Biological Chemistry
- Plant and Animal Biology
- Ecology
- Climate Research
- Earth Sciences
- Meteorology

More information:

- **SRG-LEE activities**: http://www.esf.org/hosting-experts/scientific-review-groups/life-earth-and-environmental-sciences/activities.html
- **SRG-LEE publications**: http://www.esf.org/hosting-experts/scientific-review-groups/life-earth-and-environmental-sciences/publications.html
- **SRG-LEE press releases**: http://www.esf.org/hosting-experts/scientific-review-groups/life-earth-and-environmental-sciences/news.html

5. Events

- Conference
- Seminar
- Others

Link with relevant website/document

ESF-EMRC Forward Look "Personalised Medicine for the European Citizen" (iPM)

The Scientific Committee of this activity was made of: Stephen Holgate (Medical Research Council, School of Medicine, University of Southampton (UK)), Aarno Paalotie (Director of the Finnish Genome Center, University of Helsinki (FI) and Senior Group Leader, Wellcome Trust Sanger Institute (UK), Barbara Prainsack (Deputy Director, CBAS, Sociology and Communications, Brunel University), Angela Brand (Center for Public Health Genomics, University of Maastricht (NL), and Hans Lehrach (Professor, Vertebrate Genomics, Max Planck Institute for Molecular Genetics, DE).

This foresight exercise brought together international experts from a wide range of disciplines, such as Molecular and Systems Biology, Clinical Research, Humanities and Social Sciences, Health Economy and Health Technology Assessment, to identify the core issues affecting the development and implementation of personalised medicine in Europe and to generate recommendations to make personalised medicine a reality. Four meetings were organised between September 2011 and April 2012 to discuss different key issues, including the role of technology, the challenges and opportunities for specific disease areas and overarching economic, social and other issues that will influence the future of

personalised medicine. At the final stakeholder meeting held in April 2012, the experts discussed and drew up the final recommendations for the implementation of personalised medicine in Europe. The outcome of this process was a report on personalised medicine containing a set of recommendations to ensure the successful development and transformation of personalised medicine into personalised healthcare. The report was launched and discussed in Brussels (BE) on 28 January 2013 at a launch and implementation event.

Dissemination of these results has taken/will take place throughout 2013 at different meetings including the Irish Presidency conference on personalised medicine, 'Innovation and Patient Access to Personalised Medicine' in Dublin (IE) on 20-21 March 2013 organised by the European Alliance for Personalised Medicine (EAPM) in association with eu2013.ie. The report will also be presented at the Euromedlab Pre-Congress Satellite Meeting "The quality of molecular methods in the age of personalized medicine" on 18 May 2013 in Florence (IT) (http://www.milan2013.satellitemeetings.org/index/firenze) and at the 16th European Health Forum Gastein to be held on 2-5 October 2013 in Bad Gastein (AT) (http://www.ehfg.org/home.html).

Different articles are also planned for publishing in various journals, along with some follow-up activities with a working group to include implementation meetings and publication of a report of the launch event. ESF is now part of a coordinated strategic action ("PerMed") funded by the European Commission. The funding starts in autumn 2013.

Several participants of the meeting have volunteered to be part of a follow-up implementation group. The European Association of Personalised Medicine (EAPM) has volunteered to support the implementation; ESF is now a permanent guest in this association and there may be the possibility of organising small follow-up meetings jointly with EAPM in the future.

More information about the Forward Look report published in December 2012 (**Annex 1**) and the Position Paper on European Biobanks published in May 2011 is available from: http://www.esf.org/ipm

Annex1_ESF_Forward_Look_Personalised_

Related activities or potential involvement of the DH-BIO:

1. Report on the sessions of the Council of Europe/DH-BIO Symposium on "Biobanks and Biomedical Collections - An Ethical Framework for Future Research" (19-20/06/2012, Strasbourg, FR).
2. Re-examination of Recommendation Rec(2006)4 on collections and use of biological materials of human origin for research purposes.
3. Re-examination of Recommendation (2006) 4 on collections and use of biological materials of human origin for research purposes.
4. Green Paper on predictivity, genetic testing and insurance (DH-BIO-CO-GT4 (2010) 11 e REV3 greenpaper.doc).
5. Leaflet on genetic testing for health purposes.
6. Implementation of fundamental ethical principles in transnational biomedical research. (confRED(2101)7 rev E.doc).

