2. Summaries of the interventions
Introduction to the NEC

Prof. Assuntina Morresi, member of the Italian National Bioethics Committee, conveys to all NEC participants a warm welcome **message by Italy's Minister of Health – Hon. Beatrice Lorenzin** - expressing her very best wishes for a successful and fruitful event.

Dr. Isidoros KARATZAS
Head of Ethics Sector, DG RTD, European Commission

The selected issues for the NEC discussion are very close to the political reality of the world around us. This is simultaneously the best and the worst of times for ethics. We constantly see ethical matters being debated in the news and within expert committees. It is always a great opportunity to tackle these issues. The challenge is not only how to deal with ethical questions and carry out related activities, producing viable scientific and ethics advice, but how actually to use this advice and make the work of all the committees visible both to the wider public and the political establishment, in order for them to take it into account whenever devising their own decisions and strategies.

We are experiencing a very challenging time. Therefore, we shall find the way to collaborate with all actors involved in the ethics work: the national committees, the research ethics bodies and the scientific community at large, in order to do more justice to the efforts undertaken by the different national bioethics committees in issuing their opinions.

Prof. Laura PALAZZANI
Vice-chair of the Italian National Bioethics Committee, Member of EGE

We are facing an unprecedented technological and scientific progress in terms of quantity, quality and speed of innovation, as well as the broadness of its scope. The "classic" bioethical problems that have been at the forefront in this field (beginning and end of life issues) are combined with ever increasing new ones (neuroscience, synthetic biology, enhancement, biometrics, nanotechnology, telemedicine, robotics).

We are dealing with emerging issues that can only be tackled, from an interdisciplinary perspective, building on an updated knowledge of the social-scientific context and in a pluralistic perspective, bringing together different moral theories. Society feels the need to gather information, in order to develop a critical consciousness that provides guidance when making choices. At the same time, governments perceive the necessity to regulate society.

National Bioethics Committees are set up with the purpose of creating a platform for interdisciplinary and pluralistic discussion, while seeking ethics mediation through the identification of 'minimum common values' for the elaboration of Opinions. Opinions that play a dual role: advising governments on regulation and raising citizen awareness.

It has become increasingly clear that answers to the questions arising from techno-sciences can not only be national, but require efforts to foster international discussions leading to a possible and desirable, albeit complex, harmonization of bioethics and bio-law.

The Forum of National Ethics Councils of the European Union, currently, plays a key role in facilitating interactions and the creation of an international dialogue by exchanging experiences and sharing insights.

At this meeting in Rome, we tried to build continuity with what was achieved during the last NEC Forum held in Dublin. Some topics will be addressed again: others have been added also upon suggestion of the single Committees in relation to the issues perceived as highly sensitive at the European level, within the international framework.

The topics being dealt with in these two challenging days are the following: international collaboration, security and new surveillance technologies, biological samples and health data, research integrity, neuroscience. Working groups will also take place – a long-standing practice at the NEC Forums - which will further stimulate the exchange of ideas and discussion on specific issues: citizenship and science, ethics in education, robotics.

No Borders:
The Importance of International Collaboration in Bioethics

Prof. James WAGNER
Vice-chair of the U.S. Presidential Commission
for the Study of Bioethical Issues

The rapid globalization of research has created not only new opportunities for collaboration, but also new challenges and concerns. The need for global cooperation in deliberating bioethical issues and enhancing bioethical decision-making is imperative. The US Bioethics Commission and its predecessors provide one example of how this process can take place and affect policy. However most countries have differing structures for deliberating bioethical issues and recommending how to include those discussions into policy. In order for us to embrace cutting-edge research and innovation, which is inherently global, understanding each other's processes and norms is essential. Creating a place discussions about moral science around the world will lead to great outcomes for the global community.

Prof. Julian KINDERLERER
Chair of EGE

Presentation of EGE Opinions: "Ethics of Information and Communication Technologies", An ethical framework for assessing research, production and use of energy, Ethics of Security and Surveillance Technologies.

Presentation of the last Opinion on Citizen Science and New Health Technologies.

Aided by the proliferation of digital technologies, citizen involvement initiatives in health are thriving. Health appears to offer fertile ground for citizen engagement, being a subject high on the public's list of concerns, and an area in which each and every individual has a particularly personal stake. The knowledge and perspectives of non-experts may enrich the global understanding of scientific problems. The logging of personal information has a rich history. Digital self- tracking devices–often connected to the Internet through our smartphones–take the effort out of recording and compiling. You get better, more regular data, and it's harder for you to fudge it to make yourself feel better. We have to think about the manner in which all the information can be collated and *mined.* Who has access to both providing and using any data. How are experiments designed, and how reliable is data. What are the ethical issues of involvement in design of research, collection of data, of sharing data, of sharing results. Where in the research or treatment process are citizens to be involved as passive or active contributors. Citizens could be the scientists, either designing or being part of the data collection process.

Citizens could be users of technology or knowledge – again actively or passively. Respect for freedom which secures, *inter alia*, the right to uncensored communication and agency in the digital era. Respect for democracy, citizenship and participation, which includes, *inter alia*, protection against unjustified exclusion and protection against unlawful discrimination; respect for privacy which secures, *inter alia*, the personal private sphere against unjustified interventions.

EGE Opinion on the Ethics of Security and Surveillance Technologies

Dr. Siobhan O'SULLIVAN
Member of EGE, Chief Bioethics Officer of the National Advisory Committee on Bioethics, Ireland

The digital revolution and subsequent advances in mobile, wireless and networked devices have significantly contributed to the development of security and surveillance technologies. Shared characteristics of this technological development include trends towards miniaturisation, inter-connectivity, varying degrees of in-built automation and deployment of devices in an increasingly ubiquitous fashion. The progressive convergence of security and surveillance technologies is creating more powerful networked systems, with greater potential societal impact.

Additional drivers of technological trends include general perceptions of societal insecurity, low levels of trust and tolerance for risk which in turn may be fuelling the securitization approaches adopted by governments in Europe and elsewhere. While security technologies are progressively accepted as universal security enablers by governments, they can also be characterized by important limitations in accuracy and effectiveness.

The regulatory landscape regarding security and surveillance is fragmented, governed by a patchwork of global, regional, and national regulatory instruments. A fundamental dilemma posed by this multi-level governance system is that while human rights such as privacy are global rights, and data protection and certain other regulatory areas are covered by EU law, national security remains primarily a privilege for each member state. This can present tensions where security functions to limit privacy rights or is presented as a protected value or right. A second key challenge is the need for the regulatory framework to keep pace with the rapid advances in the technological development of surveillance capacities (areas such as drone technology and telecommunications represent a case in point).

Security, in its narrowest conceptualization, is the protection from physical harm or the threat of harm, with states committed to provide security for the citizenry in exchange for the power to curtail individual liberty. However, security needs to be viewed in the broader context which encompasses both human and societal security. Excessive surveillance exerts societal control, and can erode trust, social cohesion, solidarity and intellectual freedom, thus undermining the security of citizens, as broadly understood.

The shared values and rights enshrined in the EU's Human Rights instruments provide the framework on which to re-assess the debate on security and surveillance. The core ethical principles of privacy and freedom, autonomy and responsibility, and justice serve as guiding values that can both establish security and impose restraints on the use of security and surveillance technologies. Transparency, efficacy and proportionality are additional key procedural principles which should underpin the application of security and surveillance instruments.

The rather limited approach to achieving security, most especially when it comes to the narrow interpretation of state security, has been to engage in the narrative of trade-offs, the classic example being the trade-off between freedom, often embodied as privacy, and security. While a proper balance needs to be struck between competing principles or values when they come into conflict, there are some core principles such as human dignity which cannot be traded away. This requires us to move beyond the rhetoric of trade-offs and into a more nuanced approach where security technologies and measures are assessed on the basis of proportionality and effectiveness and rights are prioritised rather than traded.

