OPINION OF THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES TO THE EUROPEAN COMMISSION

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ETHICAL ASPECTS OF ICT IMPLANTS IN THE HUMAN BODY
Reference: Opinion produced on the direct initiative of the EGE
Rapporteurs: Professor Stefano Rodotà and Professor Rafael Capurro

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The European Group on Ethics in Science and New Technologies (EGE),
Having regard to the European Union Treaty and in particular Article 6 of the common provisions concerning the respect for fundamental rights;
Having regard to the EC Treaty and in particular Article 152 on public health;
Having regard to the Charter of Fundamental rights of the European Union of 28 September 2000, approved by the European Council in Biarritz on 14th October 2000 and proclaimed solemnly in Nice by the European Parliament, the Council and the Commission on December 7th 2000, in particular Article 1 on « Human dignity », Article 3 on the « Right to the integrity of the person », and Article 8 on « Protection of personal data »; 1
Having regard to Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector; 2
Having regard to Directive 95/46/EC of the European Parliament and of the Council of the European Union of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data; 3
Having regard to the Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices; 4
Having regard to the Council of Europe Convention on Human Rights and Biomedicine, signed on 4 April 1997 in Oviedo; in particular Article 1 “Purpose and object”, Article 2 “Primacy of the human being”, Articles 5 to 9 on consent and Article 10 “Private life and right to information”; 5
Having regard to the Universal Declaration on the human genome and the rights of man adopted by the UNESCO on 11 November 1997; 6
Having regard to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of the Council of Europe of 1 January 1981; 7
Having regard to the Declaration of Principles of the World Summit on the Information Society of 12 December 2003, in particular Article 58 on the use of ICTs and Article 59 on the abusive uses of ICTs; 8
Having regard to the hearings of experts and Commission Services by the EGE on 15/12/2003, 16/03/2004 and 15/06/2004 in Brussels;
Having regard to the report by Dr Fabienne Nsanze “ICT implants in the human body – A

Review", February 2005; 9
Having regard to the Roundtable organised by the EGE on 21st December 2004 in Amsterdam; 10
Having heard the EGE rapporteurs, Professor Stefano Rodotà and Professor Rafael Capurro;

WHEREAS:

1. INTRODUCTION

Information and communication technologies (ICT) pervade our lives. Thus far, this pervasive influence has mainly involved devices that we use for private purposes or at the work place such as personal computers, mobile phones, laptops and the like. Due to new developments these devices are becoming more and more part of our bodies, either because we wear them (wearable computing) or because they are implanted in our bodies. At first sight ICT implants are ethically unproblematic if we think for instance about cardiac pacemakers. However, although ICT implants may be used to repair deficient bodily capabilities they can also be misused, particularly if these devices are accessible via digital networks. One might even think of such devices as a threat to human dignity and particularly to the integrity of the human body (see Section 5), while for others such implants might be seen primarily as a means for restoring damaged human capabilities and therefore as a contribution to the promotion of human dignity.
The idea of letting ICT devices get under our skin in order not just to repair but even to enhance human capabilities gives rise to science fiction visions with threat and/or benefit characteristics. However, in some cases, the implantation of microchips is already taking place with the potential for individual and social forms of control.
The intimate relation between bodily and psychic functions is basic to our personal identity. Modern neurosciences are emphasising this view. Language and imagination influence in a unique way our perception of time and space; the way we perceive ourselves and others; the way we relate to other non-human living beings and to the natural environment; the way we create historically, culturally, politically, legally, economically, and technically our societies; the way we acquire knowledge about ourselves and about the world; and the way we produce, create, and exchange things.
ICT devices are the products of human invention. The functions they achieve are based on programmable or algorithmic calculations mostly using non-biological substances such as silicon. This allows a simulation of some biological and psychic functions11.
Furthermore, it is in principle, and today also in practice, possible to implant ICT devices in the human body in order
to restore bodily functions or, as in the case of prostheses and artificial limbs, to substitute some body parts.
These are the essential reasons why potential and actual ICT implants in the human body have large and important ethical consequences.
Consequently, the objective of this Opinion is primarily to raise awareness and questions concerning the ethical dilemmas created by a range of ICT implants in this rapidly expanding field. Ethical awareness and analysis must take place now in order to ensure an appropriate and timely impact on the various technological applications. Nevertheless,

where necessary this Opinion proposes clear ethical boundaries, legal principles and suggests several steps that should be taken by responsible regulators in Europe. The Opinion focuses on ICT implants in the human body (see Section 6.1).

2. GLOSSARY

ICT devices: Devices using information and communication technologies usually based on silicon chip technology.
Active medical device: Any medical device relying for its functioning on an internal and independent source of electrical energy or any source of power other than that directly generated by the human body or gravity.12
Active implantable medical device: Any active medical device which is intended to be totally or partially introduced surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.13
Passive ICT implants: ICT implants in the human body that rely on an external electromagnetic field for their operation (see for example Section 3.1.1 the "Verichip").
Online ICT implants: ICT implants that rely for their operation on an ("online") connection to an external computer or which can be interrogated ("online") by an external computer (see for example Section 3.1.2 Biosensors).
Offline ICT implants: ICT implants that operate independently of external ICT devices (perhaps after an initial setting up operation) (see for example Section 3.1.1 Deep Brain Stimulation).

3. SCIENTIFIC AND TECHNICAL BACKGROUND

(See detailed report by Dr Fabienne Nsanze "ICT implants in the human body – a review" of February 2005 – annexed to this Opinion)

3.1. Current Applications and Research

3.1.1. Applications: ICT implants on the market

This section contains information about implants in the human body that are available in commercial form and have been researched, in some cases, for decades.

Active medical devices

The history of implantable devices in clinical practice started in the 1960s with the development of the first heart pacemakers to replace the autonomic rhythm of the heart. Systems for bladder stimulation that allow paraplegics (paralysis of the lower limbs often resulting from spinal cord injuries) to control voiding followed in the 1980s. The most recent examples of active implants for functional electrical stimulation are stimulators to treat pain in patients with tumours and trembling caused by Parkinson's disease, and to restore the grasp function in quadriplegics (paralysis of the arms, legs and trunk below the level of an associated spinal cord injury). Typical devices include the following:

• Cardiovascular pacers for patients with conduction disorders or heart failure
• Cochlear implants: the cochlear implant differs from the hearing aid in that it does not amplify sound and bypasses the damaged part to send sound signals directly to the auditory nerve.
• Auditory Brainstem implant (ABI) is an auditory prosthesis that bypasses the cochlea and auditory nerve to help individuals who cannot benefit from a cochlear implant

because the auditory nerves are not working. The brainstem implant stimulates directly the cochlear nucleus situated in the brainstem.
• Implantable programmable drug delivery pumps:
��Administration of Baclofen for patients with Multiple Sclerosis with severe spasticity (intrathecal administration i.e. within the spinal canal)
��Insulin pump for Diabetes
• Implantable Neurostimulation Devices: the term “neurostimulation” relates to technologies that do not directly stimulate a muscle as a functional electrical stimulation device (i.e., cardiac pacemakers). Rather, neurostimulation technologies modify electrical nerve activity.
��Spinal cord stimulation for chronic pain management
��Sacral nerve stimulation for treatment of refractory urinary urge incontinence
��Vagus nerve stimulation (VNS) for seizure control in epilepsy or for mood control in severe depression cases
• Deep brain stimulation (DBS):
��for tremor control in patients with Parkinson's disease
��for essential tremor: Patients with essential tremor have no symptom other than tremor, which may occur in their hands, head, legs, trunk or voice. As for patients with Parkinson’s disease, they can be helped with deep brain stimulation therapy.
• Artificial chip-controlled leg: the German company Otto Bock Healthcare GmbH has developed a prosthesis called “C-Leg®” which is a chip-controlled leg.

