



Memorandum to the Code of Conduct

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MEMORANDUM AND EXPLANATIONS

Pertaining to article 1

- The terms Informed Consent and Authorization have been adopted in the Code of Conduct after the definitions in Convention on Human Rights and Biomedicine and Recommendation on research on biological materials of human origin by the Council of Europe. The terms are used to distinguish between the decision of the person with regard to their own affairs (informed consent) and consent given on behalf of incompetent person or deceased person (authorization). Examples of Informed Consent, in the terms of this Code of Conduct, would include a living will to post-mortem removal of the brain signed by the donor. Intent to donate refers to living will made by the donor on condition that the next of kin assents to post-mortem interventions and can be perceived as Informed Consent in the meaning of this Code of Conduct. Consent to post-mortem intervention signed by the next of kin is referred to as Authorization.
- “Express” informed consent should be distinguished from “implied” consent. Implied consent means a presumption that there where no explicit objection has been made, consent has been given (also known as “opting out” system). The “opting out” or “no objections” systems do not satisfy the condition that the consent should be “express”.
- Information and consent and authorization need to be as specific as possible. This provision has been adopted after the art. 10 of the Recommendation Rec (2006)4 of the Council of Europe. As specific as possible means in this context “specific with regard to any foreseen research uses”. Considering the fact that brain banks collect large quantities of biological material for different research projects it should be recognized that a fully specific consent is not feasible. Clear guidelines on information which should be provided with consent or authorization shall be laid down in the Brain Bank Regulations.
- Progeny means: unmodified descendant from the material, such as DNA from DNA, cell from cell.
- Unmodified derivatives means: purified or fractionated subsets of material, such as cells, DNA and RNA.

Pertaining to article 2

- Pertaining to paragraph 3 as research is often aimed at producing general statements which apply to a certain population, Research which will lead to stigmatization or discrimination of a certain group for example on the basis of race or sexual orientation should not be undertaken.
- Provision in paragraph 4 has been adopted in accordance with the preamble to the Recommendation of the Committee of Ministers to member states on research on biological materials of human origin Rec(2006)4.
- Pertaining to paragraph 5 originally the Code of Conduct stated “meaningful scientific research”. Because it can be controversial as what can be defined as meaningful research the word “meaningful” has been substituted with ethically acceptable and scientifically sound.

Pertaining to article 3

- Examples of material removed through therapeutic intervention include temporal lobe from epilepsy surgery, brain tumors. Muscle biopsies are examples of material removed for diagnostic purposes. Where Human Biological Material has been removed by carrying out an intervention on a living person, solely for the purpose of scientific research, additional provisions for protecting of human research subjects must be applied. Additional provisions meaning: national and international laws and regulations with

regard to biomedical research with humans, e.g. Additional Protocol to the Convention on Biomedicine concerning biomedical research and The WMA Declaration of Helsinki (Ethical principles for medical research involving human subjects).

Pertaining to article 4

Pertaining to article 5

- For background information on the decision of the Consortium please see letter to the BNE partner, signed on May 16, 2007.

Pertaining to article 6

- Guidelines with regard to information to be provided prior to signing of Informed Consent or Authorization are stated in the Brain Bank Regulations.
- Pertaining to paragraph 5, the article addresses restrictions for animal research or commercial research.
- When restrictions are too constraining or incompatible with the objectives of the Brain Bank, the Material offered or donor registered can always be declined, provided the dismissal is appropriately motivated. Inclusion and exclusion criteria for brain donation should be carefully defined by the Brain Bank to prevent painful misunderstandings.

Pertaining to article 7

- Article has been adopted in analogy to art. 6 ETS 164 – Convention on Human Rights and Biomedicine, 4.IV.1997, with the difference that no “intervention on a person” in the meaning of the Convention is carried out.
- Pertaining to paragraph 1 and 2 the criterion of permanence in this article is crucial. Those whose incompetence is temporary (such as patient with a psychotic episode or a minor which is expected to reach the legal age of competence) are explicitly excluded from this group by the criterion of permanence. Individuals, who plead and / or were found to be temporarily insane in criminal procedures, are also excluded, due to the temporary nature of their insanity.
- Local legislations on minor decisions may differ and each case should be considered according to the law of the country in which the problem arises.
- Pertaining to paragraph 3 a Brain Bank should only collect and use tissue from incompetent persons when this is strictly necessary / no other means for research are available. If the objectives of research can be achieved by using tissue from competent adults from whom informed consent has been obtained, a Brain Bank should abstain from using tissue of the incompetent person. This has to do with autonomy of the person. Autonomy of the incompetent is always a difficult issue. Authorization, given on behalf of the incompetent is a proxy consent is does not weigh as heavily as an informed consent. This a so-called principle of subsidiary mean: resort to using tissue of the incompetent only when no alternative is available, and research is important.