The EGE issued 16 recommendations regarding the use of security and surveillance technologies. These can be grouped and summarised under the four categories of oversight and accountability; data protection and processing; design and development; and public awareness and information.

Introduction and chair:

Dr. Christiane DRUML
Chair of the Austrian Bioethics Commission

Since the codification of research laws in the 1960s and later on, we have witnessed a change of paradigm. This session deals with issues such as biobanking, data protection, direct-to-consumer testing, etc., where the traditional measures of regulating clinical research are not valid anymore.

We are compelled to choose a new risk-based approach to research, according to the OECD. There is also a new awareness of the importance of research. A significant number of clinical measures are evaluated and data is collected. On the other hand, we are also witnessing a change of paradigm with regard to patients versus their physicians. Patients have much more autonomy nowadays and the "age of paternalism" is over. This is, thus, one of the reasons why the position of the human being in research has undergone considerable transformation. Additionally, with the internet and another kind of health literacy, it becomes increasingly clear that there is an urgent requirement of a new approach. People are participating themselves in research, in a completely different way and as they are also using social media, the whole landscape of research, along with the protection of personal data, has been changed.

The New Data Protection Regulation

Dr. Caroline GANS COMBE,
Chair of the DG RTD Research Ethics Group on the Data Protection

The presentation places a strong focus on the Data Protection Regulation in health data contexts. In this regard, nothing has been finalized. The discussion between the EU Commission, the Parliament and the Council of Ministers is supposed to occur at the beginning of next year.
The core issue hinges on how the revision process will impact health data.
The legal framework related to the topic is larger than commonly considered and it particularly involves:

- The 95/46 data protection directive, which will become a regulation;
- The e-health network, the clinical trials directive (Art. 3) and the patients' rights directive (Art. 14-2011/24);
- The e-privacy directive (2002/58) last amended by directive 2009/136;

Moreover, there is an ongoing revision of the medical device directive in relation to m-health diagnostics.
Data are often collected, stored, processed under electronic format, while the types of retrieved data are polymorphic (i.e. patients data, but also environment-contextual data, pathologies etc.). Furthermore, there is no shared definition with regard to sensitive data.
Concerning the impact of the political agenda on the issue, one should consider the Transatlantic Trade and Investment Partnership (TTIP) and the Data Protection Umbrella Agreement.

As for the former, in order to ease exchanges between the EU and the USA, both parties discuss around common standards, including on data (e.g. privacy by design).
As for the latter, the issue on which the debate will be rough is data transfer to third countries and "sunset clauses" on adequacy decisions. For this reason, even if the legal provisions currently consider certain countries to adequately cover DPP *per se*, evidence of such proper treatment must be provided. Therefore, this "adequacy" is no longer insured in time.
The potential revision's impact must be taken into account, in light not only of the text pertaining to the directive but of all of the different elements that may directly or indirectly affect the nature, collection, use, retention and processing of the data.

Major changes to be introduced by the revised directive include the following aspects:

- A single pan-European law for data protection, replacing the current patchwork of national laws and establishing harmonized rules, while shifting from directive to regulation;
- Institutions will only have to deal with one single supervisory authority;
- An enhanced right to personal access and to be forgotten: the passage to the digital age, enhanced deletion rights and possibilities including for third party countries (under the May 2014 ECJ decision known as the "Google" decision);
- Explicit consent required for data processing and enhanced information of individuals: consent cannot be assumed. Saying nothing is not the same as saying yes. Businesses and organizations will also need to inform people, without undue delay, about data breaches. Given the principle of equality in front of the law (Art. 7, UDHR), there cannot be a difference of treatment between patients, research subjects and other individuals. Thus, this battle around consent has, in a way, already been settled (in Europe) by the existence of the Clinical Trials Directive. It must be, however, noted that consent should be understood "by all means" and not limited to the face to face paper-physical presence version.
- Data protection embedded: "Privacy by design" and "privacy by default" should become essential principles in EU data protection rules. Data protection safeguards are to be built into products and services from the earliest stage, and privacy-friendly default settings should be the norm.
- Future Art. 79 will provide for financial sanctions in case of privacy breaches from 1M to 100M euros, up to 2 to 5% of the worldwide turnover.
- Future Art. 3 will set out the enlarged territorial scope: "national courts could not recognize the decisions of non-EU courts which ordered the disclosure of personal data".
- Art. 17 will lay down the erasure right, leaving the question of judicial redress to be negotiated.

Moreover, researchers shall identify:

1) The source/origin of data (newly collected/reuse);
2) The nature (individuals/patients data, technical data, epidemiological data, clinical data, metadata);
3) The use (e.g. project use);
4) The becoming (discarded, kept for future use, etc.).

Research, even more when targeting pre-competitive objectives, falls under these rules. NGOs and other not for profit bodies are concerned by the establishment clause (where a non-EU Structure has established a subsidiary in a Member State).

Direct-to-consumer Genetic Tests and Biological Samples

Dr. Vasiliki MOLLAKI
PhD Scientific Associate,
Hellenic National Bioethics Commission

Genetic services that are offered directly to the consumer have sparked an ongoing debate over the past 10 years. In particular, Direct-to-Consumer Genetic Tests (DTCGT), which are offered directly to consumers without the involvement of a health care professional, remain controversial regarding their scientific validity and clinical utility. However, DTCGT raise a number of additional ethical and legal issues.

Ethical and legal issues include: The validity of informed consent, data privacy and confidentiality, data sharing, ownership of genetic and/or phenotypic data, duration of data maintenance, use of biological sample and data for research purposes, genetic testing in minors, closure or sale of the company, and the consumption of limited healthcare resources. DTCGT companies address (or not) the above mentioned issues in different ways and regulatory frameworks (general or specific) vary widely between countries.

Specific reference is made to the market of DTCGT in Greece and specific points of the relevant Opinion issued by the Hellenic National Bioethics Commission are also presented.

Pediatric Biobanks

Prof. Lorenzo d'AVACK
Deputy Vice-chair of the Italian National Bioethics Committee

There is a lack of attention, in general and particularly in our country, regarding the treatment of the samples obtained from children. The European regulations governing the clinical use of biological samples, never make explicit reference to children, speaking only in general of "persons granting authorization on behalf of the donors" (2004/23/EC, Art. 13 para 2), and with respect to consent refer to national laws, regardless of age for the donor. And the limited references available are insufficient, as they concern situations related to a possible diagnostic and therapeutic benefit for the minor, while in the case of pediatric biobanks, the sample is donated and used for research with the predominant philanthropic purposes, regardless of any possible or certain clinical benefit for the donor.

In addition to the usual legal and ethical rules drawn up in collecting genetic materials from adults, which are completely acceptable, even for the granting of children's biological material (among others: certification through a transparent procedure, approved by a body recognized by the government; the principle of gratuity and the prohibition of personal discrimination; the concession in the general formula of the 'concession for use', etc.), other rules should be considered for research using pediatric biobanks, given that minors are a particularly vulnerable population, and this requires measures meant for appropriate protection.

This speech will take into account, very briefly due to time constraints, some of the most problematic aspects of pediatric biobanks: consent, subsidiarity, the risk/benefit and return of results.

1. The consent of parents and the minor/adult

Before any collection of biological material is carried out, it is necessary and of primary importance to have the free and clear consent of the actual donor.

However, in the case of pediatric biobanks, this prerequisite for various and not marginal aspects raises issues with respect to biobanks collecting material obtained from adult donors given that: the material collected does not actually belong to the person granting it, but to another individual, in this case a minor who is not able, until he/she acquires the capacity of discernment, to give informed consent concerning the destiny and future of his/her biological material.