Identification and location devices
Microchip devices come in three forms:
1) Read-Only: this is the simplest form of devices that have a read-only character, similar to that now used for identification of animals. Even this most basic form would have numerous applications, for example, to identify Alzheimer’s patients, children and the unconscious. A broader use would be as a sort of national identification card, based upon the identifying number carried on the microchip.
2) Read-Write: this type of microchip would be capable of carrying a set of information which could be expanded as necessary. It allows the storage of data and is programmable at distance. For example, when the microchip carries a person’s medical history and the history evolves, the subsequent information could also be added to the microchip without the necessity of removing the implanted chip. It could also facilitate and record financial transactions. The third important set of information that a read-write microchip could carry might be criminal records.
3) Devices with tracking capabilities: besides the read-write capabilities described above, a device can also emit a radio signal which could be tracked. Applications would again be numerous as evidenced by the less advanced technologies already in existence. Such a device needs a power source that has to be miniaturized before being implantable. With a microchip implant, constant monitoring would be possible. If each chip emitted a signal of a unique identifying frequency, implanted individuals could be tracked by simply dialling up the correct signal. Because the receiver is mobile, the tagged individual could be tracked anywhere.
Typical devices include:
• RFID devices: millions of Radio frequency identification (RFID) tags have been

sold since the early 1980s. They are used for livestock, pet, laboratory animals, and endangered-species identification. This technology contains no chemical or battery. The chip never runs down and has a life expectancy of 20 years.

• **VeriChip™ or the "human bar code":** VeriChip™ (www.4verichip.com) is a subdermal RFID device, about the size of a grain of rice, which is implanted in the fatty tissue below the triceps. Current applications of the VeriChip include:

Medical records and healthcare information (blood type, potential allergies and medical history)

Personal information/identity: In the Baja Beach Club (in Spain and The Netherlands, http://www.baja.nl/), people use the VeriChip™ like a smartcard to speed up drink orders and payment.

Financial information (secondary verification)

Besides these areas, the extended applications include public transportation security, access to sensitive buildings or installations and tracking down people on parole, ex-convicts, criminals, etc. Currently, a person has to stand within a few feet from a scanner for the tag to "wake up". Thus, the tags can be used to follow someone's steps only when they are near scanners. Consequently, the VeriChip™ is, for the moment, not an implantable GPS (Global Positioning System) device.

• The Bavarian company Ident Technology (http://www.ident-technology.com) offers tracking devices using the human body (particularly the skin) as a digital data transmitter.

• Female remote-control Orgasm Implant: A machine that delivers an orgasm at the push of a button was patented in the US in January (2004).

3.1.2. Research on ICT Implants

Medical devices

• **Biosensors:** Biosensors or MEMS (Micro Electro-Mechanical System) devices are sensors implanted inside the human body for accurate monitoring of inaccessible parts of the body. The biosensors form a network and collectively monitor the health condition of their host. This involves the collection of data about physiological parameters like blood pressure or glucose levels and making decisions based on it, such as alerting doctors to a potential medical crisis.

The information to be transmitted is crucial medical information that is required by law to be secure. Consequently, information technology is a critical component of these biological implants that, with the energy, memory and computational capabilities, present challenging research issues.

There are several biomedical applications where this technology will be useful. Examples include sensors implanted in the brain of patients with Parkinson's disease or epilepsy, acoustic and optical biosensor arrays for blood analysis, and sensors implanted in the body of a recovering cancer patient to detect cancer cells.

Artificial hippocampus: an example of a future brain prosthesis is the implantable brain chip that could restore or enhance memory. The hippocampus plays a key role in the laying down of memories. Unlike devices such as cochlear implants, which merely stimulate brain activity, this chip implant will perform the same processes as the damaged part of the brain it is replacing. It promises to be a way to help people who have suffered brain damage due to stroke, epilepsy or Alzheimer's disease.

• Cortical implant for the blind: it has been known for many years that electrical

stimulation of the eyes evokes phosphenes leading to visual perception. With a cortical implant, information from a tiny digital camera could be transmitted to electrodes implanted in the visual cortex, bypassing the non-working retina or optic nerve.
• Ocular implant or artificial retina: other researchers are focusing on new technologies to replace damaged retina, the light-sensitive cell layer in the eye.
A retinal prosthesis involves electrically stimulating retinal neurons beyond the receptor layer with signals (light) from a microscopic digital camera; it is feasible when the inner retina and optic nerve remain intact. In fact, currently two approaches are being investigated for retinal prosthesis: sub-retinal and epi-retinal.
• Brain-computer interfaces (BCI) or direct brain control: the technologies involved above are communication technologies; they take information from the brain and externalize it. There are internalizing technologies (cochlear or optic-nerve implants) whose purpose is to take information from the outside and provide individual access to it. These two technologies will eventually come together to form interactive technologies which would allow input-output interactions. These systems could allow people to use signals directly from the brain for communication and control of movement.
Although human studies demonstrate the feasibility of using brain signals to command and control external devices, researchers emphasize that many years of development and clinical testing will be required before such devices - including “neuro-prosthetic” limbs for paralyzed people, become available.

Surveillance or tracking devices

• Wearable ICT devices for tracking the human body: such a device allows an individual with a receiver to pinpoint someone's position worldwide.
• Subdermal GPS Personal Location Devices: in May 2003, Applied Digital Solutions (ADS) (http://www.adsx.com/) claimed that “Digital Angel”, a prototype implantable GPS tracking device had been successfully tested. However, technical experts are questioning whether the system could really work. The disc-shaped "personal location device" measures 6.35 centimetres in diameter and 1.27 centimetres in depth - roughly the same size as a pace-maker. This GPS monitoring could be used for several purposes, such as for example, in case of medical emergencies (heart attack, epilepsy or diabetes), or for identification and location purposes (for people in high risk occupations, children, stalkers or suspected terrorists).

Enhancement or commodity devices

Computer scientists have predicted that within the next twenty years neural interfaces will be designed that will not only increase the dynamic range of senses, but will also enhance memory and enable “cyber think” — invisible communication with others.
Possible devices include:
• Prosthetic cortical implant (intelligence or sensory “amplifiers”): initially developed for the blind, the cortical implant will allow “healthy” people permanent access to information from a computer based either on what a digital camera sees or based on an artificial “window” interface. • Artificial Vision: according to recent research undertaken to develop an artificial retina, it will be possible, one day, to see light in the infrared. In this case, instead of using a standard video camera, an infrared camera could be used.
• Audio tooth implant or tooth phone: designed in 2002, the Audio tooth implant, still only exists in concept form. A micro-vibration device and a wireless low frequency receiver are implanted in the tooth during routine dental surgery. The tooth

communicates with an array of digital devices, such as mobile telephones, radio and computers. Sound information is transferred from the tooth into the inner ear by bone transduction. Sound reception is totally discreet enabling information to be received anywhere at anytime.
• Artificial hippocampus: as mentioned above, this implantable brain chip could enhance memory.