EMRC Expert Group on a European Academic Proposal for a Revision of the Clinical Trials Directive (2001/20/EC)

Follow-up of the Forward Look "Investigator-Driven Clinical Trials" (IDCT) and OECD Global Science Forum (GSF)

In January 2012, EMRC published the **position paper on a 'Proposal for a Revision of the Clinical Trials Directive 2001/20/EC and other recommendations to facilitate clinical trials'**. The revision of the Clinical Trials Directive resulted in a proposal for a regulation which would immediately come into force once approved by the European Parliament. Currently the draft is under discussion at the European Parliament.

The final report of the OECD Global Science Forum (GSF) working group to 'Facilitate Cooperation in International Non-Commercial Clinical Trials' was published in January 2012. The OECD council recommendation on the governance of clinical trials has been published and has now to be implemented in the different countries. See:
http://www.oecd.org/sti/sci-tech/oecdrecommendationonthegovernanceofclinicaltrials.htm
Several follow-up working groups are running. The education and training group is currently very active and in the process of preparing a document for WHO to harmonise education in the field of clinical trials. Professor Kirsten Steinhausen (now ESF consultant) is still involved in this working group as well as Dr Øyvind Melien from the Norwegian Directorate of Health in Oslo (NO).

Related activities or potential involvement of the DH-BIO:

1. Background paper on clinical ethics committees elaborated by Professor Eugenijus Gefenas (Lithuania).
2. Information collected on clinical ethics committees in member states.
3. "Modernisation of Convention 108: new proposals" to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data [ETS No. 108].

ESF-SCSS Strategic Report "Developing a new understanding of enabling health and wellbeing in Europe"

Building on a 2010 Exploratory Workshop, its convenor Professor Michael Rigby was commissioned in 2012 by the Standing Committee for the Social Sciences (SCSS) to prepare a position paper. The paper was published in early February 2013; Professor Rigby was the main author, supported by Professor Sabine Koch, Dr Debbie Keeling and Penny Hill; Dr Albert Alonso and Dr Els Maeckelberghe also contributed.

As social care and informal care are essential to improving health and preventing health problems, especially in an ageing population, there are still large gaps of knowledge in how best to organise this and how best to combine it with healthcare. The position paper sees Information and Communication Technologies (ICT), which are increasingly deployed in service sectors to enable consumer customisation and better resource management, as the way forward for improved healthcare.

The publication presents a vision for a new model of integrated care support for citizen's health through linked social and healthcare. It exposes current developments and challenges concerning demographic changes, ageing and established a concrete research agenda for ICT application focusing for instance on the relationship between patients and carers, the acceptability of ICT, the role of data, the organisation and legal aspects or the financing challenge.

A main message is that "Research programmes need developing at national and European level to stimulate a comprehensive and cohesive pattern of social science research into the

means of achieving optimal ICT support as the enabler for a new integrated and partnership paradigm of health-related care". The paper further highlights a number of priorities for important advances to be made towards the harmonisation of healthcare delivery and informatics support:

- Integrated delivery of healthcare and social care support of individual's health;
- Personalised care delivery including reasonable accommodation of individual choice;
- Ensure effective use of ICT applications based on user acceptability;
- Bring processes of consent, delegation, representation, coordination and privacy into the electronic era;
- Ensure respect for and teamwork with formal carers and the informal care team;
- Ensure equity in an electronic era regardless of digital literacy, assets and connectivity;
- Examine stable, sustainable models of trusted infrastructure provision;
- Establish governance, authentication, management, and sustainability principles.

Dissemination is currently in progress. The report can be found in **Annex 2.**

Annex2_ESF_strateg
ic_report_Health_We

Related activities or potential involvement of the DH-BIO:

1. "Modernisation of Convention 108: new proposals" to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data [ETS No. 108].
2. Document prepared by Mrs Isabelle Erny on access to medical file.

ESF activities in the field of neurosciences and mental health

1. ESF strategic report "The Human Brain: from Cells to Society - Towards Better Mental Health in Europe"

Triggered by the large number of ESF activities revolving around neuroscience and more generally the human brain, the strategic initiative "The Human Brain: from Cells to Society" aimed to develop medium to long-term views and an analysis of future research developments in neuroscience with the aim of defining research agendas at national and European levels. The initiative was supported by all five ESF Standing Committees (including Social Sciences, Humanities and Biomedical Sciences).

