

INFORMATION DOCUMENT

INFORMED CONSENT: AUTOPSY AND STORAGE OF SPECIFIC BODY MATERIAL AND DATA FOR SCIENTIFIC RESEARCH INTO NEURODEGENERATIVE AND NEUROMUSCULAR DISEASES

In partnership with:

*The neurology departments
and mortuaries of:*

- UZA – UAntwerp
- UZ Gent – UGent
- UZ Brussel – VUB

*In consultation with participating
general hospitals*

*The neurology laboratory and the
IBB-NeuroBiobank services of:*

- Institute Born-Bunge (IBB) - UAntwerp
IBB-NeuroBiobank FAGG BB190113
Company Registration Number 0408.628.138
Antwerp Legal Entities Register, Antwerp dept.
Translational Neurosciences
Faculty of Medicine and Health Sciences

Dear Sir or Madam,

The Institute Born-Bunge (IBB) at the University of Antwerp wants to assist you and your next of kin, via your treating physician, by making a definite neuropathological diagnosis after examination of your body material. Depending on your pathology, you may be asked to consent to having research carried out on your brain, spinal cord, muscle tissue, skin or nerves, fatty tissue, etc., shortly after death.

In addition, it is possible to have this diagnostic body material stored, together with your clinical data, for the purpose of further scientific research. For this purpose, the IBB has created the IBB-NeuroBiobank, where this type of body material and personal data can be stored for long periods of time under strict conditions.

This provides scientists with unique opportunities to conduct important research, under controlled conditions, into neurodegenerative and neuromuscular diseases such as, but not limited to:

- Alzheimer's disease (AD)
- Parkinson's disease (PD)
- Frontotemporal lobar degeneration/dementia (FT(L)D)
- Dementia with Lewy bodies (DLB)
- Cerebrovascular degeneration (CVD)
- Multiple system atrophy (MSA)
- Progressive supranuclear paralysis (PSP)
- Corticobasal degeneration (CBD)
- Creutzfeldt-Jakob Disease (CJD)
- Amyotrophic lateral sclerosis (ALS)
- Adrenomyeloneuropathy
- Congenital fibre-type disproportion (CFTD)
- Central pontine myelinolysis (CPM)
- Leukodystrophy (adreno, metachromatic, etc.)
- Multifocal motor neuropathy (MMN)
- Multiple sclerosis (MS)
- Spinal muscular atrophy (SMA)
- Spinocerebellar atrophy (SCA)
- Down syndrome
- ...
- Age-related healthy control individuals

In the text below, we first explain the importance of a definite diagnosis and then ask for your consent to store your body material and your data in the IBB-NeuroBiobank for future research.

If you have difficulty understanding or signing this document, a family member or legal representative can give consent on your behalf.

General background on neuropathological diagnostic research and enabling future neuroscience research into brain disorders:

Scientists want to find out what factors cause these disorders. This examination of body material is important for making a precise diagnosis and helps to improve our understanding of what exactly is going wrong in the brain, muscles, spinal cord, etc., in people suffering from these neurological disorders.

In the majority of cases, the cause of the onset of a neurodegenerative or neuromuscular disease is not entirely known and a combination of genetic and environmental factors is suspected. By examining body material, we can study these factors in a more targeted manner.

In neuropathological diagnostic research, body material is examined under a microscope. By using certain colourings, specific tissue structures, cells and proteins can be made visible. Neurogenetic, neurobiological or neurochemical research can also help. This allows us to make a definite diagnosis. In addition, tissue fragments are sometimes frozen at -80°C to allow for the broadest possible future neuroscientific research. The systematic controlled storage of body material/data offers exactly these opportunities.

The neurologists at the university hospitals of Antwerp, Ghent and Brussels are actively supporting this scientific research from their respective Neurology departments, in cooperation with the general hospitals. These university hospitals offer the possibility to have body material collected from bodies stored in their mortuaries. A definite diagnosis can then be made and, pending further research, the body material/data will be stored confidentially in the IBB-NeuroBiobank.