3.2. Other Potential Uses

Other potential uses of implantable ICT devices include:
• Microsoft patent number 6,754,472 (June 22, 2004) concerns the human body as a medium for transmission of data (and energy) to "other devices" like PDAs (Personal Digital Assistant), cellular phones, medical devices (for surveillance purposes: like for instance in retired people's homes), RFID making possible to localize other persons. In a family website your children could log onto the surveillance system and look at what their parents or grandparents are doing. The patent does not describe any specific device.
• "Smart guns": Applied Digital Solutions (ADS), which created the VeriChip™, announced in April 2004 a partnership with gun manufactures FN Manufacturing to produce so-called "smart guns". Such weapons can be fired only if operated by their owner with a RFID-chip implanted in his or her hand.

3.3. The 6th Research and Development Framework Programme (FP6)

"The objectives of the Information Society Technologies (IST) theme within FP6 are to ensure European leadership in generic and applied technologies at the heart of the knowledge economy. It aims to increase innovation and competitiveness in European businesses and industry and to contribute to greater benefits for all European citizens. The focus of IST in FP6 is on the future generation of technologies in which computers and networks will be integrated into the everyday environment, rendering accessible a multitude of services and applications through easy-to-use human interfaces. This vision of "ambient
intelligence" places the user at the centre of future developments for an inclusive knowledge-based society for all".14

Examples of Projects funded by the FP6

Nano scale materials and sensors and Microsystems for medical implants improving health and quality of life

In this project key micro system technologies and communication methods will be developed that bring intelligence directly to the human, in the form of medical implants and ambulatory measurement systems, and also enable information from these devices to be transmitted out into the wider environment. The overall objective is to develop the technologies that go to make up a micro system, and then to produce specific medical devices to exploit these technologies. The resulting final medical products include cochlear and retina implants, nerve stimulation, bladder control and pressure monitoring systems. It is estimated from the available statistics that around 50% of the western population i.e. around 500 million citizens, will suffer from at least one of the health problems targeted in this project.

The OPTIVIP project

The aim of OPTIVIP is the optimization of an implantable visual prosthesis based on the

stimulation of the optic nerve and its demonstration within a pre-clinical study.
Ethical issues are tackled in this project by specific project tasks being devoted to obtaining input from the blind community and especially from patients and their representatives. Various aspects of the prosthesis, namely functionality, appearance and ethics are covered. This is essential in order to direct research efforts in accordance with real needs.

4. LEGAL BACKGROUND

4.1. General Principles

The innovative features of the issues addressed in this Opinion make it difficult to pinpoint rules that are specifically applicable to ICT implants in the human body. Therefore, the legal background should be derived from general principles underlying national legislation and international instruments. Such general principles can provide the guidance required to outline the legal standards necessary for the regulation of a technology that modifies the body and its relationship with the environment and thereby impacts deeply on personal identity and life. These legal principles can be found in texts concerning different subject matters: from bioethics to electronic information processing, from the limitations on consent to the definition of medical devices.
As for the European legal background, specific importance should be attached to the Charter of Fundamental Rights of the EU, which is currently Part II of the Treaty Establishing a Constitution for Europe. This sets out the general principles of dignity, freedom, equality, solidarity, citizenship and justice, as well as integrity and inviolability of the body, with particular regard to informed consent (Article 3), and personal data protection (Article 8). Data protection issues are developed in Directives 95/46 and 2002/58. The precautionary principle is expressly referred to in Article 174 of the EC Treaty as well as, in greater detail, by the Commission's Communication (2000/1) of 2 February 2000.15 Active medical devices are defined and regulated by Directive 90/385.
Among international instruments, specific importance is to be attached to the Convention on Human Rights and Biomedicine of the Council of Europe (1997) and UNESCO's Universal Declaration on the Human Genome and Human Rights (1997), in particular as regards respect for the dignity and integrity of individuals and the informed consent principle. Significant guidelines are also provided by points 58 and 59 of the Declaration of Principles of the World Summit on the Information Society (2003), which point out the need for ICT to be always implemented in such a manner as to respect fundamental rights and private life.
National constitutional charters and domestic laws contain several provisions applying to respect for dignity, protection of physical integrity and health, informed consent, and transplantation matters.
A number of judicial and administrative decisions deal directly or indirectly with the issues addressed in this Opinion, such as the judgment of 14 October 2004 by the European Court of Justice in the Omega v. Oberbürgermeister Bonn case (Case C-36/0216) and the Order of 12 October 2004 by the US Food and Drug Administration on the testing of the VeriChip for medical purposes.
On the whole, these instruments allow one to derive a set of principles on which the legal framework can be built and on which the lawfulness of ICT implants in the human body

can be assessed.

4.2. Human Dignity

The Charter of Fundamental Rights of the European Union opens with the dignity principle. Article 1 of which states that "human dignity is inviolable". This is modelled on the German Grundgesetz and is in line with the declaration made in the Preamble to the Charter, whereby the Union is said to "place the individual at the heart of its activities". This principle was upheld as an absolute boundary in the Omega decision, which considered it lawful for German authorities to prohibit a game called "Playing at Killing" because it was found to be "a threat to public policy by reason of the fact that, in accordance with the concept prevailing in the public opinion, the commercial exploitation of games involving the simulated killing of human beings infringed a fundamental value, enshrined in the national constitution, namely human dignity".

This "affront to human dignity" is not only of such import as to legitimise a prohibition limiting freedom of enterprise; it also acts as a boundary on the freedom of individual choice, because it rules out that the players' informed consent can be regarded as an item making the game in question something that is socially and legally acceptable. Therefore, the dignity principle should be regarded as a tool to identify the cases in which the body should be absolutely "inviolable".

In the very well-known Census Act Case of Germany, it was stressed exactly that "the focus of the constitutional order is the value and dignity of the person, who operates in self-determination as a member of a free society" (Judgement of the Bundesverfassungsgericht of 15 December 1983). This is in line with the clear-cut guidance contained in the Preamble as well as in Article 1 of the 1948 Universal Declaration of Human Rights, which expressly refers to dignity as an essential component of the human being and a condition for freedom and equality. As regards more recent constitutional experiences, one need only consider Article 16 in the French Civil Code or Article 2 in the Italian Data Protection Code, which expressly mention dignity. This also applies in international instruments such as the Helsinki Declaration (1964), the Council of Europe's Convention on Human Rights and Biomedicine (1997), which begins by re-affirming the principle of human dignity, and UNESCO's Universal Declaration on the Human Genome (1997). Finally, Article 1 of the Charter of Fundamental Rights of the EU (2000) states that "Human dignity is inviolable. It must be respected and protected".

One can therefore reach the conclusion that dignity is a universal, fundamental, and inescapable term of reference even though it should always be seen against a specific cultural background. This conclusion might be supported nowadays by underlining that dignity is referred to with ever-increasing frequency in the instruments adopted by international organisations representing all world cultures – such as UNESCO (indeed, dignity is mentioned fifteen times in the Universal Declaration on the Human Genome). From this standpoint, dignity is bound to become a cross-cultural concept. However, one should take into account that there is also a measure of ambiguity in the reference made to this word. "Dignity" is used both to convey the need for absolutely respecting an individual's autonomy and rights and to support the claim to controlling individuals and their behaviour for the sake of values that someone plans to impose on other individuals. Moreover, Article 1 of the Charter of Fundamental Rights provides that dignity is to be

not only “respected”, but also “protected” – after the pattern followed in the German Grundgesetz. This means that public authorities are required not only to refrain from tampering or interfering with an individual’s private sphere, but also to take steps actively in order to bring about the conditions allowing individuals to live with dignity.