The strategic report published in December 2012 (see **Annex 3**) addressed the following challenges:

- Levels of (brain) organisation – levels of understanding
- Expanding views of brain development and plasticity
- Translating knowledge into practice – treatment and prevention of brain disorders
- Towards a brain-aware society – Dealing with the implications of advances in the brain sciences.

Annex3_ESF_strateg
ic_report_TheHumanI

2. ESF-FENS Research Conferences

The ESF Research Conferences series "The Dynamic Brain – from genes to behaviour" has been selected for funding. The partnering organisation is the Federation of European Neuroscience Societies (FENS). Two conferences will take place this year in Stresa (IT): "Neurobiology of Synapses and their Dysfunction" (13-17 October 2013) and "Neurobiology of Action" (20-24 October 2013).

More information at:

http://www.esf.org/index.php?id=9729 and http://www.esf.org/index.php?id=9731

3. European Month of the Brain (May 2013)

a. **FENS-European Brain Council (EBC)-ESF event "The prospects of brain research within Horizon 2020: responding efficiently to Europe's societal needs"**, 30 May 2013, European Parliament, Brussels (BE). Professor Josef Syka (Czech Science Foundation and Academy of Sciences of the Czech Republic, Prague, CZ; SRG-MED member) will attend this event on behalf of ESF as well as Professor Daniel David (Babes-Bolyai University, RO; Steering Committee member for the strategic report "The Human Brain: from Cells to Society - Towards Better Mental Health in Europe"; SRG-SOC member).

b. **"Healthy Brain: Healthy Europe – A new horizon for brain research and healthcare"**, 27-28 May 2013, Dublin (IE). Professor Stig Slørdahl, SRG-MED Chair, will attend this event on behalf of ESF. http://ec.europa.eu/research/conferences/2013/brain-month/index_en.cfm

Related activities or potential involvement of the DH-BIO:

1. Document on neurosciences elaborated by Doris Wolfslehner (Austria).
2. Information collected in member states on neuro-imaging enhancement.
3. Future additional Protocol to the Convention on Human Rights and Biomedicine on the protection of the dignity and fundamental rights of persons with mental disorders with regard to involuntary treatment and placement.

7. Other information

a. Forward Look final report and Science Policy Briefing "Implementation of Medical Research into Clinical Practice" (FLIP)

Research implementation into daily clinical practice still has to be improved and this is why the Forward Look process was started in 2010 to discuss the question, 'how can the treatment of patients be improved through better research and better use and implementation of research results?' These discussions resulted in a Forward Look report launched in May 2011 in Berlin (DE) and a Science Policy Briefing published in October 2012. Some further follow-up activities could be established and for instance, Professor Gunter Ollenschläger, who actively worked in the implementation group, suggested building up a model for the implementation of guidelines in a hospital or in primary care. This is currently under discussion.

The Science Policy Briefing and Forward Look final report are available from:

www.esf.org/flip

Related activities or potential involvement of the DH-BIO:

1. Additional protocol to the Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin. (DH-BIO(2010)3REV_compilation_quest_CoE_UN_study_E).
2. "Modernisation of Convention 108: new proposals" to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data [ETS No. 108].
3. Document prepared by Mrs Isabelle Erny on access to medical file.

b. Stem Cell Research

ESF-EMRC have advocated for stem cell research throughout the year 2012 by 1) presenting the 2010 Science Policy Briefing "Human Stem Cell Research and Regenerative Medicine – A European perspective on scientific, ethical and legal issues" at a dedicated workshop organised by the European Parliament, and at a stakeholders roundtable organised by Business Europe at the British Embassy in Brussels; 2) endorsing a support statement issued by the Wellcome Trust (UK) and 3) publishing an invited editorial in *Public Service Review*. The ESF has undertaken a survey across Europe on stem cell research policy, as well as a compilation of brief case studies showing successful applications of stem cell research in healthcare. The aim is to share the final report with the European Commission and other policy makers, so as to better inform decisions. For both matters, ESF has requested the input from its 35 health-related Member Organisations in 29 countries and from the DH-BIO national representatives. The report, currently being finalised, includes success stories and an updated table on human stem cell research regulation and legislation in Europe. It will be sent to the DH-BIO national members in due course.