What can you expect from the diagnostic research and the storage of your body material/data?

In most cases, neuropathological examination of your body material leads to a definitive diagnosis, allowing us to identify your condition with certainty. The results of this examination are communicated to the referring physician. Your family can make an appointment with this doctor to know the results of the examination and the definite diagnosis.

In addition, your carefully stored body material and data are very valuable for future scientific research into the causes of these diseases. In the past, the combination of genetic, neuropathological and neurochemical research has led to important breakthroughs. It is highly likely that increasing knowledge about the mechanisms causing these conditions will eventually lead to new and effective therapies.

Finally, you or your family member/legal representative have the right to inquire about the study at any time, via your treating physician.

What are the risks and expected benefits if you consent to our storing specific body material/data?

Storing your body material for future use in scientific research does not involve any risks.

The Institute Born-Bunge at the University of Antwerp is the 'custodian' of your body material and your data in the IBB-NeuroBiobank. This biobank has a Belgian accreditation number, obtained via the Federal Agency for Medicines and Health Products (FAMHP): BB190113. You and your legal representative are the 'owners' of your body material/data. This means that your next of kin can always instruct the Institute Born-Bunge to destroy your stored body material/data or to transfer it to another biobank. This can be done by contacting the IBB-NeuroBiobank manager in writing. You will receive a written confirmation stating that your body material/data has been destroyed. If your body material/data has already been used or is in use in an ongoing study, it cannot be withdrawn, but it will not be made available for other scientific research.

Personal and health data are collected during the scientific research. These data will not be passed on to third parties such as employers, insurance companies or family members, unless required by a legal procedure. Only a few authorised IBB staff members will have access to these data. Researchers requesting access to the samples or data will receive these data in encrypted form, so that identification of your person is not possible. Great care is taken to ensure the confidentiality of your data.

Privacy and confidentiality of body material/data

In accordance with the Belgian law of 8 December 1992 on the protection of privacy, the Belgian law of 22 August 2002 on patients' rights and the General Data Protection Regulation (GDPR) of 25 May 2018, your privacy will be respected and your next of kin will have access to the personal data collected.

All information collected during the controlled storage of your body material will be **pseudonymised** (encoded), so that your data can still be linked back to your personal medical file with the correct codes. The key to these codes will be accessible only to the physicians involved who work at the participating departments of neurology and neuropathology. Only the pseudonymised (encoded) data will be used in documentation, reports, education or publications in medical journals or conferences. This means that the confidentiality of your data is always guaranteed. Both your personal data and your health data will be processed and stored for at least 20 years.

Representatives of the sponsor, auditors, the Medical Ethics Committee and the competent authorities, all bound by professional secrecy, will have direct access to your medical records in order to monitor the procedures of this scientific research, without breaching confidentiality. This can only be done within the bounds of the relevant laws. By signing the Informed Consent Form after having taken note of this explanation, you agree to this access.

More information can be found at

<https://www.uantwerpen.be/en/about-uantwerp/organisation/organisational-structure/privacy-policy/> . DPO: privacy@uantwerpen.be; DPA: contact@apd-gba.be

Access to body material/data

Only research projects that have been approved by a competent Medical Ethics Committee can obtain access to body material or pseudonymised data for scientific research. The research protocols are then reviewed by a scientific committee that assesses whether the study design falls within the scope of the consent given by you for the intended scientific research.

These research projects are led by researchers affiliated with an academic centre, a healthcare institution, a non-profit organisation, a public institution or a private/commercial company. On the Informed Consent Form, you can specify whether or not you allow such access to your body material/data. Your body material/data may also be used outside Belgium in the context of projects to be approved. You can also indicate your preference in this regard on the Informed Consent Form.