4.3. Human Inviolability

The principle of inviolability of the body and physical and psychological integrity set out in Article 3 of the Charter of Fundamental Rights rules out any activity that may jeopardise integrity in whole or in part - even with the data subject’s consent. WHO observes that “health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. However, here one has to deal with a different situation because integrity is not regarded as absolutely inviolable – reference being made to interventions that cause “permanent diminution” of one’s body (as per Section 5 of Italy’s Civil Code) or else are in conflict with public order and/or morals. This is the framework applying, for instance, to the assessment of the lawfulness of organ donation, which is limited by the loss of essential functions. This consideration might lead one to conclude that the integrity principle should not be referred to whenever body functions are actually reintegrated and/or enhanced. Furthermore, the freedom to use one’s body is specifically limited by the many provisions under which it is prohibited to turn the body, its parts and/or products into sources of profit (Article 3 of the Charter of Fundamental Rights; Article 21 of the Convention on Human Rights and Biomedicine; Article 4 of UNESCO’s Universal Declaration). Extensive construction of the principles of non-commodification and non-instrumentalisation might lead one to conclude that implanting ICT for purposes that are, broadly speaking, profit-related (e.g. to get into a disco under preferential conditions) should not be permitted. (see Opinion Section 6.4).

4.4 Privacy and Data Protection

The view that data subjects are not free to make whatever use of their own bodies they wish is confirmed, albeit indirectly, by Article 8(2) of EC Directive 95/46 on personal data protection. Here, it is stated that States can provide that the data subject’s express consent is not enough to allow others to use his/her “sensitive data” – concerning sex life, opinions, health, ethnic origin – without an ad hoc authorisation issued, for instance, by a supervisory authority (see Section 26 of the Italian Personal Data Protection Code). This is meant to protect the most sensitive portion of the “electronic body” by preventing data subjects themselves from making available parts of their electronic bodies in such a manner as to jeopardise their integrity.

From a more general standpoint, the Charter of Fundamental Rights of the EU has drawn distinctions between the protection of private and family life (Article 7), and the protection of personal data (Article 8), which consequently has become an autonomous individual right. Thus, one has to deal with a kind of protection that is opposed to any relevant intrusion into one’s private sphere and, on the other hand, confers the right of informational self-determination on each individual – including the right to remain master of the data concerning him or her. This is a veritable instance of “constitutionalisation of the individual”, which mandates respect for both the physical and the electronic body. More specifically, protection of personal data in the EU is based on EC Directive 95/4617 as well as on EC Directive 2002/5818. The latter also contains

specific provisions applying to the location of individuals. The set of principles and rules on personal data protection is currently shared by all the Member States of the EU as well as by several other states that – from Canada to Australia, from Japan to many Latin American countries – have endorsed a strong data protection standard based first and foremost on the provision of detailed information coupled with the data subjects' explicit consent. Therefore, any type of ICT implant requires a strict preliminary evaluation in order to assess the "privacy impact".

4.5. The Precautionary Principle

The precautionary principle does not necessitate impassable boundaries or downright bans. It is a general risk management tool, which was originally restricted to environmental matters. In the Commission's Communication of February 2000 it is stated that "The precautionary principle is not defined in the Treaty, which prescribes it only once - to protect the environment. But in practice, its scope is much wider, and specifically where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community" (Communication Summary paragraph 3). Accordingly, the Commission believes that "the precautionary principle is a general one" (i.e. a general principle) (Section 3 of the Communication), whose scope goes beyond the EU – as shown by several international instruments starting with the Declaration on Environment and Development adopted in Rio de Janeiro in 1992.

The basic constituents and the prerequisites for the application of the precautionary principle are existence of a risk, possibility of harm, and scientific uncertainty concerning the realisation of this harm. Having invoked the precautionary principle the risk manager has to decide on precautionary actions that are proportionate to the potential harm being mitigated and which do not attempt to create "zero risk" situations. The risk management actions should be aimed at identifying the "acceptable risk" threshold with regard to the values at stake – and respect for the human body is undoubtedly one of the values deserving the highest legal protection. However, though rooted in fundamental requirements, the precautionary principle is of a "procedural" rather than "substantive" nature, which means that it is not applied to gauge an innovation as such but rather its effects. If the negative effects are found to be absent, or if the application mechanisms are modified, then a given scientific or technological innovation may be regarded as acceptable. Therefore, the precautionary principle is a dynamic tool that can follow the evolution of a sector and continuously verify that the acceptability conditions of a given innovation are fulfilled – thereby enhancing governance in what has been called the "risk society".

The risks related to ICT implants were highlighted by the Order of the US Food and Drug Administration in respect of a subcutaneous chip called "VeriChip" (see Section 3): "adverse tissue reaction; migration of the implanted transponder; compromised information security; failure of implanted transponder; failure of inserter; failure of electronic scanner; electromagnetic interference; electrical hazards; magnetic resonance imaging incompatibility; and needle stick". One might wonder that the tests on the VeriChip were authorised for medical purposes in the face of such a detailed list of potential risks! The authorisation might have been denied if the precautionary principle

had been taken into account in regard to those risks with high uncertainty.

4.6. Data Minimisation, Purpose Specification, Proportionality Principle and Relevance

Specific importance is also to be attached to the principles of data minimisation, purpose specification, proportionality, and relevance. All of these principles are unrelated to the lawfulness of using the individual ICTs, but relate more to the specific conditions applying to their use – i.e., the context within which they are used.

The data minimisation principle is expressly referred to, for instance, in Article 16(2) of the French Civil Code, where it is provided that "il ne peut être porté atteinte à l'integrité du corps humain qu'en cas de nécessité pour la personne" (it can only violate the integrity of the human body in the case of personal necessity). Objectively, this principle means that one should only avail oneself of a given tool if the relevant target cannot be achieved by means of less "body-intrusive" tools. This is basically the "minimisation" principle set out in several privacy laws, such as Section 3(a) of the German Bundesdatenschutzgesetz and Section 3 of the Italian data protection code. Subjectively, the data minimisation principle postulates the existence of a personal condition that cannot be coped with unless by using a specific tool, which proves indispensable.

The purpose specification principle entails the need for selecting the targets to be achieved. For instance, the Convention on Human Rights and Biomedicine provides that tests predictive of genetic diseases "may be performed only for health purposes or for scientific research linked to health purposes" (Article 12). Basically, a relationship is established between specific circumstances, available tools, and reference values. Only those tools that, within a given context, pass the consistency test with such values may be used lawfully.

The proportionality principle is also grounded on the relationship between tools to be used and purposes sought. However, here emphasis is not put on the nature of the purposes in question, but on the proportionality of the tools that are used, i.e., even if the purpose as such is legitimate, it may not be pursued by using disproportionate tools. In fact, the aforementioned Communication by the Commission sets forth an express relationship between precaution and proportionality when it says that "A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk."

As for the relevance principle, which is expressly laid down in Article 6 of Directive 95/46, it can be taken into consideration with regard to ICT implants as well. Indeed, a given technology may be lawfully applied if it is closely and unambiguously relevant to the circumstances. This is meant to prevent excessive and/or inappropriate applications of the available tools.

Ultimately, all these principles supplement one another. After identifying a legitimate purpose for using an ICT implant, one should establish whether this is actually necessary as well as whether the tools (to be) used are relevant and proportionate.