In the juridical context, it is believed that the will and wishes of minors, in view of their best interests, are manifested by the parents or legal representative. However it should be subject to the information to be given to the minor at the time of the concession of the samples, taking into account the degree of maturity reached by the minor and the ability to understand the information sheet: any possible refusal of the minor shall prevail over the consent of the parent/legal representative.

It should also be considered that doctrine and legal systems provide for different modalities of consent to the concession of biological samples: "limited consent" to the use of the sample, only for immediate, specified research, which prohibits use in other studies not provided for at the time of signing; "partially restricted consent", which authorizes the use of samples not only for specific current research, but also for future research that is directly related to the initial one; "multi-option consent," which allows to make different choices; "broad consent", which allows the use of samples for current and future research of all kinds.

In the case of "broad consent", the donor relies on a general information sheet and it is clear that in this way a relationship of trust is established with the biobank, based on the prevailing

principle of social solidarity, a reason which in itself justifies the research. An agreement of this type is often called for by researchers in order to have greater freedom in the use of materials and not negatively affect subsequent research on the samples provided.

In the other cases, it is expected that donors may have constant control over their own samples and may withdraw given consent at any time, resulting in the destruction of biological samples and related data.

In view of these various options, the CNB reiterates, as in another document of the same Committee, that the samples should not be rendered anonymous irreversibly and the authorization of the parents or legal representative should not be "broad", but rather given for a specific research or one directly related to it ("partially restricted consent").

Therefore, parents should have the possibility to retain the "control" over the use that is made of the biological material of their child and should be reassured about the management plan and the manner in which the biobank ensures the retention and the "confidentiality" of the collected data.

In addition, as part of the consent from parents and legal representative, prohibited access of certain third parties, such as insurance companies and employers, should also be made explicit.

However, we are aware of the difficulty of setting these objectives in a comprehensive way at the moment in which the biological material is transferred. Partly because the time span of the research is generally long and it is difficult to predict at the moment of giving consent, the possible studies which, after several years, could involve the material being re-utilized. This implies that for the proper management and utilization of the material granted to a pediatric biobank the essential rule, when the minor heads towards maturity, is the loss of importance of the consent given by the parents and the start of a process aimed at listening to the actual adolescent in order to renew, modify or withdraw consent to the use of their samples and data in the biobank.

However, even within the regulation of pediatric biobanks, there may be exceptions to the continuation of research if there is no expressed will regarding a greater or different use of samples and data.

In the first place, should the processing of data and samples be necessary for conducting studies, with no significant impact on the individual participant, carried out with organic material collected previously for the purposes of protection of public health or for the execution of earlier research projects.

A second exception may be construed when it has not been possible to contact the minor, now adult or the parents, even though reasonable efforts have been made to do so.

However, in these cases, as in all biobanks, research can only be carried out on the basis of a project that has received the approval of the competent territorial ethics committee, which has assessed its scientific appropriateness and ethical acceptability.

2. Subsidiarity, risks and benefits

The ethical and legal principles which legitimize scientific research on groups of vulnerable individuals include those that research must be responsive to the health needs and priorities laid down by that category of persons, and that the same research can not be carried out on non-vulnerable persons. In addition, this group should benefit from the knowledge, practices or intervention deriving from the research.

It should also be noted that there are established general ethical principles for research on incapacitated persons "with no direct benefit":

- The research project must envisage collective utility;
- The risks and inconvenience to the persons involved should be minimal.

The need for scientific research on the biological samples of minors, even if replaceable in some cases with research on the biological samples of adults, in accordance with the principle of subsidiarity justifies the use of the samples collected in pediatric biobanks.

In the present case, therefore, the possibility of a minor to obtain some future medical benefit, not in immediate and specific relation to the time of concession, should not be totally ruled out.

The other aspect, that of "minimal risk" has been discussed in the context of research, especially on incapacitated persons, and consequently in pediatric biobanks. Primarily, the difference between the two types which jeopardize varying interests should once again be emphasized: health in the first case, in the second the right to protection of personal data. Therefore, it is of primary importance in the context of biobanks to have regulations that guarantee specific protection of privacy, particularly when samples are shared with other researchers not connected to the biobank, which has acquired the sample. Therefore, the preference given to "partial anonymity" through codes both for the samples and the data from a minor is justified for the obvious reinforcement of privacy.

With regard to the risks to health at the time of data collection, given the general difficulty in the field of research on the incapacitated and minors to define what risks and inconveniences are minimal and therefore tolerable for the benefit of scientific and social interests, the NBC, instead of referring to fixed and predefined standards, endorses evaluation of the situation, taking into account the context of the study and the particularity of collections by the appropriate ethics committee.

3. The Right to "know" and the right "not to know" of parents and the legal representative

Some data obtained from the study of samples can provide useful information on the subject's health (prevention, diagnosis, treatment) or identify genotypic characteristics that may be passed on in the family (significant in the context of procreative choices).

Normally biobanks do not communicate to those who have conceded samples the data obtained from the research carried out utilizing their samples, except at the express request of the person concerned, as expressed at the time of consent.

It is now known that as part of the right to self-determination established in our society, both on an ethical and juridical level, with reference to choices in the context of genetic information, there is also the right to remain in "ignorance about one's future", i.e. the "right not to know." Donation of a biological sample that is immediately completely anonymised is characterized by not asking or expecting anything in return, not wanting to know the next phases and results of the research. This is a possibility as part of the informed consent of adults.

With regard to pediatric biobanks, the Committee believes that the informed consent of the parents/legal representative to the donation of biological samples should explicitly provide for the information sheet to be given, if the research provides sufficiently substantiated, reliable and useful information for the health of the minor on the preventive, diagnostic, therapeutic level or in terms of reproductive health. In this case - in the face of actual and potential benefits - there is the researcher's duty to inform and a right/duty to know on behalf of the parents/legal representative in the interests of the minor, even if this entails a burden in terms of costs and on an organizational level for biobanks, as well as a psychological burden for the parents themselves. The parents /legal representative should therefore not be granted the opportunity to express their dissent to being informed and to assert their "right not to know." Those responsible for the biobank should do everything possible to contact the parents or the legal representative of the minor and give them the informative report.

The Committee also considers it necessary that the parents or the legal representative must be informed, even in the case of possible data, not explicitly searched for (so called 'incidental findings', or 'unexpected results'), which highlight genetic diseases with either certain or high probability of late-onset with no current cure (e.g. Huntington's disease).

It will, however, be the duty of physicians to select the relevance of the information and the duty of parents to use this medical data in accordance with the appropriate needs of the minor and to assess when and how to transmit this knowledge to their child.

It will be the latter when an adult, as part of his consent to research to make use of the right to be informed or the right not to know.

Prof. Peter DABROCK,
Vice-chair of the German Ethics Council, Member of EGE

The physical wellbeing of individuals is a goal that health care providers, researchers and politicians share with citizens. In order to accomplish this goal, a large amount of data needs to be collected, stored and exchanged between researchers, clinics and biobanks. However, this data often contains sensitive information. In particular, the idea of personalized medicine depends on these arrangements. The Private-Gen project investigated the existing privacy regimes, which encompass statutory regulation (both national and international), self-regulation and technology-based privacy instruments, with regard to (post-)genomic research in general and, more specifically, in relation to the creation of large-scale life science infrastructures in Germany, Finland and Spain.

In order to better understand gene-environment and gene-gene interaction, increasing amounts of bio-information are collected and stored for the purpose of biomedical research. This information is subsequently shared, disseminated and used in ever more collaborative research environment, which leads to the multiplication and dissemination of personal information on a potentially global scale. These developments undermine individuals' possibilities to control information that is related to them and, therefore, increases the need to better understand issues that are related to the concept of genomic privacy.

The rapid developments almost force us to rethink the notion of genetic privacy in its wider dimension including legal, social, political, ethical, technological and organizational aspects.