Researchers who obtain body material/data must sign contracts strictly describing their access and use of this body material/data. Researchers are not permitted to further distribute, transfer or use body material/data for purposes other than those described in the research project. Researchers must also agree not to attempt to re-identify participants and to report any such attempts.

Storage of your body material/data

Your body material/data will be stored in the IBB-NeuroBiobank of the Institute Born-Bunge, located at Campus Drie Eiken of the University of Antwerp (Wilrijk, Universiteitsplein 1, building T). This is a secure environment, in accordance with current Belgian and European legislation.

Your data will be stored in the IBB-NeuroBiobank database of the Institute Born-Bunge.

The following standard measures are taken to guarantee the security of your data:

- Personal identifying data such as your name and date of birth are removed from any body material and reports, except when feedback is given to your treating physician.
- A unique code is assigned to each piece of body material.
- The references of your body material and your data are kept in a strictly secured database. Layered restrictions are imposed on the staff of the IBB-NeuroBiobank. These restrictions are described in the IBB-NeuroBiobank quality manual that was submitted to and approved by the UZA/UAntwerp Medical Ethics Committee with reference 19/13/166.

Are there any costs or fees associated with the provision of body material/data for storage and with the diagnostic examination to arrive at a definite diagnosis?

Your participation in the provision and storage of your body material/data and the diagnostic examination to arrive at a definite diagnosis does not involve any additional costs for you. There is also no payment offered to participants.

Access to results of the scientific research

As mentioned earlier, taking into account your medical situation, some of the examinations you have undergone are considered as standard hospital care. We will of course inform your treating physician of the results as soon as possible.

Your body material/data may also give rise to new insights in future scientific research, both in general and for your next of kin.

- Feedback on general scientific findings

General scientific findings and new insights such as publications can be made available on websites of the above-mentioned neurology departments and the IBB. This overview of findings does not contain any identifying data, but is important for the rapid dissemination of scientific findings within the research community.

- Feedback on individual scientific findings

Individual scientific findings are results that were discovered during a specific research project and that are potentially important for your general health or that of your offspring. These are also called incidental findings.

If such scientifically validated and clinically relevant findings could lead to either therapeutic or preventive actions regarding your health status or that of your next of kin, feedback may be provided to you. If you agree to have your next of kin informed, you can indicate this on the Informed Consent Form. Your doctor will then discuss the findings with you or your next of kin.

Possible commercialisation

Future research involving your body material/data may give rise to new insights that could lead to the commercialisation of new therapeutic substances, agents, tests or procedures. This can be done by a university, a hospital, a commercial firm, or any combination of these three. This means that researchers and commercial firms might end up benefiting financially from your donation. Your next of kin will not be able to claim any financial benefit that might arise from this commercialisation.

Responsibilities of the researchers and outline of the scientific research.

The Institute Born-Bunge, closely linked to the University of Antwerp, is a facility set up to accelerate research in the field of neurodegenerative and neuromuscular diseases. The institute provides an accredited IBB-NeuroBiobank (BB190113) that houses body material including a neuropathologically documented brain and muscle collection. Their expertise in this field enables them to assist scientists in groundbreaking fundamental research.

The neurologists at the university hospitals of Antwerp, Ghent and Brussels, together with your treating physician, are responsible for the correct description and explanation of the procedures mentioned in this Informed Consent Form. They are responsible for the practical aspects such as the collection and safe transfer of body material/data to the IBB-NeuroBiobank. Your primary point of contact for this procedure remains your treating physician.

The secondary point of contact is the manager of the IBB-NeuroBiobank with registration number BB190113 obtained from the Federal Agency for Medicines and Health Products (FAMHP) in accordance with the 'Belgian law on the acquisition and use of human body material with a view to human medical application or scientific research' of 19 December 2008.

