

Ethical and legal declaration of the Netherlands Brain Bank

This document summarizes the ethical principles abided by the Netherlands Brain Bank (NBB) and describes legal embedding of the procedures of the NBB. You can cite or use this document when submitting project proposals for review by a designated ethics committee, research council or in proposals for Framework projects financed by the European Commission.

Information and consent

All Material and Data collected by the NBB are obtained on the basis of written informed consent. Where it concerns persons who, for reasons of their health, are unable to give informed consent (incompetent persons), informed authorization is obtained from the legal representative as defined in the Netherlands Civil Code (Burgerlijk Wetboek).

Informed consent/ authorization explicitly permit:

- a. To perform an autopsy during which the brain and optionally spinal cord will be removed, in accordance with the Burial and Cremation Act (Wet op de Lijkbezorging);
- b. To store and distribute the tissue to scientific research projects reviewed by the scientific committee of the NBB;
- c. To use anonymized donor data for the purposes of scientific research.

Registration as a donor is voluntary, without any payment or undue incentives.

Post-mortem procedures and subsidiarity of brain donation

At the time of donor's death the NBB is notified by the next of kin or a designated person. Although rapid autopsy protocol is practiced, the family is always consulted as to the details of transportation and autopsy.

Autopsies for brain donation are only performed when the person does not qualify as an organ donor in terms of Organ Donation Act (Wet op de Orgaandonatie). Where it concerns unnatural causes of death¹, brain autopsy is only performed when the body has been released by the public prosecutor (Officier van Justitie).

All autopsies are performed at the designated premises of the VU Medical Center in Amsterdam. Diagnostic examination and dissection of the central nervous system organs are performed by pathologists registered in accordance with Individual Health Care Professions Act (Wet BIG). The body of the deceased is restored by trained professionals (autopsy assistants).

¹ This includes the cases of Euthanasia or physician assisted suicide, which can be legally performed in the Netherlands subject to fulfilment of conditions laid down in Termination of Life on Request and Assisted Suicide (Review Procedures) Act (Wet toetsing levensbeëindiging op verzoek en hulp bij zelfdoding).

Privacy

Any data collected about the donors and next of kin is processed in accordance with the General Data Protection Regulation (Algemene Verordening Gegevensbescherming, since May 25 2018, before that the Wet Bescherming Persoonsgegevens) and the principle of medical confidentiality (World Medical Association, The International Code of Medical Ethics, 1949). The data protection authority has been notified of the processing of personal data by the NBB. Employees of the NBB who are granted access to the identifiable information have been informed about the obligations to keep such data confidential and have signed a nondisclosure agreement.

The material distributed to researchers is accompanied by anonymized donor information. **The recipient of the tissue is never granted access to identifiable information of the donor.** The researcher is not allowed to carry out any procedures by which the identity of the donor could be derived.

Safety

All tissue recipients are informed that the material has not been tested for infectious agents and should always be handled as potentially hazardous. Researchers are informed of the safety methods in handling the material.

Fair and Regulated Distribution

Material and Data are only distributed on the basis of approved application, disclosing the relevant research project details, including the amount and nature of the requested material and proposed use of the material. All applications for NBB tissue for research projects are evaluated by a scientific committee, on feasibility and scientific quality.

Tissue is transferred under the conditions of the Material Transfer Agreement, which restricts the use of the material to approved research projects only and forbids utilizing material for commercial purposes.

All recipients are responsible to return unused samples to the NBB and dispose of tissue rests according to local safety regulations.

Miscellaneous

Procedures, information - and consent forms of the NBB have been approved by the Medical Ethics Committee of the VU Medical Centre at April 30, 2009.

Dr. I. Huitinga, Director of the Netherlands Brain Bank
Amsterdam, September 21, 2009