Among the challenges encountered for responsibly setting up biobanks there is the issue of how to deal with data of a personal nature, i.e. informed consent. Information about future use in the consent form can be either broad or specific, and this distinction divides the bioethics community. The main findings of the Private-Gen focus group show that people compare and contrast biobanks to issues, technologies and systems already familiar to them, for instance electronic health records. They have become accustomed to data gathering and have different ways of either accepting it, going around it, or even fooling the data-gathering systems. The fact that people see bio-information as personal and delicate, however, does not mean that they would not provide information to biobanks.

The project identified four strategies that describe the reactions of people with regard to retaining influence over the course of data streams. They 1) expressed reliance on and the need for external control, 2) were keen to exercise self-regulation, 3) were concerned over how to control the goals and benefits of biobanks and also 4) accepted a loss of control over their private information in certain cases.

Social media present a borderline case, where people often share personal information in full awareness of potentially limited control and protection. Biobanks are, however, significantly different from social media, since the amount of data and the nature of materials are largely different and there is hardly any two way communication between the researcher or the biobank, on the one hand, and the donor or participant, on the other hand. On biobanking, people argue that if control is diminished, at the very least, the option of full anonymization of donors or refusal to participate should be considered. Consequently, their attitudes often take on a certain acceptance of loss of control, when the data is not perceived as overly personal or when the investment of time and energy to exert control over data flows is deemed too high. Globalization and commercialization are the main drivers behind concerns. While national biobank projects that are publically financed meet a higher level of trust, international public-private collaborations and networking efforts are viewed with some scepticism, resulting in a Europe-wide trend towards narrow consent.

Different dimensions of responsible governance were devised in this field:

- *Choice and control* (giving donors the opportunity to set up and flexibly change their personalized consent; exercising personal control through individualized choices; interdisciplinary research to develop synergies between scientific efficiency and data protection and personal information control).
- *Delegation and deliberation* (organizing a political and ethical discussion; offering opportunities for donors and lay people to influence, debate and make choices).
- *Protection* (elaborating a credible data protection strategy).
- *Transparency* (delivering an official access policy at the disposal of researchers and donors; making privacy protection publicly available; encompassing all privacy relevant measures throughout all stages, from donation to sharing of data; donors should be given the opportunity to follow the scientific routes of their samples).
- *Harmonization* (legal determination and clarification on consent forms).

Several proposals to use existing and prospective information and communication tools have been discussed to improve research flexibility, data protection and donor control. Biobanks collect data from various sources, interfacing with and integrating into IT architectures.
The overall task is to generate economically, scientifically, legally and ethically sound frameworks of exchanging data in ways that are socially robust. Another way of achieving this goal, instead of laying sole responsibility with researchers, is to involve participants interactively in consent procedures through web-based technologies that, at the same time, give donors control and increase research efficiency. A so-called 'disclosure filter' is a software component that helps the biobank hosts to answer to following multi-layered question: *who* is allowed to receive *what* under *which* circumstances and *how*?

Another matter concerns the future uses of data that cannot be predicted, which require informed consent to take on different forms. In this regard, a technology-based form of dynamic consent for biobank donors has been foreseen. In this model, consent is not a mere communicative exercise but a bidirectional, ongoing, interactive process between patients and researchers. Individuals can make and express preferences about the choices they are given with regard to the use of their data and samples for research and change or revoke these over time.

Benefits of Dynamic Consent Interface:

- Recruitment for future studies becomes easier, less costly and more efficient;
- Legal and ethical requirements of consent can be easily met;
- Greater transparency and accountability;
- Research findings can be returned to research participants as part of a personalized medicine approach.

Biobanks can gain trust and legitimacy if they show their willingness to allow donors and citizens to become true "co-managers" of their data.

Research Culture and Research Integrity: Ethical Challenges

Introduction and chair:

Prof. Cinzia CAPORALE
Member of the Italian National Bioethics Committee and National Research Council

This meeting represents a great opportunity for us all. There is mutual interest for an active cooperation and close connections in Europe for bioethics and research ethics. Opinions and documents issued by each national committee in the continent are aiming at orientating collective and individual choices. Therefore, they play a key role towards a progressive convergence of the several morals and legislations in Europe. Of course, a convergence and not an equalization of morals. Bioethics principles and practices represent one of the deepest aspects of human identity and human life. We do not approach mere abstract concepts but life stances and views about life and the world. Dialogue in this field should, then, be taken seriously, in the sense of pursuit of agreement and achievement of minimum common ground. This should be envisaged, at least, on the most relevant and striking issues. I believe that research integrity falls within these topics. It is, in fact, one of the most important issues to be addressed, both at the national and European level for moral, scientific and economic reasons, as well as for the efficiency of the European research area, combined with innovation and competitiveness.

Misconduct in medical research

Prof. Kjell ASPLUND
Chair of the Swedish Council on Medical Ethics

The most descriptive definition of unethical research misconduct is the "FFP model" (fabrication, falsification, and plagiarism) presented by the United States' Office of Research Integrity. In less serious cases, there is little agreement on the limits of research deceit and deception, Duplicate publications and gift/ghost authorship may be ethically unsound, but do they represent outright deception? Suppression of data and unplanned post-hoc analyses are more common examples of unethical research practices in the twilight zone of misconduct.

How common are fraud and other forms of scientific misconduct? There are examples of large-scale research fraud that has gone undetected for decades, so any estimates are bound to be just estimates. The proportion of retraction of articles from scientific journals because of detected fraud, plagiarism and duplicate publications has, however, risen sharply during the last two decades. As for plagiarism and duplicate publications, this may be due to improved detection methods, but as to fraud, the increase is probably real.

Much of research misconduct is driven by current incentive structures applied by universities and funders with emphasis on many publications in prestigious journals. The preferential emphasis placed by the journals on novelty over veracity makes research misconduct even more tantalising. Significance chasing and other beautification of data are the consequences of the 'publish or perish' culture. The increasing availability of large datasets (e.g. genetic, metabolic

and epidemiological Big Data), and the ease with which they can be interrogated for associations (data mining) seem to contribute. It also seems that some spectacular frontline areas, such as stem cell research, are particular risk domains.

The four most common defence lines against scientific fraud are:

- *The journals' peer review systems.* They serve as goalkeepers of scientific quality rather than of scientific integrity and are not designed to reveal cheaters;
- *Replication studies.* Scientists value novel contributions. Studies that replicate (or fail to replicate) others' findings are almost impossible to publish in top scientific journals;
- *Whistleblowers.* It takes courage, determination and solid documentation to be a trustworthy whistleblower. Junior and senior colleagues and universities have so much to lose. Nevertheless, most revelations of large-scale fraud have come from whistleblowers;
- *Punishment.* In many countries, scientists who are found to be fraudulent are severely punished by their peers, universities and funders. Few of the downright cheaters find their way back to an academic position similar to that they once had. This is probably a strong deterrent to fabrication and falsification of data, but not to less severe forms of research misconduct where retributions are milder or non-existing.

It may be questioned how effective these defences really are. In healthcare practices, fraud is common; it has been estimated that 3-10 % of health care spending is lost to health care fraud and abuse. Therefore, auditing has been strengthened. In comparison, medical science is naïve; honesty and good faith remain two cornerstones in the ethics of biomedical publications.

The consequences of research misconduct are not restricted to the incorrect data presented. In an editorial in Science, referring to the revelation of a spectacular case of fraud in an article published in the journal, it was stated: "The costs of the fraud for the careers of young scientists and others who worked with him [the fraudulent scientist], for science, and for public trust in science are devastating".