IBB-NeuroBiobank 'BB190113' curator – neurobiobank@uantwerpen.be
Campus Drie Eiken, Universiteitsplein 1, BE-2610 Antwerp
Phone number: +32 3/265 2688 – Fax: +32 3/265 8501
<https://www.uantwerpen.be/en/projects/neurobiobank/>

This document, entitled 'INFORMED CONSENT: AUTOPSY AND STORAGE OF SPECIFIC BODY MATERIAL AND DATA FOR SCIENTIFIC RESEARCH INTO NEURODEGENERATIVE AND NEUROMUSCULAR DISEASES', was submitted to and approved by an independent Medical Ethics Committee affiliated with the Antwerp University Hospital (UZA) and the University of Antwerp. This project is carried out according to the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki, which protects participants in clinical trials. Under no circumstances should you consider the approval by the Medical Ethics Committee as an inducement to participate in this study.

Contact details for the coordination of the autopsy of your body material, for the secure transfer of your data, for sending this signed Informed Consent Form, and for practical questions:

The referring physician, a nurse or your next of kin can contact the IBB-NeuroBiobank on the following general telephone number: +32 3 265 2688

The coordination of the autopsy and the secure transfer of your data and body material is done in consensus with the Department Head of Neurology and Pathology of:
Antwerp University Hospital (UZA) and UAntwerp;
Ghent University Hospital (UZ Gent) and UGent;
Brussels University Hospital (UZ Brussel) and the VUB;

Procedure

- Your treating physician will explain to you or your legal representative the possibility of obtaining a definite diagnosis.
- Your treating physician will inform you or your legal representative (partner, child) of the possibility of participating in future scientific research by having your body material/data stored in the IBB-NeuroBiobank BB190113.
- If you or your legal representative (partner, child) are able to consent to this, a copy of this signed Informed Consent Form will be handed to you or your legal representative.
- Your treating physician will send the original signed document to neurobiobank@uantwerpen.be and will also provide a copy of your neurological clinical file. Both documents will be safely stored in the IBB-NeuroBiobank database with respect for your privacy.
- Upon your death, the treating physician or a nurse or a family member should contact the IBB-NeuroBiobank as soon as possible by calling the central telephone number (+32 3/265 2688) to schedule an autopsy.
- Your family can ask the undertaker they have appointed to transport your body. A funerary transport service provider appointed by us can also be used to have your body transported to the mortuary and back to your undertaker. Your body will be taken to the agreed mortuary at the agreed time.
- The autopsy takes up to 100 minutes, after which the undertaker or funerary transport service provider will transport your body to a mortuary chosen by your family. This procedure results in little or no visible scarring, except in case of baldness.
With the exception of services provided to external services, costs related to this transport and the autopsy shall be borne by the Institute Born-Bunge. As a scientific institution, the IBB asks the transporter to apply the official rate for the transport of bodies as for judicial research, cf. Belgian Official Gazette 31/01/2020, 5631, circular letter 131/7.
- Your body material will be taken to the Institute Born-Bunge, where it will be prepared for preservation and stored in the IBB-NeuroBiobank BB190113 and linked to your previously obtained data. From this moment on, your body material/data will be referred to with a code.
- A routine neuropathological diagnostic examination is then carried out.
- Your treating physician will receive a report of this within a few days to three months (depending on the examination). This almost always leads to a definite diagnosis. Your family has the option of contacting your treating physician about this to obtain further clarification.
- Your body material may be used at a later date for the benefit of scientific research into neurodegenerative or neuromuscular diseases. For this purpose, a researcher must submit a request to the IBB-NeuroBiobank which stores your body material/data. Each new study is first submitted to a Medical Ethics Committee for approval.