4.7. Autonomy and Limits on ICT Implants

The limitations on ICT implants in the human body as deriving from an analysis of the principles contained in various legal instruments should be assessed further by having regard to general principles and rules concerning the autonomy of individuals, which here

takes the shape of freedom to choose how to use one's body, to quote a well-known slogan, "I am the ruler of my
own body", freedom of choice as regards one's health, freedom from external controls and influence.
As regards any choice related to one's body, the considerations made in respect of integrity and inviolability principles still apply – in particular as for the consent requirement. Indeed, consent is necessary, but is not sufficient, in order to legitimise use of implants – which anyhow should never be performed against the data subject's wishes and/or unbeknownst to him/her.
As regards any choice related to one's health, the data subject has the right to always object to an implant and have it removed, if this is technically possible – without prejudice to the informed consent requirement as well as to the right to refuse medical treatment.
As regards external controls and influence, autonomy of the individual becomes especially important in connection with the right to rule out that a person's conduct may be determined and/or influenced by the entities managing electronic links – if the latter give rise to permanent connections with external entities. Even in the absence of this type of permanent connection, it should be taken into account that ICT implants may:
a) allow individuals to be located on a permanent and/or occasional basis;
b) allow the information contained in electronic devices to be changed remotely without the data subject's knowledge.
These risks are bound to increase with the adoption of unified technical standards, which may allow data to be read and modified also by entities other than the data subject and the bodies/organisations lawfully managing the relevant plant or connection. Both circumstances are clearly in conflict with data protection rules concerning collection and processing of the information. In particular, "re-writing" the data impacts on the right to personal identity that is expressly recognised by Article 1 of EC Directive 95/46.

4.8. Concluding Comments

For the legal background, it should be noted that:

a) the existence of a recognised serious but uncertain risk, currently applying to the simplest types of ICT implant in the human body, requires application of the precautionary principle. In particular, one should distinguish between active and passive implants, reversible and irreversible implants, and between offline and online implants;
b) the purpose specification principle mandates at least a distinction between medical and non-medical applications. However, medical applications should also be evaluated stringently and selectively, partly to prevent them from being invoked as a means to legitimise other types of application;
c) the data minimisation principle rules out the lawfulness of ICT implants that are only aimed at identifying patients, if they can be replaced by less invasive and equally secure tools;
d) the proportionality principle rules out the lawfulness of implants such as those that are used, for instance, exclusively to facilitate entrance to public premises;
e) the principle of integrity and inviolability of the body rules out that the data subject's consent is sufficient to allow all kinds of implant to be deployed; and
f) the dignity principle prohibits transformation of the body into an object that can be

manipulated and controlled remotely – into a mere source of information.
These considerations might lead one to conclude that, given the current circumstances, many actual or potential ICT implants in the human body are legally inadmissible, subject to the specific consideration of exceptional situations as set out hereunder in the Opinion Section (see Section 6.4.6).

5. ETHICAL BACKGROUND

Contemporary society is confronted with changes that have to do with the anthropological essence of individuals. There is a stepwise shift in progress – after being observed, via video surveillance and biometrics, individuals are being modified, via various electronic devices, under skin chips and smart tags, to such an extent that they are increasingly turned into networked individuals. Thus we might be continuously connected and could be configured differently so that from time to time we would transmit and receive signals allowing movements, habits and contacts to be traced and defined. This would be bound to modify the meaning and contents of an individuals' autonomy and to affect their dignity.
This unrelenting erosion of personal prerogatives – going as far as transforming the body – co-exists not only with the growing attention paid to dignity, but also with the already mentioned fact that the person is at the centre of the constitutional order (see Preamble and Articles 1, 3 and 8 of the Charter of Fundamental Rights of the European Union and see the Legal Background of this Opinion, Sections 4.2 and 4.4).

5.1. Fundamental Ethical Principles

As in former EGE Opinions, as well as in a number of Conventions, Declarations and Charters accepted in Europe and as highlighted in the Legal Background (Section 4), the fundamental principles are human dignity and integrity. These fundamental principles entail in turn several derived principles (described below) which are relevant in the context of this Opinion and which are closely related to one another.
Human Dignity (also discussed in Legal Background Section 4.2)
The EU's draft Treaty Establishing a Constitution for Europe19, which states that "Human dignity is inviolable. It must be respected and protected" (Article II-61), goes on to explain that "The dignity of the human person is not only a fundamental right in itself but constitutes the real basis of fundamental rights" (Declaration concerning the explanations relating to the Charter of Fundamental Rights). This explanation doesn't strictly define human dignity and so various writers have attempted to fill this gap. One such attempt20 suggests that human dignity be defined as follows: "the exalted moral status which every being of human origin uniquely possesses. Human dignity is a given reality, intrinsic to human substance, and not contingent upon any functional capacities which vary in degree. (…) The possession of human dignity carries certain immutable moral obligations. These include, concerning the treatment of all other human beings, the duty to preserve life, liberty, and the security of persons, and concerning animals and nature, responsibilities of stewardship."
This provides the essential context for the following derived ethical principles, which are of direct relevance to this Opinion on ICT implants.
• Non-instrumentalisation: The ethical requirement of not using individuals merely as a means but always as an end of their own (see for example Opinion Section 6.4.2).

• Privacy: The ethical principle of not invading a person's right to privacy (see Charter of Fundamental Rights of the European Union, Articles 7 & 821) (see for example Opinion Sections 6.4.2 and 6.4.3).
• Non-discrimination: People deserve equal treatment, unless there are reasons that justify difference in treatment. It is a widely accepted principle and in this context it primarily relates to the distribution of health care resources (see for example Opinion section 6.3.5).
• Informed Consent: The ethical principle that patients are not exposed to treatment or research without their free and informed consent (see for example Opinion Section 6.3.3).
• Equity: The ethical principle that everybody should have fair access to the benefits under consideration.
• The Precautionary Principle: The EGE has stressed that modern information and communication technologies make mankind more powerful but at the same time more vulnerable. Ethics should aim at ensuring the respect for human rights and freedoms of the individual, in particular the confidentiality of data. In other words, the EGE has recommended caution as a general ethical principle with regard to information and communication technologies. This principle entails the moral duty of continuous risk assessment with regard to the not fully foreseeable impact of new technologies as in the case of ICT implants in the human body22. This assessment concerns particularly the analysis of present and future situations in which the use of ICT implants in the human body may be considered as a potential risk, or even as a potential threat to human dignity or to other ethical principles. It should be stressed that there are no reliable scientific investigations concerning the long-term health impact of ICT implants in the human body (cf. Legal Section 4.5) (see also for example Opinion Section 6.5.1).

5.2. Value Conflicts

There could be conflict between the personal freedom to use one's economic resources to get an implant that will enhance one's physical and mental capabilities and what society at large considers desirable or ethically acceptable. Another value conflict concerns the potential conflict between limiting the freedom of people dangerous to others by surveillance and promoting the safety of others. Freedom of researchers may conflict with the obligation to safeguard the health of research subjects. Concern for economic competitiveness and other economic values (economic growth) may come into conflict with respect for human dignity. The unrestricted freedom of some may endanger the health and safety of others. Therefore a balance has to be struck between values that are all legitimate in our culture.

As in other areas, the freedom to use ICT implants in ones own body, i.e. the principle of freedom itself might collide with potential negative social effects. In these cases ethical counselling as well as social and political debate might be necessary.

The borderline between repairing and enhancing is not strict. (Although there are clear examples of both applications.) Legislation is necessary in order to avoid a situation in which society is becoming more and more dependent on such intrusive technology in order to provide social security while at the same time the technical perfection of such implants is helpful for all kinds of medical purposes as well as for legitimate social applications. Consequently, the EGE stresses the need for a continuing, inclusive debate on which kinds of enhancement should be allowed – under what conditions and in which

situations (see Opinion Section 6.4.4).
A particular case, which challenges the view that there is a general standard for human capabilities, concerns cochlear implants for deaf children. The technological drive to promote cochlear implants raises ethical questions concerned with how this drive impacts on the individual and on the deaf community (and of the signing community in particular). It leaves unquestioned the social integration of the deaf person with the deaf community. It does not pay sufficient attention to the psychological, linguistic and sociological issues. Above all it promotes a particular view of "normality". In the view of the EGE this issue, the risk benefit assessment and the problem of fair access need further study (paying attention to the distinction between unilateral and bilateral cochlear implants).