Related activities or potential involvement of the DH-BIO:

1. Additional protocol to the Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin. (DH-BIO(2010)3REV_compilation_quest_CoE_UN_study_E).
2. Re-examination of Recommendation Rec(2006)4 on collections and use of biological materials of human origin for research purposes.
3. Industrial use of material derived from human embryos or foetuses: ethical and legal issues: informal exchange of views at the request of the delegation of Hungary.

c. ESF-EMRC Position on the Directive on the Protection of Animals used for Scientific Purposes (2010/63/EU)

Dr Francois Lachapelle (CHU Pitié-Salpêtrière, Inserm, Paris, FR) nominated by Inserm will represent both ESF and Science Europe at the European Commission working group meetings on project evaluation in the implementation process of Directive 2010/63/EU. He will be invited to the November 2013 SRG-MED meeting to report on the activity in the field.

d. General bioethics activities

From 28 January to 2 February 2013, the city of Strasbourg organised the third edition of the European Forum on Bioethics which is a major outreach event to the public audience. Dr Vanessa Campo-Ruiz attended the session "Humans and their prostheses: the human meccano" as "Grand Témoin" and was asked to formulate the conclusions.

Students from the Syracuse University (US) came to the ESF on 26 March 2013 to be given a short overview of the ESF activities related to (bio)ethics. Various ESF staff members (Dr Maria Manuela Nogueira, Dr Paola Campus and Dr Roberto Azzolini) briefly presented the activities in the fields of stem cell research, use of animals in biomedical research, clinical trials, natural hazards, climate change and its links to polar areas.

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ANDORRA / ANDORRE

Le Comité que l'Andorre vient d'incorporer dans son code pénal (loi du 10 octobre 2013), un délit de protection des sentiments vers les personnes décédées. Je vous en donne la traduction (libre):

« Celui qui profane ou outrage une sépulture, un cadavre ou ses restes, les cendres ou l'urne funéraire ou l'espace dédié à cette finalité, doit être puni d'une peine de prison jusqu'à une (1) année ».

AUSTRIA / AUTRICHE

Research on persons without the capacity to consent—with special consideration of the concept of risk Opinion of the Austrian Bioethics Commission, Austrian Federal Chancellery

Broschüre_Forschung_DE.pdf

BELGIUM / BELGIQUE

Législation. Modification de la loi du 7 mai 2004 relative aux expérimentations humaines. Cette loi crée deux catégories de comités d'éthique : ceux disposant d'un agrément partiel et ceux disposant d'un agrément complet. Le comité d'éthique local hospitalier dispose désormais d'un agrément partiel. Il n'est donc habilité qu'à formuler un avis sur l'aptitude des investigateurs, l'adéquation des installations ainsi que sur les méthodes et documents visant à recueillir le consentement des participants. Mais à défaut d'agrément complet, il ne peut donc plus formuler d'avis sur le protocole d'expérimentation en tant que tel. Pour obtenir un agrément complet, une demande doit être introduite à l'Agence fédérale des médicaments et des produits de soins de santé.

Modification de la loi du 29 décembre 2008 relative à l'obtention et à l'utilisation de matériel corporel humain destiné à des applications humaines ou à des fins de recherche scientifique : insertion d'un chapitre consacré aux biobanques ; diminution du nombre de médecin de 3 à 1 pour constater le décès avant un prélèvement (>< loi du 13 juin 1986 relative au prélèvement et à la transplantation d'organes : le décès doit être constaté par 3 médecins).

Débats. Débats depuis mars 2013 au Sénat concernant l'éventuelle modification de la loi relative à euthanasie. Les principaux points de discussion sont les suivants : élargissement de l'euthanasie aux mineurs, suppression du délai de validité de 5 ans d'une déclaration anticipée relative à l'euthanasie, extension de l'euthanasie aux cas de maladies dégénératives (élargissement de la notion d'inconscience).

LUXEMBOURG

Débats et discussions récentes concernant, d'une part, la ratification de la Convention d'Oviedo et, d'autre part, des textes légaux concernant le domaine de la bioéthique.

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1. La Convention d'Oviedo et ses protocoles additionnels

Les élections parlementaires, qui eurent lieu le 20 octobre 2013, créèrent une situation politique nouvelle au Luxembourg. Le parti chrétien social (PSC) de Monsieur Juncker perdait un certain nombre de sièges au Parlement. Dès lors une coalition n'incluant pas ce parti devenait possible. En fait, après les élections, des pourparlers entre libéraux, socialistes et verts furent entamés en vue de former un gouvernement tripartite. Un député libéral, Monsieur Xavier Bettel, fut nommé formateur. Les concertations entre les trois partis mentionnés restent en cours, mais semblent se développer favorablement. Le nouveau gouvernement pourrait, en fait, être mis en place en décembre.