INFORMED CONSENT: AUTOPSY AND STORAGE OF SPECIFIC BODY MATERIAL AND DATA FOR SCIENTIFIC RESEARCH INTO NEURODEGENERATIVE AND NEUROMUSCULAR DISEASES

By signing this Informed Consent Form, I agree to make the specified body material/data available to the IBB-NeuroBiobank for preservation. The IBB neuropathology lab will first make a neuropathological diagnosis and inform my treating physician. My body material, my personal data and my neurological clinical data will be stored and managed securely in the IBB-NeuroBiobank and may be used for the benefit of scientific research into neurodegenerative and neuromuscular diseases. It is also possible to participate as a healthy control individual without any suspicion of neurodegenerative or neuromuscular disease.

I, and/or my legal representative (e.g. partner, child), declare the following:

<ul style="list-style-type: none"> • I have read the document titled 'INFORMED CONSENT: AUTOPSY AND STORAGE OF SPECIFIC BODY MATERIAL AND DATA FOR SCIENTIFIC RESEARCH INTO NEURODEGENERATIVE AND NEUROMUSCULAR DISEASES', consisting of 7 pages, and my treating physician has explained it to me once more. I have received a copy of it. <ul style="list-style-type: none"> ○ I have received an explanation of the purpose and organisation of the storage of my body material/data. ○ The possible risks and benefits have been explained to me. ○ I was given the opportunity and sufficient time to ask questions. 	<i>Tick to agree</i>
<ul style="list-style-type: none"> • I understand that my participation is voluntary. <ul style="list-style-type: none"> ○ I understand that I may ask for the body material/data stored in the IBB-NeuroBiobank to be destroyed or transferred to another biobank, without the need to state a reason. ○ This will in no way affect my further treatment (in this case, that of the next of kin). 	
<ul style="list-style-type: none"> • I am aware that any scientific research involving my body material/data is subject to prior approval by an independent Medical Ethics Committee. <ul style="list-style-type: none"> ○ This project will be carried out according to the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki, which protects participants in experiments. ○ This approval has not prompted my decision to consent to storage of my body material/data. 	
<ul style="list-style-type: none"> • I understand that auditors, representatives of the sponsor, the Medical Ethics Committee or competent authorities may wish to inspect my data in order to verify the information collected. By signing this document, I consent to such inspections. 	
<ul style="list-style-type: none"> • I have been informed that both my personal data and data concerning my health are processed and stored as part of the preservation of my body material. I agree to this and I am aware that my legal representative has the right to access and correct this data. 	

Please tick to agree:

I agree to have the following body materials collected. I understand that only body materials which are neuroscientifically relevant to the differential diagnosis will be stored.

Brain	
Spinal cord	
Muscle tissue	
Skin tissue	
Nerves	
Fatty tissue	
Cerebrospinal fluid	
Blood and derivatives	
Other neuroscientifically relevant body materials	

The body material/data will be stored and may later be used for scientific research into neurodegenerative and neuromuscular diseases. I also agree that:

The pseudonymised body material/data will be stored in the IBB-NeuroBiobank of the Institute Born-Bunge, affiliated with the University of Antwerp.	
The pseudonymised body material/data will be available for future research, even if I am no longer able to make decisions about it myself or after my death.	
The administrative and medical records will be consulted for scientific research purposes and kept up to date.	

Your family may be contacted to provide more information for future scientific research, to discuss additional research, or to receive feedback on individual findings.

I agree that my family may be contacted again to provide additional information, e.g. through questionnaires.	
I do want my next of kin to be informed of 'incidental findings' that may have an impact on their health.	

Signed for approval, pages 1 to 9:

Participant name and surname: _____

Date of birth: ___/___/_____

Name of treating physician:

Phone number / email address of treating physician:

Date: ___/___/_____ Signature: _____

If you are no longer able to understand or sign this document, a family member or legal representative can give consent on your behalf.

Name and surname: _____

Relationship of family member/legal representative to the patient:

spouse – child – friend – legal guardian – ...

Date: ___/___/_____ Signature: _____

A scan of this document, pages 8 and 9 will be sent to neurobiobank@uantwerpen.be and will be stored by the IBB-NeuroBiobank. The original is to be handed over to the participant or family member/legal representative.