Pertaining to article 8

- This article addresses a situation wherein a living person is giving consent to remove the Biological Materials through post-mortem autopsy after his death. This person retains the right to change the scope or to withdraw such consent. “Any Biological Material then obtained...” refers to e.g. blood samples which have been obtained from that person and stored at the Brain Bank facilities, prior to that person’s death.
- Provision in art. 8 paragraph 4 addresses the question of what should be done with the data when consent has been withdrawn. When a person withdraws his consent, all the Biological Materials and Identifying and Pseudo Anonymised Data collected and processed for (future) research purposes, should be disposed of in an appropriate manner. If this person is also a patient and the Data or Biological Materials have been collected for the purposes of providing medical care and treatment, the Data and Biological Materials of course must not be destroyed. The Data and Biological Materials however may not be used for other purposes than providing medical treatment and care, thus may not be used for research purposes.
- Up to the time of withdrawal of consent, it is possible that both the material and the related data will have already been used for research and may have progressed to publication. As soon as withdrawal of consent is notified, corresponding material and data cannot be further used for research. However research results already obtained and possibly published cannot be recalled. A record of Authorization can be retained to indicate that the research use was legitimate prior to receipt of the withdrawal of Authorization. The material itself should be respectfully disposed off, unless it is legally required to be retained for diagnostic or verification purposes.

Pertaining to article 9

- Whenever appropriate the Brain Banks should make appointments with competent national authorities, such as Public Prosecutors Office or Coroner’s Office.
- Brain Banks should make appointments with the competent national authorities such as Transplant Coordination Centers.
- The words “unless Informed Consent or Authorization explicitly orders otherwise” mean that the donor may grant priority to brain donation, above organ donation for transplantation purposes. Although uncommon, this is in accordance with the donor’s right to autonomy.
- Pertaining to paragraph 3, here it concerns forensic experts or very rare diseases which require a highly specialized pathologist.

Pertaining to article 10

- The article has been adopted after the example of “The Guidelines on autopsy practice”, Report of a working group of The Royal College of Pathologists, September 2002.

Pertaining to article 12

- This article addresses a situation wherein the Biological Materials have been removed for other purpose than scientific research. Other purposes may include materials removed for diagnostic purposes, surgical rests, organs removed for transplantation but found unsuitable for such purposes.

Pertaining to article 13

- This article has been adopted after art. 21 of the ETS 164 – Convention on Human Rights and Biomedicine, 4.IV.1997, citing the Meeting Reports of the plenary Committee (CAHBI/CDBI) and its Working Party responsible for drafting (CDBI-CO-RED) until the adoption of the Convention CDBI 6-9/07/93 “...certain organs or tissues were the subject of certain procedures (tests, conservation, transportation etc) which legitimately gave rise to a payment. The purpose of the Article was to prohibit any trafficking in organs and tissues as such, without any accrued value, not to ban normal remuneration for operations of the type previously mentioned.”
- Article 7 § 35, CDBI (Steering Committee on Bioethics), Explanatory Memorandum to the Recommendation on Research on Biological Material of Human Origin, CDBI (2005)5REV2, Strasbourg, 15 March 2006, citing: “This provision should not prevent payments for legitimate scientific or technical services rendered in connection with use of such Biological Materials.”
- A non-profit organization is an organization which is defined as a public or private body according to national law and has no intention of making a profit according to its statutes. A non-profit organization does not have shareholders and does not share profit with them. Sharing profit by divided payments to shareholders is the essence of a for-profit organization. Surplus income is not the same as profit or financial gain in that sense, meaning that a non-profit organization can have surplus income.
- It is broadly recognized that the donated tissue cannot be sold. Therefore it is important to avoid any suggestion of selling tissue. When asking for financial contribution in the costs Brain Bank should strive to cost recovery. Cost transparency is of paramount importance.
- For-profit organizations (such as pharmaceutical companies, commercial research laboratories) also conduct meaningful research and should not be excluded from access to material. The fact that the inventions of the research may be exploited commercially does not mean that the material as such (human tissue) is commercially exploited.
- For background information on this article see letter on November 1, 2007.

Pertaining to article 14

Pertaining to article 15

- Identifying data and Material should not be transferred to anybody until that person/organization makes it clear (presents some sort of evidence) that he/she is entitled to receive such information. E.g. the legal representative of some relative of the deceased donor requests medical records at the Brain Bank because he wants to prove that donor was mentally ill and therefore incompetent, when he made his will. The legal representative is third party (or a relative for that matter) and should provide proof that he is entitled to receive information, for example a court order.

Pertaining to article 16

- This article concerns the situation where the case is so exceptional or rare, that anonymisation or coding, do not achieve its purposes. For example: the oldest woman in Europe is known to be 122 years old. Publishing: female, 122 years old makes this person Identifying.

Pertaining to article 17

Pertaining to article 18

Pertaining to article 19

Pertaining to article 20

- In the context of the Code of Conduct “third party” means any legal entity or a person which is not a part of the same organization or in case of contract not a party to that contract.

Pertaining to article 21

- During the meeting in Amsterdam the SOPs for application review have been discussed (amongst others the intensiveness of due review by the Brain Bank). A distinction should be made between (funded) peer-reviewed studies and pilot studies. Pilot studies should not be excluded from access to the material. The Brain Banks can adhere to the policy where it is more prepared to support peer-reviewed studies than pilot studies, due to the fact that these studies have been properly evaluated on the scientific merits.

Pertaining to article 22

- To prevent misunderstandings and unrealistic expectations from scientific research appropriate information should be provided to the persons concerned. For example the following statement can be offered as information. Taking into account current state of the art, uncertain character of research facilitated by Brain Banks and the time elapsing between outcomes of research and diagnostic or therapeutic applications thereof, it is unlikely that research undertaken upon the Material obtained from the Brain Banks shall generate information of direct clinical importance for the individuals concerned.