En ce qui concerne la ratification de la Convention d'Oviedo, on peut, bien entendu, se demander si le consensus qui était en train de s'esquisser au cours de la précédente législature ne risque pas d'être remis en cause. A priori toutefois, cette hypothèse ne paraît pas vraisemblable.

D'un côté, l'actuel Ministre de la Santé, Monsieur Mars di Bartolomeo (LSAP, c'est-à-dire socialiste), était favorable à la ratification. Notons qu'il préside actuellement le groupe de travail santé mis en place en vue de la formation du nouveau gouvernement. L'attitude de son parti, le LSAP, à l'égard de la Convention semble être semblable à la sienne.

D'un autre côté, la position du parti libéral (de Monsieur Bettel), semble être fort claire. Une résolution fut déjà déposée en 2005 par le député libéral Claude Meisch, « visant à instaurer une commission spéciale chargée de l'étude de la problématique relative à la recherche sur les cellules embryonnaires humaines, et cela en vue de l'élaboration de propositions législatives en la matière ». Dans cette résolution, Monsieur Meisch se référa, d'une part, à l'avis favorable de la Commission nationale d'éthique de 2003 consacré à la recherche sur les embryons et, d'autre part, aux « potentialités de la thérapie cellulaire », à « l'attention que mérite la recherche sur les cellules embryonnaires humaines », et au « potentiel des méthodes biotechnologiques pour l'Université de Luxembourg ».

Le programme électoral du parti libéral comporte, par ailleurs, le passage suivant (que je traduis en français) : « Le DP (c'est-à-dire le parti démocratique libéral) s'engagera en vue de l'élaboration au cours de la législature à venir d'une loi-cadre concernant la recherche sur les cellules embryonnaires ».

Tout semble indiquer dès lors que le gouvernement en cours de formation sera favorable à la ratification de la Convention d'Oviedo et s'orientera vers un encadrement législatif favorable à la recherche sur les sur les embryons surnuméraires[2]

2. Vote d'une nouvelle loi concernant l'avortement.

A la fin de 2012, une nouvelle loi sur l'avortement, portant modification des articles 351, 353 et 353-1 du Code pénal, fut votée.

L'objectif du gouvernement était « d'adapter la législation luxembourgeoise relative à l'avortement aux réalités de la société »[3].

« Le gouvernement ne va pas, indique un document officiel, dans le sens d'une dépénalisation de l'avortement au Luxembourg et ne veut pas non plus favoriser les interruptions volontaires de grossesse ». « La première nouveauté de la réforme, indique encore ce texte, réside dans le fait qu'elle facilite les conditions d'accès à l'avortement. Le texte inclut parmi les situations autorisant le recours à l'interruption volontaire de grossesse celles qui résultent d'une situation de détresse de la femme enceinte, détresse qui peut non seulement être d'ordre physique ou psychique, mais aussi d'ordre social ». « La deuxième nouveauté réside dans la procédure de double consultation obligatoire … avant tout

[2] A noter aussi que l'avis 24 de la Commission Consultative Nationale d'Ethique pour les sciences de la Vie et de la Santé (C.N.E.) sur les embryons surnuméraires a été rendu public lors d'une conférence de presse le 1 juillet 2013 (dispoible en ligne : www.cne.lu)

[3] Je m'appuie ici sur un document officiel

avortement. Après avoir consulté un médecin-gynécologue ou obstétricien, qui sont tenus d'informer la femme enceinte, entre autres, sur les méthodes d'interruption de grossesse existantes, les centres de consultation et les médecins disposés à pratiquer une interruption de grossesse, la femme enceinte doit consulter un centre de consultation et d'information familiale »

Néanmoins cette réforme reste contestée, notamment en raison de la procédure de double consultation obligatoire et de la large inclusion des dispositions afférentes au sein du Code pénal.

SAN MARINO / SAN MARIN

The document "Bioethical Approach to Persons with Disabilities" has been translated into English and is published on the website of the National Bioethics Committee of Republic of San Marino at the following address: http://www.sanita.sm/on-line/home/comitato-bioetica/comitato-sammarinese-di-bioetica/documenti-csb.html

Public debate:

Following this document, The Secretaries of State for Health and Culture decided to draw up a draft Framework Law on Disability, in the wake of the UN Convention ratified in 2008 by San Marino.