Dr. Hugh WHITTALL
Director of the Nuffield Council on Bioethics

In its 2012 report on *Emerging biotechnologies*, and its 2013 report on *Novel neurotechnologies* the Nuffield Council on Bioethics identified certain widespread and oft-repeated concerns about how aspects of the environment in which scientific research now operates can lead to practices that are less than ideal in ethical terms, and can affect the quality of the science itself. For example, concerns about funding criteria, publication and peer review practices, research evaluation and the 'impact agenda', are all claimed to have adverse effects. To examine further these claims, the Council initiated a project to foster constructive debate among all those involved in scientific research about the culture of research in the UK and its effect on ethical conduct in science and the quality, value and accessibility of research. This paper will report on that project and outline some of its conclusions.

Research Transparency

Prof. Jonathan MONTGOMERY
Chair of the Health Research Authority

The drive for greater transparency in research arises from a number of factors, including:
- concerns about misconduct, particularly in relation to the tobacco and pharmaceutical industries;
- inadequate feedback to research participants, failing to respect their contributions;
- scientific issues such as reproducibility, and publication bias;
- exposure of patients and participants to unnecessary harms through lack of availability of existing knowledge;
- failure to capitalize fully on the investments made by participants, researchers and sponsor/funders.

Important developments in promoting greater transparency include:
- enhanced publication practices to 'add value' by making fuller resources available and more easily accessibly;
- regulatory requirements to register trials and publish results;
- a social movement towards a consensus on the importance of transparent, exemplified by the 'All Trials' initiative;
- opening of research data to reanalysis and secondary uses (e.g. GSK initiative on access to anonymised trial data).

These developments raise important and significant ethical issues and there may be a case for a new social contract to be articulated around health research to include them.

Prof. Kenneth W. GOODMAN
Director, University of Miami Miller School of Medicine Bioethics Program

Biomedical science is in crisis. The research foundation of clinical practice and, perhaps, public health, has been challenged for its persistent failure to replicate or reproduce initial findings. It has even been suggested that most published research is false. There are several reasons for this failure: cultural mechanisms, including status, promotion and profit; methodological sloppiness, including faulty statistics, lack of blinding, and inadequately described ingredients or populations; and complexity – in some cases, the world is just more difficult to understand than we would like. Corruption also plays a role. This presentation introduces the issue of replication failure, reviews some of its causes, and offers suggestions for addressing it: (i) better education of scientists, (ii) incorporating the epistemology of confirmation in the discussion, and (iii) identifying the intersection of ethics and information technology as a resource for educators and scientists.

Prof. Linda NIELSEN
Vice-chair of EGE
Vice-chair of Unesco Intergovernmental Bioethics Committee

Research integrity is of pivotal importance in protecting persons, values, the "benefit of mankind" and trustworthy research. It is essential to secure freedom of research and publication. It basically provides for two models: "laissez-faire" and protective governance.

Rights of researchers should not interfere with:

- Research methods (suggesting, exploring, testing hypotheses, interpretations and explanations);
- Research process (pursued according to one's own logic and standards);
- Research publication (transparency and autonomy, also to publish negative results).

The European notion of research integrity, broadly conceived, is grounded in the following core principles:

- Honesty in reporting and communicating;
- Reliability in performing research;
- Objectivity;
- Openness, accessibility;
- Duty of care in relation to the subjects/objects of one's study;

Research results should be published in an honest, transparent and accurate manner, as early as possible, in the scientific process. Institutions are expected to ensure that sponsors fully respect the duty of researchers to publish research results honestly, transparently and accurately.

Furthermore, researchers should not enter into agreements (e.g. with funders) that limit their access to all data and their ability to analyse information independently, unless this may be justified by specific circumstances.

There are a number of issues to be tackled with regard to researchers and sponsors:

- The risk of prioritizing only commercially beneficial areas;
- The risk for long-term research not to be dealt with properly, because of short-term research;
- The existing risk for humanities and social sciences (it is easier to have private sponsorship in the medical field than it is in this one);
- Universities tend to favour research with potential regarding economic growth and research having achieved external funding;
- Research Councils and society at large should engage in this process aimed at ensuring research integrity.

It is incumbent upon researchers to insist on research integrity and consider canon principles, as well as consequences of research. As for sponsors, they are expected to comply with web-based policy on respecting research integrity.

University/society should be committed to making policy and education concerning research integrity (and ownership/patents etc.).

Prof. Patrick GAUDRAY
Member of the French National Consultative
Ethics Committee for Health and Life Sciences

"Building research culture" appears primarily as a concern for universities and other research institutions. Introducing ethics in this field may look a deontological task, a need for ethical conduct in science to produce high quality, valuable, accessible research. I would try to address the issue of how to make scientific research a part of our common culture, how to insert it at the basement of our society. These were issues that were addressed in a 2010 opinion of the CCNE (opinion n°109) on the communication of scientific and medical information to the Society. We must admit that the road to building a research culture is huge and we have still a long way to go. Science is not yet part of our common knowledge, part of our Culture. One may wonder what does a culture of research contribute to the idea of progress: can the legitimacy of research be measured simply by the anticipated applications of its results, or should it be questioned on the basis of its purpose and its motivations. Ethical reflection challenges ways of thinking of science and research, and, most of all, of the place that it has – or should have in the society. In this way, it is a major ground on which to build a research culture.

Introduction and chair:

Prof. Lucetta SCARAFFIA
Member of the Italian National Bioethics Committee

The human brain begins gradually to understand itself. Neuroscience is actually developing a program aimed at exploring brain mechanisms and the bio-psychic foundations governing the most intimate aspects of our lives. It is a type of research that compels us to face with great urgency the basic issues underpinning any scientific work, which involves human beings. Who is man? Is he only the most evolved animal or marked by an ontological difference from other living creatures? Providing answers to these questions enables us, of course, to explain every psychic aspect in biological terms.

Neuroscience leads us to the very heart of the question concerning the nature of the human being, since it is assumed that giving an account of human brain activity would actually help us overcome the mind/body dichotomy, which has so far dominated the reflection.

Is it possible to reduce human beings to thought or, even better, to the act of thinking? Is man reduced to his biological being, or is he endowed with capacities going beyond physical and biological law? Is mankind reduced to a form of biological life?

The attempt to naturalize spirit, beginning with emptying it of its substance, seems more ideological than based on scientific research. Claiming to explain what grounds our deepest subjectivity by setting forth results, despite their significance, however only related to basic processes underpinning our attention, perception of our episodic memory, prove to be decidedly inadequate.

We can, therefore, understand the diffusion of an antiscientism-oriented mistrust fuelled by the anthropological scientism inherited by eugenicists dating back to the nineteenth century and the genetic scientism, whose current symptoms show it is still lingering on. This is also due to fierce and often grotesque media announces ranging from the discovery of the "faithfulness gene" to the brain area of happiness, apparently confirming the fears of a wave spreading of anti-humanism.

Human brains are extremely complex biological systems. It is important not to contend only one level of explanation: cultural phenomena elude biological laws, whilst actually finding in the latter a form of influence. Nowadays, there is a tendency towards devoting primary consideration to the cultural context, denying the biological level - it suffices to recall gender theorizations – alongside providing solely biological explanations of human behaviour. How can we overcome this visible contradiction which consists of simultaneously asserting the existence of a form of biological conditioning and a sort of emancipation from biological laws? How can we distance ourselves from both spiritualism and limited materialism? Only one solution may be devised: raising awareness of this contradiction, without concealing it, and theorizing the paradox lying at the core of specific human functioning. Moreover, the finding that plasticity falls within the essential peculiarities of the human brain, e.g. its ability to change structure and functions on the basis of experience, as well as its individual variability, a factor that emphasizes the degrees of individual freedom, helps us embark on this path.

We must also remember that, during the twentieth century, some arguments were put forward concerning the history and progress of science, which have brought radical changes to this field of study. Thus, it is claimed that whenever dealing with scientific knowledge, data cannot be separated from theories: what is considered to be a fact is determined as such in light of theoretical interpretations. Therefore, one should be available to see or not see according to paradigms. The criteria that we define as criteria of rationality are actually subject to historical changes. The issue

of human freedom comes back, therefore, upstream of the research process. It is not exclusively intended as a research object, even in the case of neuroscience.