5.3. Some Important Knowledge Gaps Regarding ICT Implants in the Human Body

It is clear from the preceding sections that there are important knowledge gaps that are relevant both to future research programmes and to the primary ethical concerns. These include:

Human Dignity, Integrity and Autonomy

• How far can such implants be a threat to human autonomy particularly when they are implanted in our brains?
• How far can such implants have irreversible impacts in the human body and/or in the human psyche and how can reversibility be preserved?
• How will they influence human memory?
• Does a human being cease to be such a "being" in cases where some parts of his or her body – particularly the brain - are substituted and/or supplemented by ICT implants?

Particularly as ICT implants can contribute to creating "networked persons" that are always connected and could be configured differently so that from time to time they can transmit and receive signals allowing movements, habits and contacts to be traced and defined. This is bound to affect their dignity.

Privacy and Surveillance

• How far can ICT implants become a threat to privacy?
• How far can ICT implants give an individual, or a group, specific capabilities that could become a threat to society?
• What are the potential invasions of privacy through ICT implants as sources and/or receivers of information in a network environment?
• How far should we be subject to the control of such devices or by other people using these devices?

Enhancement and Human Self Awareness

• What lies behind the idea of an "enhanced" human being?
• What does perfectibility of human beings mean?

Does the creation of an improved "race" on the basis of ICT enhancements mean necessarily a new form of racism? The potential industrial use of ICT implants raises the question of the limits of such implants for the creation of more efficient bodies and brains for economic purposes. The question of the use of ICT implants as a cultural leap in human evolution, similar to the invention of machines or to the invention of devices complementing and enhancing such devices as human memory (through writing, printing, digital technology) or other human capabilities.

• How far should the use of such implants to enhance human capabilities be allowed?
• How far can such implants be considered as part of what could be called 'body design' including the personal free design of one's (enhanced) bodily and psychic capabilities?
Social Aspects
• How do we relate to persons with ICT implants that are connected online?
• How far should ICT implants remain invisible to an external observer?
• How far are such possibilities dependent on such values as control or efficiency that may lead human beings to become even more dependent on market forces and even on the possibility of their (legal) use in the work place?
• How far do we transform our social and cultural environment through ICT implants?
• How far can they be used in order to track human beings and in which cases should this be legally allowed?
• To what extent does this technology allow manipulation by and for advertising?
• To what extent might this technology be misused by the military?

Risk Predictability

• How far can we predict today the benefits and threats of such ICT implants?
ICT Implants for which Special Caution is Necessary
• ICT implants that cannot be removed easily.
• ICT implants that influence, determine or change psychic functions.
• ICT implants that due to their network capability could be misused in several ways for all kinds of social surveillance and manipulation, such as for instance in the case of children, or disabled persons.
• ICT implants influencing the nervous system and particularly the brain and thus human identity as a species as well as individual subjectivity and autonomy.
• Military applications.
• The distinction between therapeutic applications and enhancements (see Section 6.4.4) is not always clear.
• "Intrusive" technology that by-passes normal sensory experience.
• Implants that will influence biologically and/or culturally future generations.

5.4. Previous Relevant EGE Opinions

Opinion N° 14 on the ethical aspects arising from doping in sport
In its Opinion N° 14, the EGE stated that "There is an urgent need for policy to take into account the profound change that has taken place in sport in this century due to the influences of growing economic interests and of the mass media on an increasingly global scale. These influences have accelerated medical and technological developments in sport and related industries as well as increased the pressure put on the sports person. As a result, all action concerning doping must take into consideration, in accordance with this change, the realisation that today performance and victory prevail over competition and participation. The Group thus intends to stress the tension that exists between anti doping measures and an unlimited demand for enhanced performance."
A parallel can easily be drawn between doping in sport and implants, especially those dedicated to enhancement.
Opinion N° 17 on the ethical aspects of clinical research in developing countries
Most of the recommendations made in EGE Opinion N° 17 on the ethical aspects of clinical research in developing countries are relevant to this Opinion in respect of clinical

trials of ICT implants. This is particularly important as medical devices are not covered by Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use23.

5.5. General Ethical Questions Relating to ICT Implants in the Human Body

In former Reports and Opinions such as "Citizens Rights and New Technologies: A European Challenge" (23 May 2000), and "Ethical Issues of Healthcare in the Information Society" (Opinion N° 13, 30 July 1999), the Group has identified key ethical values with regard to information and communication technologies in particular:

• to improve the protection of privacy (data protection), respecting people's right to maintain boundaries and also to preserve privacy, autonomy and confidentiality; and

• to empower individuals against the introduction of systems likely to reduce their freedom and autonomy (video surveillance, behaviour control, and personal profiling based on Internet transactions) or likely to increase people's dependency on selection and decision mechanisms which are not transparent or understandable.

Human beings are neither purely natural nor purely cultural beings. Indeed our very nature depends on the possibility of transforming ourselves. Information technologies have been considered under this anthropomorphic bias as extensions of man. However, the transformation of the human body has consequences also on the cultural human environment. Under these premises, human beings are seen as parts of a complex system of natural and artificial messages that function on a digital basis. In this sense the human body can be seen as data. This view has large cultural effects particularly as it precludes higher level phenomena such as human psyche and human language or conceives them mainly under the perspective of its digitization, giving rise to reductionism that oversimplifies the complex relations between the human body, language and imagination. Furthermore, such a reductive view permits different kinds of scientific and technological developments and inventions. ICT implants in the human body might thus play a major role in

questions of health care and even lead to the enhancement of biological and/or psychic capabilities. Extrapolating into the future, this logic might even lead to the transformation of the human race.

How far should we let ICT devices get "under our skins"? When do ICT implants threaten the dignity of the human body, its identity and its basic capabilities? ICT implants may seem to be mainly of benefit for human health, as with e.g. cardiac pacemakers. However, are there possible situations in which ICT devices may be used for other goals, due, for instance, to the interconnection of digital data within a networked world? When might such devices be used for instance for surveillance and in which cases would this be legitimate? Where are the threats related to the hopes of enhanced capabilities based on ICT implants?

The question of ICT implants in the human body is thus located between two extremes. On the one hand, the protection of the natural human body, that is to say, the medical use of ICT implants for health care, and, on the other hand, the elimination of the human body as we know it today and its substitution by an artificial one – with all possibilities in

between. Human dignity concerns the human self as an embodied self. Thus the question of autonomy and respect of the self cannot be separated from the question of bodily care and of the possible changes due to ICT implants.