A Framework Law for the assistance, social inclusion and rights of persons with disabilities; a text that has its roots in human rights over any discrimination.

In a recent press conference, the Secretaries of State for Health and Culture have argued that "the proposed Framework Law on Disability can now take advantage of the valuable contribution of this Document in terms of inclusion, care, education and entries protected in the workplace.

The United Nations Convention on the Rights of Persons with Disabilities has changed the frame of reference, from a perspective of health care to one of human rights, thus breaking down the idea of disability.

The proposed Framework Law on Disability introduces innovative elements that will require discussion and reflection, but San Marino will lead to excellence. Also this draft law is in addition to the project's capital San Marino Health and Sustainable Development, for the protection of rights is the basis of a State Health".

The full text of the press conference at the following address:
http://www.libertas.sm/cont/comunicato/una-nuova-riflessione-bioetica-per-abbattere-gli-stereotipi-culturali-negativi/83911/1.html)

TURKEY / TURQUIE

The bioethics discipline is arousing more interest in academic and professional circles in Turkey. The teaching of ethics is compulsory in curricula of medical schools and at veterinary medical schools in Turkey. The teaching of ethics is also comprised as elective courses at technical universities due to the issues allied with professional values.

The academics are becoming more aware of the need of using the term "bioethics" instead of ethics and medical ethics at schools of higher learning because of the comprehensive

content of the discipline of bioethics.

Additionally the issue of environmental pollution; the societal issues such as violence against women, violence against healthcare providers, the patient rights arguments and some problems in access to healthcare; the burnout syndrome observed at clinical and emergency clinical setting concerned with the healthcare providers have stimulated the debates concerning ethical aspect of healthcare delivery and the professional conduct.


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UNESCO

This year was the commemoration of the XXth anniversary of the Bioethics Programme in UNESCO, as well as twenty years of the establishment of the International Bioethics Committee (IBC).

A round table took place in Paris on 6 September 2013, in the presence of:
Stefano Semplici, Chairperson of the International Bioethics Committee (IBC) and Yongyuth Yuthavong, Chairperson of the Intergovernmental Bioethics Committee (IGBC); with the participation of the following experts: John Harris, Michael Marmot, Georges Kutukdjian and Henk Ten Have (former directors of the program) and experts and former IBC memebers Michèle Stanton-Jean, Nouzha Guessous-Idrissi, Genoveva Keyeux, , and Aissatou Touré.

An online publication is being prepared, a collection of very short contributions form around the world addressing the question of what are the challenges for bioethics in the coming twenty years and what should be the role of UNESCO.

Laboratory of Ideas: *advisory bodies:*

- Twentieth Session of **IBC** took place in June in Seoul, Korea. Hosted by the Hospital and University, “Yonsei University Health System - Severance Hospital”.
- IBC has finalized the report on Traditional Medicine Systems and Their Ethical Implications**. It is available on line in English and French.**
- The IBC’s Report on Human Vulnerability and Personal Integrity is also finalized and available in English and French, both on the web and printed versions.
- The Committee is currently finalizing the report on the principle 11 of non-discrimination and non-stigmatization of the UDBHR. They are using 6 examples to explore how the development of science and technology can produce discrimination and stigmatization: Nanotechnologies, Neurosciences, biobanks, Tropical diseases, HIV and OTC transplantation and trafficking.
- The committee has chosen for the next biennium to develop article 15 of the Declaration, on Benefit Sharing. UNESCO has been invited to participate in the seminar organized by the UN High Commissioner on Human Rights, to discuss alternatives to develop the normative content of the right to enjoy from the fruits of science. This topic will be placed in the center of UNESCO´s work in the next biennium.
- They will also establish a working group to monitor developments in the field of genetics and human rights.
- Closer collaboration between IBC and COMEST (Commission for ethics of science and technology) is envisaged to begin in the near future.

- In particular, regarding two topics: The revision of the 1974 Recommendation **(Recommendation on the Status of Scientific Researchers** 20 November 1974: Scientific conduct, ethics to engage in science, the role of scientist. To update it according to the new developments-
- On the ethical, social and legal implications of convergence of technologies.

Capacity building activities.
We have continued with the training of NBC that we help to establish. Jamaica has finalized the third training as well as Côte d'Ivoire. Belgium NBC is particularly active in the collaboration with this committee.

We have signed the MoU and conducted the first training in Malaysia, in June 2013.

