



Legal and Ethical Issues in Brain Banking

Inge Huitinga¹ · Mignon de Goeij¹ · Natasja Klioueva¹

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The legal and ethical issues in brain banking are numerous. The post-mortem removal and retention of organs as well as research with human tissue and genetic information, have posed various dilemmas in the fields of law and ethics. Due to the relative novelty of these issues, the law is often lacking in clear instructions and unambiguous guidelines. The ethical problems specifically involving post-mortem cell and tissue banking for research purposes are not always specifically taken into account. This means that a brain bank frequently does not qualify for a certain well-defined legal regime. Because of this and the fact that the existing regimes differ significantly throughout the world, many uncertainties arise for the initiation and management of brain banks. Guidelines on informed consent, confidentiality, financial sustainability, accountability, and transparency are conditions *sine qua non* for the good conduct of a professional brain bank and are briefly highlighted.

The Convention on Human Rights and Biomedicine states that every person has the right of autonomy over his or her body [1]. It is therefore our conviction that we should pursue the situation where the removal of brain tissue only takes place on the basis of informed consent [2–6]. Regardless of whether the national legislation requires such consent, brain banks should implement a procedure which ensures that the donor takes an informed decision to donate tissues or organs. In a situation where the person is incapable of providing consent, a so-called

‘authorization’ procedure should be put in place. In order to disclose the etiology and pathogenesis of psychiatric and developmental brain diseases, it is unavoidable to bank tissue from incompetent persons and children, however sensitive this topic might be with the public [7, 8]. The information provided to the donor and/or next of kin should be clear and as precise as possible on the future use of the tissue [2–6]. The fact that findings can only be patented if obtained by research with tissue that was obtained on the basis of informed consent, should be kept in mind by all scientists using such tissue for research [9].

Another human right concerns confidentiality of the donor and is of equal importance [4, 5]. In order to protect this right, the tissue and data should only be used for research after identifiable parameters have been removed. At the same time, the donor or his or her relatives should be clearly informed if and how research data obtained from their tissues will be communicated, especially where it concerns genetic information. Individual data on carrier state or genetic predispositions, in certain situations should be made available to the person concerned, in particular where such data can have therapeutic consequences. It is the task of the brain bank to have the right procedure in place [4, 5].

In many cases, brain tissue collections were built up by researchers who use the collection for their own research and share the tissue they characterized with colleagues [6, 9]. Such brain tissue collections are mostly supervised by one or a few managers, are financed by research grants, and are not open-access. As opposed to tissue collections, more professional brain banks mostly run complex donor programs and aim to collect well-characterized human brain tissue to increase our understanding of the brain and brain diseases. They are aimed to be open-access for the best research groups worldwide and are mostly structurally

✉ Inge Huitinga
i.huitinga@nin.knaw.nl

¹ Netherlands Brain Bank, Netherlands Institute for Neuroscience, Netherlands Royal Academy of Arts and Sciences, Amsterdam, Netherlands

financed by patient organizations, government, and facility grants. In the case of a brain tissue collection, the most important stakeholders are the manager of the brain bank and the institution where the collection is kept. In the case of a professional brain bank, the most important stakeholders are the donors and the tissue users (Table 1). Professional brain banks are a costly initiative. They are not only expensive to establish, but also expensive to maintain. In order to obtain tissue, the dissection procedures, background clinical information, and neuropathological diagnoses require not only manpower, but also scarce specialist knowledge and expertise. To guarantee the long-term sustainability of a professional brain bank, effective cost-recovery systems could be very helpful in addition to structural funding by government or other organizations. Although legislation and guidelines permit the recovery of costs incurred by the procurement, processing, and distribution of tissue and data, the lack of clarity on calculation methods leads to reticence of many academic organizations to “ask for money in exchange for tissue” [10–14].

It is inevitable that motives rooted in continuity and financial sustainability will impact the conduct of the brain bank by the managers towards its users [6]. This could mean that tissue is granted to projects that will increase the long-term (financial) sustainability of the brain bank, secondary to the quality or the aim of the project. For instance, in cases where research grants are used to finance brain bank activities, the brain bank needs to deliver research data from the tissue and will use the brain bank as a private collection [6, 10]. In this situation, the open-access of the tissue for high quality research is jeopardized. One should always keep in mind that the donor donates his or her brain tissue altruistically for the benefit of science. Therefore, it is our opinion that professional brain banks

are open-access and objective, and transparent quality criteria should always guide tissue dissemination [3, 4, 13, 14]. To secure the visibility of the crucial contribution of the brain bank to scientific output, corporate co-authorship of the brain bank on studies could be considered. According to the recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals of the International Committee of Medical Journal Editors (ICMJE, <http://www.icmje.org>), mere provision of samples and data does not justify co-authorship in a publication, but in many cases the brain bank contributes substantially to the concepts of many studies by advising on the use of types of donors and brain regions and by analyses of the clinical files and brain tissue of donors to make the final diagnoses. Corporate authorship of the brain bank as opposed to individual co-authorship of brain bank employees will safeguard against conflict of interest, in the sense that they would provide tissue for its own sake, while the scientific output of the brain bank is guaranteed (National Institutes of Health, U.S. National Library of Medicine, 2008, <http://www.nlm.nih.gov/pubs/factsheets/authorship.html>). The latter enables demonstration of the scientific relevance of the brain bank for donor program activities and successful grant applications to ensure financial sustainability.

To ensure that the donor’s rights are protected, while the brain bank’s long-term sustainability is safeguarded and the tissue is disseminated to the best scientific proposals, we are convinced that brain banks should formulate a set of internal regulations on how the tissue is procured, stored, and disseminated. Within BrainNet Europe (BNE, www.brainnet-europe.org), a consortium of 19 European brain banks established by the European Commission, an Ethical Code of Conduct was installed [4, 5]. This Code covers the basic legal rules and bioethical principles involved in brain

Table 1 Different characteristics of brain tissue collections and brain banks

Feature of a brain tissue collection	Feature of a brain bank
Vision: Human brain tissue for in-house research projects	Vision: Human brain tissue is widely distributed to research community
Aim: Collect brain tissue that fits own research interests	Aim: Collect brain tissue that is needed to understand the human brain and improve diagnostics and therapies for brain diseases
Supervision by one person	Supervision by a management board
Most important stakeholder is the institute where the collection is housed and the keeper of the collection	Most important stakeholders are the donors and the tissue users
One person can provide resources from collection in return for co-authorship in publications or grant money	Acknowledgement policy “resources have been provided by a brain bank” or corporate authorship of the brain bank
Scientific collaborations and informal transfers	Open access policy by including formal tissue request procedures and supply under the terms of a Material Transfer Agreement after evaluation by an independent tissue advisory board
Financing: Research grant funding	Financing facility oriented funding and cost recovery

banking and is based on legislation and guidelines issued by international governmental and non-governmental key organizations, such as the Council of Europe (CoE), the European Commission, the United Nations, the World Medical Association and the World Health Organization and is mostly based on the Recommendation of the Committee of Ministers of the CoE to member states on research on biological materials of human origin (Council of Europe Committee of Ministers, Explanatory Report, 2005, <http://conventions.coe.int/Treaty/EN/Reports/Html/195.htm>; Recommendation, 2006, <https://wcd.coe.int/ViewDoc.jsp?id=977859>). In June 2008, all BNE II partners signed this Code of Conduct. This type of self-regulation is hoped in the long run to contribute to uniform and unambiguous European legislation guiding transparent brain banking and to guide new and professionalize existing brain banks.

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