EGE OPINION:
Against this background, the European Group on Ethics of Science and New Technologies submits the following Opinion:

6.1. SCOPE
This Opinion focuses on the question of ICT implants in the human body. It does not deal with the whole field of ICT devices or with "wearable" computing in general, although there may be cases in which such devices could be considered as quasi-implants.
This Opinion does not address the question of ICT implants in animals although these applications provide examples of what could be done with humans.
This Opinion addresses the ethical problems raised by the potential or actual online accessibility of such ICT implants as well as of stand-alone devices (i.e. those that do not form part of a network).
Legal principles and rules act in general as a check against technological drift and serve to highlight that not everything that is technically possible is also ethically admissible, socially acceptable, and legally approved. On the other hand, the power of a technology manifesting itself with an unlimited range of applications cannot be constrained by a weak law that lacks its ultimate reason. Hence, it is necessary to always refer to strong values, capable to breathe life into the constitutionalisation of the individual that is the outcome of a complex process and was clearly outlined in the Charter of Fundamental Rights of the EU – starting from its Preamble, where it is stated exactly that the Union "places the individual at the heart of its activities".
"We shall not lay hand upon thee". This was the promise made in the Magna Carta – to respect the body in its entirety: Habeas Corpus. This promise has survived technological developments. Each intervention on the body, each processing operation concerning individual data is to be regarded as related to the body as a whole, to an individual that has to be respected in its physical and mental integrity. This is a new all-round concept of individual, and its translation into the real world entails the right to full respect for a body that is nowadays both physical and electronic. In this new world, data protection fulfils the task of ensuring the "habeas data" required by the changed circumstances – and thereby becomes an inalienable component of civilisation, as has been the history for habeas corpus.
At the same time, this is a permanently unfinished body. It can be manipulated to restore functions that either were lost or were never known – only think of maiming, blindness, deafness; or, it can be stretched beyond its anthropological normality by enhancing its functions and/or adding new functions – again, for the sake of the person's welfare and/or social competitiveness, as in the case of enhanced sports skills or intelligence prostheses. We have to contend with both repairing and capacity enhancing technologies, the multiplication of body-friendly technologies that can expand and modify the concept of body care and herald the coming of "cyborgs" – of the post-human body. "In our societies, the body tends to become a raw material that can be modelled according to environmental circumstances". The possibilities of customised configuration undoubtedly

increase, and so do the opportunities for political measures aimed at controlling the body by means of technology.
The downright reduction of our body to a device does not only enhance the trend – already pointed out – towards turning it increasingly into a tool to allow continuous surveillance of 29
individuals. Indeed, individuals are dispossessed of their own bodies and thereby of their own autonomy. The body ends up being under others' control. What can a person expect after being dispossessed of his or her own body?

6.2. ICT IMPLANTS AND HUMAN DIGNITY

The respect for human dignity must be the fundamental basis of discussions of where the limits should be drawn for different uses of ICT implants.
The Group considers that ICT implants are not per se a danger to human freedom or dignity but in the case of applications, which entail for instance the possibility of individual and/or group surveillance, the potential restriction of freedom must be carefully evaluated (see Section 6.4.6). The protection of the health and/or security of people with severe neurological disorders on the basis of ICT implants does not create necessarily an ethical dilemma between the inviolability of freedom and the need for health protection. However, even in these cases, the use of such implants should not result in any discrimination or abuse contrary to human rights.

6.3. ICT IMPLANTS FOR HEALTH PURPOSES

It goes without saying that informed consent is required, when ICT implants are to be used for health purposes. This information should not only concern possible benefits and health risks, but also risks that such implants could be used to locate people and/or obtain access to information stored in these devices without the permission of the person in whom the devices are implanted. When risks are difficult to predict, this should be made clear in the supplied information.
Implantation of ICT devices for health purposes should be governed by the principles that:
a) the objective is important, like saving lives, restoring health or improving the quality of life;
b) the implant is necessary to achieve this objective; and,
c) there is no other less invasive and more cost-effective method of achieving the objective.
The question of mixed bio-artificial implants should be specifically considered taking into consideration their problems and possibilities.

6.3.1. The Individual and the Network

To the extent that an individual via an ICT implant has become part of an ICT network, the operation of this whole network – not just the ICT implant – needs to be considered. It is particularly important that the power over this network (who has access to it, who can retrieve information from it, who can change it, and so forth) is transparent. This is based on the principle of respect for persons, as well as the principle of avoiding harm.

6.3.2. Freedom of Research

Although the necessity for research can sometimes be questioned, new knowledge is essential for the development of individuals and societies. However, the freedom of research has to be restricted by respect for other important values and ethical principles, for example respect for persons and the obligation to avoid physical, mental and economic harm as a result of participation in research.

The ethical notion of the inviolability of the human body should not be understood as a barrier against the advancement of science and technology but as a barrier against its possible misuse.

The freedom of research in this field should be subject not only to the informed consent of the persons willing to participate in new experiments aiming at health recovery but also to the awareness of the possibility of damaging not only bodily but also psychic functions of the people participating in clinical trials (see EGE Opinion N° 17 on the ethical aspects of clinical research in developing countries, February 2003).

6.3.3. Participation in Research on ICT Implants

Informed consent is required when research on e.g. the effects of ICT implants is carried out on healthy volunteers or on patients. This information should not only concern possible benefits and present health risks, but also long term risks as well as risks that such implants can be used to locate people and/or obtain access to information stored in these devices without the permission of the person in whom the devices are implanted. The right to discontinue participation in a research project should always be respected, and it should be made clear to participants how this right (when ICT devices are implanted in a person's body) will be respected, in practice.

6.3.4. ICT Implants, Minors and Legally Incapacitated

Informed consent is an ethical principle which applies also in the field of ICT implants in the human body. However, this needs specification particularly in cases in which persons due to their age (children, elderly people) and/or psychic constitution are supposed to submit to ICT implants for reasons of health surveillance. ICT devices should be implanted in minors and legally incapacitated only if this is done in accordance with the principles set out in the Council of Europe Convention on Biomedicine and Human Rights.

The question of cochlear implants for children requires special attention (see Section 5.2 – Value Conflicts).

6.3.5. Access to ICT Implants for Health Purposes

There should be fair access to ICT implants for health purposes. This means that such access should be based on health care needs rather than on economic resources or social position.

6.3.6. Irreversible ICT Implants

The requirements of informed consent and data protection (privacy and confidentiality of the data in particular) need to be strictly enforced in cases where the ICT implants are irreversible and cannot be removed from the body without risk of severe damage or the individual's life. Such implants should not be used for research purposes unless the

objective of the research is to provide a clear therapeutic benefit for the individual research subject.

6.4. ICT IMPLANTS FOR NON-MEDICAL PURPOSES

The wide range of potential non-medical applications of ICT implants also demands informed consent, respect for privacy, etc. Some of these applications are analysed in the following sections. The EGE makes the general point that non-medical applications of ICT implants are a potential threat to human dignity and democratic society. Therefore, such applications should respect in all circumstances the principles of informed consent and proportionality and, whenever aiming at surveillance purposes, they should comply with the rules set out hereunder in Section 6.4.6.

The EGE emphasizes that where adults give their informed consent to specific applications, the provided information should include clear data on possible health disturbances in the short and/or long term as well as problems of unwilling data processing.

6.4.1. Mental Functions and Personal Identity

Personal identity is crucial for the attribution of moral responsibility according to many ethical theories. ICT devices should therefore not be used to manipulate mental functions or change personal identity. The right to respect of human dignity, including the right to the respect of physical and mental integrity, is the basis for this.

6.4.2. ICT Implants and Personal Data

The principles of data protection need to be applied to this area, since data about the human body can be generated via such implants. The privacy and confidentiality of such data need to be guaranteed. The individual has a right to determine what data about oneself is to be processed, by whom and for what purposes. In particular the right of the individual to decide who should have access to such data and for what purpose is crucial. These rights are particularly important in the case where ICT implants function with an online system and particularly in the case where the implants are part of a surveillance system. This means that the EGE stresses the importance that not only the individual has the right to protect his or her own personal data but that society should take care that such systems, where they are permitted, should not become systems of untenable restriction or even negation of basic rights. This should be particularly considered in case such systems become part of health systems in which data is permanently or occasionally transmitted to other parties. The use of ICT implants in order to have a remote control over the will of people should be strictly prohibited.