UNESCO is expanding its target populations for trainings in bioethics:

- Journalists: a module on bioethics has been introduced in the already existing curricula for journalist, produced by the Communication Sector of UNESCO. The book is called: Model Curricula for Journalism Education: A compendium of New developed by UNESCO´s Communication Sector. (2013) ISBN : 9789230011864It is inEnglish and available at: http://unesdoc.unesco.org/images/0022/002211/221199E.pdf

It's a training that can be delivered online.

- UNESCO´s Moscow office of UNESCO in partnership with UNESCO´s Institute of Information and Technologies (IITE) , developed E-learning module on Bioethics for Journalists in the CIS region, which is available in Russian language: http://Ims.iit.unesco.org/ and it has been also translated into English,

- Judges: We have conducted a training for Judges in Mexico with the Mexican Supreme Court and Institute for Judiciary Education
  - In Italy in collaboration with the Chair of Bioethics in Haifa, the International Organization for Judicial Training (IOJT), the American National Center of State Courts, and the Ethics Committee of the Naples Federico II University "Carlo Romano".

- We are currently working on the book for bioethics and judges

- The Casebooks on "Human Dignity and Human Rights" and "Benefit and Harm" have been translated into French. Available on line.

UN Interagency collaborations:
As agreed in the last Global Summit for National Bioethics Committees in Tunis, a steering committee has been established to prepare this Summit, from Tunis on. The SC is composed by 12 NBC, two from each of WHO geographical regions, the past and future hosts, and WHO and UNESCO to ensure the outmost support for the NBC´s from both organizations that work on the field.
The next Global Summit will take place in June 2014 in Mexico City, host by the Mexican National Bioethics Commission.
International collaborations:

- With World Medical Association in different workshops as part of the last revision of the Declaration of Helsinki;

- With CIOMS in the current revision of CIOMS 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects;

The responsible of the bioethics program is members of the Scientific Advisory Committee of the UNESCO Category 2 Center: International Center for Biotechnology in Nigeria. The first meeting of the Committee was on January 2013.

As Members of the Advisory Committee of the Project "Progress", **Pro**moting **G**lobal **Re**sponsible Research & **S**ocial and **S**cientific Innovation, funded by the European Commission, the bioethics program of UNESCO hosted the *Kick-off Meeting, from* 20-22 March 2013, at its HEADQUARTERS in Paris.

ProGReSS concentrates on the underexplored and least converging part of RRI, namely achieving societal desirability. The project will link existing international networks of RRI from all continents with European partners and policy-makers, policy-advisors, funders, industry and non-governmental organizations to achieve the following objectives:

1. Link existing international networks of RRI with relevant societal actors on a global scale to focus innovation on societal desirability.
2. Complete a major fact-finding mission comparing science funding strategies and innovation policies in Europe, the US, China, Japan, India, Australia, and South Africa.
3. Advocate a European normative model for RRI globally, using constitutional values as a driver to inform societal desirability.
4. Develop a strategy for fostering the convergence of regional innovation systems at the global level.

European Science Foundation / Fondation Européenne de la Science

In the new European Science Foundation (ESF) structure, five smaller Scientific Review Groups (SRGs) now replace the previous Standing Committees. For more information (activities, publications and news) about the different SRGs, see: http://www.esf.org/hosting-experts/scientific-review-groups.html (access to all SRGs from the left menu)

We present in this report the developments at the ESF in the Scientific Review Groups for the:

- Biomedical Sciences (SRG-MED, formerly Standing Committee for the European Medical Research Councils EMRC)
- Humanities (SRG-HUM, formerly Standing Committee for the Humanities SCH)
- Social Sciences (SRG-SOC, formerly Standing Committee for the Social Sciences SCSS)
- Life, Earth and Environmental Sciences (SRG-LEE, formerly Standing Committee for the Life, Earth and Environmental Sciences LESC)

Report "Human Stem Cell Research and Regenerative Medicine - Focus on European policy and scientific contributions"

As a follow-up to the ESF-EMRC 2010 Science Policy Briefing no. 38 'Human Stem Cell Research and Regenerative Medicine - A European Perspective on Scientific, Ethical and Legal Issues', this new report was published on 6 November 2013. It includes success stories illustrating the added value of this field in biomedical research as well as an updated table on human stem cell research regulation and legislation in Europe. It has been disseminated through various media and will be shared with scientists as well as various policy makers including the European Commission to help them in their decision-making. The ESF is grateful to all the country representatives at DH-BIO who generously provided input on their national legislative frameworks.