These are exactly the reasons why the ethical dimension of this research is crucial: on one hand, we witness the huge benefits stemming from the treatment of neurological disorders, severe accidents, on the other, the underlying dangers that this research might develop an oversimplified explanation of human beings and that the findings be exploited for military purposes.

In an NBC document, we stressed the dangers related to these possible developments in the military field and, for this very reason, we pointed out the need for neuroscience researchers to keep a vigilant eye upon the procedures they comply with and especially on research funding conditions. In this regard, it is worthwhile recalling that the totalitarian regimes of the twentieth century have taught us that technical and scientific progress may coexist with the total annihilation of ethical standards.

Human Brain Project in Europe: Ethical Aspects

Prof. Christiane WOOPEN
Chair of the German Ethics Council

It is important to learn how the Human Brain Project deals with ethical aspects in different working forms. In this regard, several work packages have been envisaged, along with a research ethics committee and an ethical, legal and social aspects committee (ELSA). It is considerably useful to foster our understanding of the role of ethics in this project, which may enhance and stimulate reflection in view of the NEC Working group on Citizenship and Science.

The Society and Ethics Program in the Human Brain Project

Dr. Kevin GRIMES
HBP PI collaborating on Work Package on Ethics Governance and Regulation, Karolinska Institutet

We are dealing with a major international scientific research project: it involves 100 academic and corporate entities, in more than 20 countries. The 1 billion euro project was launched in 2013, funded by the EU Commission, while setting the goal "to build a completely new ICT infrastructure for neuroscience, and for brain-related research in medicine and computing, catalysing a global collaborative effort to understand the human brain and its diseases and ultimately to emulate its computational capabilities."

The project swings along in the ongoing discourse taking place within European society. Many different aspects are tackled: dual use and misuse, citizen engagement, tissue donation, implementing results for society, humans as subjects, social justice, informed consent, data protection, implementing results for society etc.

Ethics is about communicating, ensuring that resources are spent wisely towards responsible innovation. It engages in communication among different stakeholders, in order to more deeply understand and influence the discourse and to make sure that results and innovation meet key needs of Society. The project was funded by the FP7 Framework for Emerging Technologies, along with the ICT-theme Flagship Program.

The HBP set out to create an independent ethics program, organized in its Society and Ethics Division.
During the ramp up phase, the work plan was structured into three thematic cycles corresponding to the three main areas present in HBP:

- Future neuroscience
- Future medicine
- Future ICT

The Ethics and Society Programme has foreseen a set of goals for the ramp-up phase, in particular, establishing and supporting two independent, management-level committees to provide ethical governance within the project:

- An Ethical, Legal and Social Aspects Committee (ELSA; WP12.5.1) to monitor and provide strategic guidance on the project's long-term ethical and social implications;

- A Research Ethics Committee (REC; WP12.5.2) to manage and provide advice on issues related to practical and procedural research ethics (studies using human volunteers, animal research, use of clinical data collected for other purposes, applications to ethics committees etc.);

- Set up and start operating the Foresight Lab, which will be responsible for monitoring HBP research and investigating its social and ethical implications for European citizens, industry, economy and society (WP12.1).

- Investigate conceptual and philosophical implications of brain simulation and the emergence of new insights into the relationship between brain and mind. The first results will be published before the end of the Ramp-up Phase (WP12.2).

- Launch the HBP online deliberation, a European Citizens' Convention and a stakeholders' forum – all part of the HBP's broader programme of public dialogue and engagement (WP12.3).

- Launch a survey of ethical perceptions among HBP researchers. This will form the basis for a broader programme of researcher awareness during the operational phase (WP12.4).

The ELSA competencies will deal with the following topics:

- Research ethics issues (e.g., handling of data and biological material)
- Issues related to brain intervention/manipulation/enhancement
- Issues of dual-use, misuse of HBP innovations
- Issues related to the methodologies used (e.g., simulation approach)
- Economic impact, innovation
- Effects on the health system (e.g., distributive justice)
- Legal issues, e.g. related to privacy
- Long-term effects of HPB results on societal organization
- Bioethics / Medical Ethics more generally
- Ethical issues of new technologies (e.g., robotics)
- Informed consent

Concerning WP1 – Foresight lab –already 6 scenarios were devised to address outcomes in medical informatics, including:

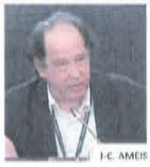
- Hospital enrolment
- Anonymisation
- Creating disease signatures
- Getting approval to access patient data without express and informed consent

WP2 – Conceptual and Philosophical Research focuses on working out concepts, among which: simulation, consciousness and memory.

Regarding WP3 – Public Dialogue and Engagement, attention is devoted to promoting constructive dialogue among the public and private stakeholders and to gain Public's trust and acceptance, through strategies, including: citizen conventions, online deliberation, and various other forums (webinars, seminars and workshops).

As for WP4 – Researcher Awareness, it encompasses engaging researchers in reflection using workshops, webinars and other means in order to consider social and ethical implications of research strategy, results, implementation, etc.

Ethics and Neuroscience: the Question of Free Will



Prof. Jean-Claude AMEISEN
Chair of the French National Consultative Ethics Committee for Health and Life Sciences

Free will has been, for a long time, a subject of speculation of theology and philosophy before it began to be a subject of neuroscience experiment. In French, the notion of "free will is" translated with "*libre arbitre*", which means "free choice". Therefore, it is interesting to see that in different languages freedom is applied either on the will, e.g. the intention to act, as in English, or on weighing different options, like in France.

More than 65 years ago, since the Nuremberg Code, one of the pillars of biomedical ethics foundation has been the free and informed consent, which we now call the free and informed choice, implying the possibility for somebody to be informed, deliberate and freely choose "to participate" or "not to participate" in research programmes. In the meantime, neuroscience has begun to explore what free will is and how it can be detected. A series of results have suggested that free will does not exist. The coexistence of neuroscience and ethics has a kind of retrospective irony, because more and more neuroscientists are asking an increasing number of persons to participate freely, to make a free and informed choice, to take part in research whose aim is to prove that free will does not exist. Neuroscientist Benjamin Libet was the first to make this statement. He performed an experiment where he asked people to push a button when they freely decided to do so, requiring them to note the exact time of decision. He concluded that free will is an illusion, a retrospective re-appropriation by the conscience of a process which has started unconsciously. There has been a debate for 25 years due to several main reasons: 1) the time lapse prior to conscious decision was very short, so it was possible to say that a switch of attention of somebody deciding to press a button and looking at the clock might explain the slight discordance between the activity and the decision; 2) there may be an indication that a readiness to decide was already ongoing but not a decision process itself; 3) the findings said something about the "when" of a free

decision but not about its content, which was already posed from the beginning (e.g. to press a button).

In 2008, John-Dylan Haynes published a paper in "Nature Neuroscience" which broke the question of the "when" and the question of the "what". As for the former element, he explained that using cerebral imagery one could predict the answer of the decision of a person 8 seconds before the actual decision is made. As for the latter, prediction concerned whether the person would push the button with the right hand or the left one. In 2011, other works by Haynes showed that the "what" could be even more specific (e.g. the person, 4 seconds in advance, will choose to subtract or add numbers from a random series). It was concluded that, maybe, what we call "free will" or "*libre arbitre*" is a retrospective illusion, a feeling that something is starting when it is just the echo of something that has begun earlier. Therefore, what are the implications? Maybe, what we call "free will" is an intermittent retrospective emergent process, but we know also that what we call "consciousness " and that we perceive as a permanent process is also an intermittent retrospective and emerging process. This is likely to give evidence of the fact that "free will" is different from what we intuitively believe. The question whether it exists or not goes probably beyond neuroscience. What are the consequences for people whose research might conclude that "free will" does not exist? There is a paradox at the heart of the scientific process: it made the postulate, which is extraordinarily fruitful, that the world is deterministic (e.g. the state of the world today is a consequence of the state of the world yesterday). According to this view, in someway, free will cannot exist, because it proves to be only the consequence of causes acting in the past. On the other hand, there is no human endeavour where the value of individual freedom is considered as a condition of the scientific process. In fact, if science were ever to describe the world as entirely deterministic, the scientific description would have no other value than providing an account of whatever occurs in terms of consequential reasoning. Conversely, for science to have a meaning, it should accommodate the coexistence of a postulate based on the conception that the world is deterministic and one grounded on the notion that we are free to explore and interpret this determinism.