Legislation and guidelines should be developed to ensure this. The responsibility for this rests with the Member States. However, the EGE suggests that the European Commission should initiate such a process (see Section 6.5.4).

6.4.3. Privacy and ICT Implants

Provided that ICT devices are implanted in accordance with the principles outlined in this Opinion, there is no need to declare these implants. They could and should remain unrecognizable to an external observer. The right to privacy includes the right to have an

ICT implant.

6.4.4. ICT Implants and Enhancement of Physical and Mental Capabilities

Efforts should be made to make sure that ICT implants are not used to create a two class society or to increase the gap between the industrialized countries and the rest of the world. Access to ICT implants for enhancement should be used only:

• To bring children or adults into the "normal"24 range for the population, if they so wish and give their informed consent, or,

• To improve health prospects (e.g. to enhance the immune system to be resistant to HIV). As for health purposes, access to ICT implants for these purposes should be based on need rather than on economic resources or social position.

The EGE stresses that the following possibilities should be banned:

• ICT implants used as a basis for cyber-racism.

• ICT implants used for changing the identity, memory, self perception and perception of others.

• ICT implants used to enhance capabilities in order to dominate others.

• ICT implants used for coercion towards others who do not use such devices.

6.4.5. ICT Implants, Commercialisation and Consumer Interests

Whilst the human body, as such, should not give rise to financial gain, there is – as has been documented in the scientific background part of this report – already a commercial market for various kinds of ICT devices. It is essential that these products are not put on the market without adequate control. For instance, products that can be regarded as medical products should be controlled according to the relevant legal framework. Efforts should be made to make sure that all ICT devices are checked for safety and security before being put on the market.

6.4.6. ICT Implants for Surveillance Purposes

ICT implants for surveillance in particular threaten human dignity. They could be used by state authorities, individuals and groups to increase their power over others. The implants could be used to locate people (and also to retrieve other kinds of information about them). This might be justified for security reasons (early release for prisoners) or for safety reasons (location of vulnerable children).

However, the EGE insists that such surveillance applications of ICT implants may only be permitted if the legislator considers that there is an urgent and justified necessity in a democratic society (Article 8 of the Human Rights Convention) and there are no less intrusive methods. Nevertheless the EGE does not favour such uses and considers that surveillance applications, under all circumstances, must be specified in legislation. Surveillance procedures in individual cases should be approved and monitored by an independent court.

The same general principles should apply to the use of ICT implants for military purposes.

6.5. GENERAL CONSIDERATIONS

6.5.1. Development of the Information Society

The EGE considers that the ethical questions related to ICT implants in the human body

are intimately related to the development of the Information Society as a whole. The EGE strongly supports the vision of a people-centred, inclusive and development-oriented Information Society as proclaimed in the Declaration of Principles of the World Summit on the Information Society (Geneva 2003).

6.5.2. Public Debate and Information

A broad social and political debate is needed as to what kind of applications should be accepted and legally approved, particularly concerning surveillance and enhancement. A precautionary approach is recommended by the EGE. The Member States and their national ethics councils (or corresponding institutions) have a responsibility to create conditions for education and constructive, well-informed debates in this area.

6.5.3. Democracy and Power

This Opinion differs from several of the earlier ones of the EGE in that it moves into a new and rapidly expanding area. The Opinion contains the essential elements for a future agenda for responsible regulators in Europe.

Public debate and education are essential to ensure transparency and the Member States have a responsibility to ensure that the power of development and access to ICT implants are decided through democratic processes.

6.5.4. Need for Regulation

It is clear that this field needs regulation. Currently, non-medical ICT implants in the human body are not explicitly covered by existing legislation, particularly in terms of privacy and data protection. Any regulations need to be based on the following principles: dignity, human rights, equity, autonomy and the derived principles, precautionary, data minimisation, purpose specification, proportionality and relevance (see Sections 4 and 5).

In the EGE's view, implantable devices for medical purposes should be regulated in the same way as drugs when the medical goal is the same, particularly as such implants are only partly covered by Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices.

The EGE recommends that the European Commission should launch legislative initiatives in these areas of ICT implant applications.

6.5.5. Impact Research and ICT Devices

More research on the long term social, cultural and health impact of different types of ICT implants needs to be carried out, with a particular focus on risk characterisation, risk assessment, risk management and risk communication. The EGE considers that this should be kept in mind for the Seventh EU Research Framework Programme. This sort of precautionary research in a rapidly developing field is of crucial importance.

6.5.6. Need for Review

The field of ICT implants is in its infancy and rapid developments are taking place that raise societal fears as well as hopes. Consequently, the EGE has addressed the key ethical issues regarding developments that are current or can be foreseen at the present time. However, it is clear that the EGE will have to return to this subject to update our advice

in the light of future applications of ICT implants. Particularly care will need to be taken concerning developments that appear benign at first sight (addressing for example a serious health problem) but which prove to be less benign when used for other applications. Consequently, we consider that a review of this Opinion by the EGE may be necessary in about three to five years time.

The European Group on Ethics in Science and New Technologies

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NOTE:

1 Official Journal C 364 of 18th November 2000, p. 1 - 22
2 Official Journal L 201 of 31 July 2002, p 37-47
3 Official Journal L 281 of 23rd November 1995, p. 31 – 50
4 Official Journal L 189 of 20th July 1990, p. 17 - 36
5 http://conventions.coe.int/treaty/en/treaties/html/164.htm
6 http://portal.unesco.org/shs/en/ev.php-URL_ID=2228&URL_DO=DO_TOPIC&URL_SECTION=201.html
7 http://conventions.coe.int/Treaty/en/Treaties/Html/108.htm)
8 http://www.itu.int/wsis/
9 Annexed to this Opinion
10 Proceedings of the Round Table Debate – The ethical aspects of ICT implants in the human body dated 21st December 2004
for instance 11 It should be noted that there is a lively debate about the mechanistic view of the brain, which is not addressed in this Opinion.
12 Definition taken from Council Directive 90/385/EEC on active implantable medical devices.
13 Definition taken from Council Directive 90/385/EEC on active implantable medical devices. 14 FP6 2003-2004 work Programme IST theme, http://www.cordis.lu/ist/workprogramme/en/2_2.htm
15 http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf
16 http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&alldocs=alldocs&docj=docj&docop=docop&docor=docor&docjo=docjo&numaff=36%2F02&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100
17 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data Official Journal L 281, 23/11/1995, pages 31 - 50
18 Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002

concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) Official Journal L 201, 31/07/2002 pages 37 - 47
19 Official Journal of the European Union, Volume 47, C 310, pages. 1 – 482, 16 December 2004
20 William Cheshire, Ethics and Medicine, Volume 18:2, 2002
21 Charter of Fundamental Rights of the European Union, Official Journal of the European Communities, 18.12.2000, C364, pages 1-22
22 Precautionary Principle: Article 174 of the consolidated version of the Treaty establishing the European Community and Communication from the Commission on the precautionary principle (COM (2000)1 of 2nd February 2000).
23 Official Journal L 121 of 1st May 2001, p. 34 - 44
24 The concept of "normal" is not precise. However, what is implied in 6.4.4, in using this term, is the condition generally prevailing and not caused by genetic malfunction, disease or deficiency and lacking observable abnormalities.