Report available from: http://www.esf.org/publications/medical-sciences.html

Press release available from: http://www.esf.org/media-centre/ext-single-news/article/new-report-calls-for-sustained-public-endorsement-and-funding-for-human-stem-cell-research-978.html

Forward Look report "Personalised Medicine for the European Citizen" (iPM)

The iPM Forward Look final report was published in December 2012 and launched on 28 January 2013 in Brussels (BE). First implementation ideas were discussed and detailed in a follow-up report that will be available in late autumn 2013. The publication of this Forward Look final report has been a great success leading to numerous invitations to events such as the 16th European Health Forum Gastein (EHFG) on 2-5 October 2013 in Bad Gastein (AT). In addition, ESF is now part of a coordinated strategic action ('PerMed') funded by the European Commission that was kicked off in Berlin (DE) on 8 October 2013. ESF is now a permanent guest in the European Alliance for Personalised Medicine (EAPM: www.euapm.eu) who has volunteered to support the implementation of the Forward Look report. An EAPM roundtable entitled 'Horizon 2020 and the future of European research: How to develop the right prevention and treatment to the right patient at the right time' was organised on 10 September 2013 at the European Parliament in Strasbourg (FR) with ESF's financial support, hosted by Petru Luhan, MEP. A meeting report was released with ESF's sponsorship.

Clinical Trials: WHO-NIH-OECD follow-up project proposal

EMRC and now SRG-MED have been involved in implementing the different recommendations of the OECD Global Science Forum report published in January 2012 mainly in the areas of education and training and risk-based approach. A project proposal (preliminary title: 'Facilitating international co-operation and quality assurance in clinical trials') has been drafted by the World Health Organization (WHO) and the US National Institutes of Health (NIH) with the support of various organisations (e.g. OECD, Norwegian Directorate of Health) and will benefit from participation and financial support from the ESF SRG-MED.

Science Policy Briefing "Science in Society: Caring for our futures in turbulent times"

This Science Policy Briefing was released during a launch event that took place on 24 September 2013, with Professors Ulrike Felt (Chair of the Scientific Committee), Helga Nowotny (President of the European Research Council) and Paul Boyle (President of Science Europe). A video that will be published on the ESF website soon is being prepared with extracts from the launch event and brief interviews with participants.
Report and additional information available from: http://www.esf.org/hosting-experts/scientific-review-groups/social-sciences-soc/activities/strategic-activities/the-future-of-science-in-society.html

Press release available from: http://www.esf.org/media-centre/ext-single-news/article/science-in-society-caring-for-our-futures-in-turbulent-times-967.html

EUROCORES Programme "Synthetic Biology: Engineering Complex Biological Systems" (EuroSYNBIO)

This EUROCORES (European Collaborative Research) programme was composed of 5 Collaborative Research Projects including SynMod ("Synthetic biology to obtain novel antibiotics and optimized production systems"). SynMod focussed on the **ethical, legal and societal impacts of the field of synthetic biology** and turned out to be most successful and of high interest for all the other CRPs. This non-lab group investigated the potential impact of synthetic biology on the safety of biotechnological processes and its ethical implications for our society. These considerations will be shared with the public in the format of a video (to be released by the end of the year) to institute a constructive dialogue about a potentially transformative novel technology. In addition, a workshop entitled "**Global Challenges - Opportunities for Nanotechnology**" took place in Venice (IT) on 15-19 April 2013, co-organised by one of the EuroSYNBIO Principal Investigators, Professor Daniel Müller (ETH Zurich, CH), with the aim to "raise the next generation of nanoscientists' awareness of the global challenges looming on the horizon".

A workshop report was published, available from: http://www.cens.de/international/joint-workshops/globalchallenges13/

For more information, see: www.esf.org/eurosynbio


FINAL_HumanStemCellResearch.pdf


ESF_SPB50_ScienceInSociety.pdf

ALLEA (All European Academies) / Academies Européennes

ALLEA statement “Ethics Education in Science” prepared by the ALLEA permanent working group on Science & Ethics.

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Introducing letter from the ALLEA President Professor Günter Stock and the working group chair Professor Göran Hermerén and a digital version of the paper.

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LLEA_Statement_EES

For further information on the statement and the working group activities please visit http://www.allea.org/Pages/ALL/33/522.bGFuZz1FTkc.html.