Two concepts related to "free will" are particularly appropriate in this regard:

1) scientific processes are measurable from the outside;
2) free will shall be intended as a right, not a measurable process;

The timely question is how do we see individual freedom, despite the measurability of its scientific expression? Free will in the sense of freedom is a fundamental right. Thus, we are responsible for the emergence of the free will of others. Whenever we deny it, it has a tendency to diminish or disappear.

The coexistence between learning as much as we can from the scientific perspective on how this process can be seen and thinking, on the other side, that free will is a postulate and human right beyond its measurability, might be a way of placing "free will" and "equality" on the same footing.

Equality means that whatever we can measure about existing differences between people, would not impinge on our essential postulates, which cannot be measured and compared. For this reason, the value of every human being remains the same, regardless of whatever can be measured, understood, manipulated or modified. How can we ensure an harmonious coexistence between scientific knowledge progress and the protection of rights?

Free will in its dimension of a basic human right should be considered as something we cannot see, independently of whatever we can measure about the constraints being exerted in relation to this subjective feeling.

Dr. Laurence LWOFF
Head of Bioethics Unit, Council of Europe

The current activities of the Council of Europe carried out by the intergovernmental Committee on bioethics (DH-BIO) are organised around three main axes:

- developing the legal corpus on the protection of human rights in the biomedical field;
- facilitating the implementation of the principles laid down in adopted instruments;
- examining developments in the fields concerned with a view to identifying possible challenges for human rights.

Developing the legal corpus:

The DH-BIO started the preparation of a new Additional Protocol to the Convention on Human Rights and Biomedicine, concerning the protection of the human rights and dignity of persons with mental disorder with regard to involuntary placement and involuntary treatment.

A draft Recommendation is also being prepared on the processing for insurance purposes of personal health-related data, in particular data resulting from genetic testing.

Facilitating the implementation of the principles laid down in adopted instruments:

A Guide on the decision-making process regarding medical treatment in end-of-life situations was launched in May 2014.This guide does not lay down new legal principles, but aims to facilitate the implementation of the principles laid down in the Convention on Human Rights and Biomedicine including the principle set out in its Article 9 concerning previously expressed wishes.

The DH-BIO is also revising Recommendation (2006)4 of the Committee of Ministers on research on biological materials of human origin, in the light of experience acquired and developments in the field.

Examining developments in the fields concerned with a view to identifying possible challenges for human rights.

The DH-BIO has commissioned two studies on emerging technologies prepared respectively by the Rathenau Instituut (The Netherlands) and the Center for the Study of Sciences and Humanities of the University of Bergen (Norway). These two studies will provide a basis for an international conference to be held in Strasbourg on 4-5 May 2015, aimed at identifying the priority challenges for human rights raised by these emerging technologies and their convergence.

Dr. Jim DRATWA
Head of the Scientific Secretariat of EGE, European Commission

The European Group on Ethics in Science and New Technologies has been undertaking significant work on research integrity. There is an increasing prominence of the EGE's role within the EU Commission to provide ethical guidance in relation to additional measures being addressed at the institutional level, particularly with regard to ethical emergencies and possible "quick fixes".

It should be noted that the International Dialogue offers a unique platform that brings together not only the EU Commission, the EGE and representatives of the European NECs, but also chairpersons of the National ethics councils worldwide. It is an ongoing dialogue, usually taking the shape of a yearly meeting in Brussels.

Another important body is the internal Group on Ethics and EU Policies gathering various services of the EU Commission, notably the Directorate-General for Justice, tasked with the yearly report on the implementation of the EU Charter of Fundamental Rights, as well as the Directorate-General for Research and Innovation.

A noteworthy collaboration should, furthermore, be recalled, taking place between the EU Commission and other international organizations, such as the Council of Europe, UNESCO and WHO.

WORKING GROUPS

Working Group 1: Citizenship and Science

Prof. Monica TORALDO DI FRANCIA
Member of the Italian National Bioethics Committee

I - In the European Union, relationships between science and citizens, despite considerable differences across the countries, have often been marked by misunderstanding and mistrust. More precisely, within the field of biomedical sciences, advances in human genetics and neurosciences have undergone rapidly accelerating progress, leaving little room for reflective thinking on their ethical, economic, social and cultural impacts. If, on the one hand, there appears to have been a lack of communication between scientist-researcher and the public that cause misunderstandings with the risk of damaging the public image of science, on the other, the efforts undertaken at the institutional level to increase the ability of citizens to understand the complex questions raised by the developments of biology and medicine, and their practical implications, were often inadequate.

The issue was raised in the Oviedo Convention itself, where even the Preamble stressed "the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto", while devoting later on Chapter X to emphasizing the signatory States essential role in dealing with the problem:

"Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light,

in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation".

However, in spite of reiterated calls for fostering a public debate, the issue of how to gain citizens' trust towards scientific research and experimentation in the biomedical field is still open.

Obtaining this trust is all the more essential, if one considers the importance of large collections of biological samples and related data stored in biobanks when studying complex diseases (which are estimated to represent, in our country, over 70% of all illnesses, causing over 80% of all premature deaths).

Since the study of complex pathologies requires comparing a great number of individuals – affected and not affected by specific pathologies or exposed and not exposed to specific environmental factors (case-control). – it is now necessary to encourage public involvement and engage people on a voluntary sharing of samples and information, for a common resource, with the purpose of ensuring an attitude of solidarity towards other contemporary people and future generations (see CNB-CNBBSV, Collection of biological samples for research purposes: informed consent, 2009).

The urgent question arising out of the above-stated considerations is the following:

1. how can we strengthen this effect of trust?
2. What kind of strategies should we adopt at national and EU level?
3. What actions can be taken to increase transparency in the management of biobank activities and enhance citizens' direct or indirect involvement in pursuing research goals?

1.2) Among the problems that are yet to be adequately solved when carrying out research involving biological samples, in order to strike a fair balance between researchers' need for flexibility and the required protection of the rights of donors, one shall recall:

a) the problem of defining the legal status of donated samples;

b) the issue concerning the objective chance for donors of samples to large biobanks, as well as for subjects enrolled in clinical trials, to become aware of any information collected about their health condition, while their privacy is effectively protected

a.1. As for the first aspect, the management of samples is currently difficult to deal with, from a legal point of view, since there is a lack of clarity regarding the ownership/control of samples and related information.

Tissue donation shall only be a 'concession for use', according to the conditions set out in the Informed Consent, or shall we also envisage another option, such as signing a definitive and irreversible donation, however under certain conditions of 'good governance', even if samples are not fully anonymised?

a.2. As for the second aspect, instead, a return of information to the subjects involved has been widely deemed unrealistic, at least with regard to the concession of samples for research to large biobanks.

Is scepticism motivated or, on the contrary, should we foresee differentiated solutions?

II - The problem of how to implement science education in relation to the general public is a sensitive issue within many countries of the Union; nevertheless, according to a number of scholars (N.Rose, C.Novas, P. Rabinow, M.C. Tallacchini…), greater attention should also be devoted, nowadays, to a different reality, involving patient's organisations and support groups, collectivities formed around a biological conception of a shared identity and organized around specific biomedical classifications.

Indeed a new form of scientific competence is coming to the fore, carried onward by politically active citizens gathering in virtual communities; this phenomenon has been growing significantly in the Anglo-American countries, during the last decades, however, thanks to the Internet, it is increasingly reaching out to other national and supranational realities.

According to some scholars, the development of new relationships between science, individual rights and democracy is giving rise to a new form of citizenship, a so called 'biological citizenship', characterized moreover with going beyond the merely national dimension.

Recalling the well-known Thomas Marshall's sociological and evolutionary definition of modern citizenship - a status bestowed on all those who are full members of a community and, as full members, share rights, duties and a basic notion of fairness rooted in mutuality (Citizenship and Social Class, 1950) - for the above mentioned interpretation after the development of civil, political, and social citizenship, a new dimension of citizenship is now developing linked to the vital characteristics of human subjects.

The main actors of the practices and struggles of biological citizenship are individuals willing to gain scientific knowledge, to whatever extent is deemed possible, concerning their own current and future health condition (genetic risk and susceptibility included) and that of their loved ones, alongside the best way to manage it.

Citizens-patients get, therefore, involved in biosocial communities, sharing their mutual experiences, suffering, needs, fears, with the dual purpose of providing support to their members, whilst presenting within the institutional debate an entity capable of speaking out with one influential voice.

The mentioned communities are not only engaged in raising awareness campaigns against any form whatsoever of discrimination and stigmatization and in favour, instead, of medical-scientific research, they also claim their right to participate in defining biomedical research goals and biobank governance, developing new ties with scientific authorities and pharmaceutical companies; in other words, a new form of direct and fruitful alliance between patients representatives and those being capable of expediting the development process leading to novel therapies and treatments is taking shape.

The increasingly widespread presence and incisiveness of such virtual communities, although having many positive aspects – among which their availability to invest in biomedical research, donate their samples and participate in clinical trials – raises a number of concerns.

Such concerns encompass the following risks:

i.) the risk that the so-called 'ultra-rare' diseases do not find an adequate representation and, therefore, be neglected by research;

i.i.) the risk that grounding, at least partially, their self-education on information websites made available by large pharmaceutical companies, which can be accessed on the internet, alongside with the possible overuse of genetic tests offered online (DTC, Direct To Consumers tests), promising an optimal control and management of individuals 'biological risk', citizens-patients may become vulnerable to manipulation driven by health market interests, instead of experts exercising their autonomous right to know;

i.i.i.) the risk that this wide-spreading ethics of self-knowledge and informed choice, with regard to one's biomedical condition and that of loved ones, could call into question the 'right not to know': not to know information related to one's health, including genetic risks and susceptibility, as a possible condition of the free construction and definition of the self, of existential freedom. As a consequence, those willing to claim that right may be perceived as selfish and/or irresponsible individuals.

In conclusion, what kind of strategies should be devised, in order to enhance the positive potentials of such patient associations, while avoiding possible undesirable consequences?

Dr. Isidoros KARATZAS
Head of Ethics Sector, DG RTD, European Commission

Prof. Vasileios FANARAS
Director 2nd Gymnasium of Thessaloniki, Greece

1. What do we expect to achieve by teaching ethics? What is an appropriate age to start?
2. Assuming we know the answer to No 1, can we achieve the same or better using other means/courses/activities? (Social psychology, legal courses, art?)
3. Should national Ethics Committees participate in the design of such courses/activities?
4. What is the role of the educator: is she acting as a conveyer of ideas or/and the devil's advocate? Does she require informed consent from parents to engage with the students (especially young (?) students)?

Working Group 3: Robotics in the delivery of health care
Suggestion on background material/questions to be discussed

Dr. Lotta ERIKSSON
Head of the Secretariat, Swedish National Council on Medical

The application of robotics holds significant potential for health care systems, but also raises ethical concerns. The main purposes of introducing robotics in health care are to strengthen patient autonomy and self-determination and to improve quality and efficiency in health care.

The use of robots within health care raises questions regarding the following ethical aspects:

- Dual use of technology;
- Human/machine relationship (cognitive and affective bonds toward machines);
- Digital divide, socio-technological (age, socio-economic, global different areas);
- Integrity;
- Good care;
- Informed consent and understanding (especially for vulnerable patients);
- Fair access to new technologies;
- "Design ethics" in research and safety issues;
- Ethical assessment prior to introduction.

There could be a conflict between strengthening patient integrity and efficiency in health care on the one hand and a lack of human contact on the other. Depending on the kind of health care robot, different ethical questions will emerge when they are introduced within health care. Today, the use of several kinds of robots is already implemented in our health care system and some are used in clinical studies.

There are different kinds of robots in health care. For example, the report mentioned below delineates six different innovation themes:

1. Robotics assisted preventive therapies and diagnosis;
2. Robotics assistive technology. The facilitation of disabled or chronically ill in their daily activities. (Bionic arms/intelligent prosthetics, eating robots, home exploring robot butler etc.);
3. Robots supporting professional care. Robots that help health professionals both in the hospital environment and at home;
4. Robotics for the rehabilitation of patients. (Examples: Robot Suit Hal, SEM Glove, Comobot, Paro etc.);
5. Robotics for medical intervention (Examples: Robot assisted surgery, medical micro and nanobots etc.).

For an overview of robotics in health care please find the report: *Robotics for health care. Final report. 2008. European Commission.*
http://www.ehealthnews.eu/download/publications/1432-robotics-for-healthcare-final-report

Suggestions on questions to be discussed in the working group:

- To what extent do robots impact on a person's autonomy and integrity (including physical integrity)?
- To what extent do robots (including communication robots) impact on the social values of care?
- How does the introduction of robots affect the work environment of staff in healthcare and social services?
- Is there need for specific robot ethics guidelines when introducing robots into clinical settings in which they interact with patients?

Closing Remarks – The "application" of science and technologies between "respect" and "access"

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According to Article 1 of the *Universal Declaration on Bioethics and Human Rights* of 2005, bioethics addresses «ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions». The issue of *respect* has been key for the discipline (which ought rather to be understood as the overlapping field of several disciplines) from its very first steps. Respect for *vulnerability*, building on the awareness of the many ways of exploitation that may be a looming temptation for medicine and life sciences, starting with the modalities of involving human beings in clinical experimentation. Respect for *autonomy*, looking at the unprecedented opportunities of modifying the conditions of human life at its beginning and its end as well as during its course, reshaping them according to everyone's goals and values. The overarching principle was (and is) that of setting the *limits* of what we should not do, even though we are able to do it.

The responsibility to come to terms with the growing inequalities between and within the peoples and regions of the world, fuelled by the evidence that scientific progress itself may increase these gaps and therefore work as a mechanism of exclusion, imposed the issues of *access* and *sharing* as global goals that cannot be avoided and are as essential for the ethics of science and the related policies. This two-pronged approach is well epitomized in the *Declaration* of 2005, where the principles of solidarity and cooperation, social responsibility and sharing of benefits go together with the principles of respect for autonomy, personal integrity, cultural diversity and pluralism. As a consequence, the social, legal and environmental dimensions of bioethics become more and more important, at the domestic as well as the international level.

The Ebola crisis provides an illustrative and tragic example. Research is obviously essential, in order to eventually win the battle. At the same time, this new *African* emergency confirms the evidence that some peoples' diseases are more neglected than others, at least as long as they do not become a threat for the rich of the world. It should also boost the awareness that this kind of health crisis – and more in general the problem of health inequalities, which directly impinge upon a fundamental human right – cannot be addressed effectively, without addressing the situations of extreme poverty, shortcomings of health systems and lack of education and in particular health education within which people keep living and dying. Nowadays, this is the comprehensive approach that bioethics and bioethicists are called upon to develop and strengthen.