INFORMATION DOCUMENT

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

In partnership with:

The neurology and/or pathology departments 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 people with similar conditions, via your treating physician, by developing new research methods on the basis of your donated body material. Depending on your pathology, you may be asked to consent to our collecting and storing body material so that future research can be conducted on your blood or derivatives, cerebrospinal fluid, tear fluid, muscle tissue, skin or nerves, fatty tissue, stool, urine, etc.

The IBB offers the possibility to store this body material together with your clinical data for a longer period of time under strict conditions in its IBB-NeuroBiobank. Scientists can borrow these body materials upon submission of a research request approved by a Medical Ethics Committee.

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 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 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.

The systematic controlled storage of body material/data offers exactly these opportunities, to allow for the broadest possible future neuroscientific research.

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 collect body material. In some cases, this can help in determining a diagnosis. Above all, pending further research, your body material/data will be stored confidentially in the IBB-NeuroBiobank.

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

Your carefully stored body material/data is 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.

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/data 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?

Your participation in the provision and storage of your body material/data 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: PROSPECTIVE SAMPLING 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 prospective sampling 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 prospective sampling 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 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 stored securely in the IBB-NeuroBiobank database with respect for your privacy.
- The treating physician or nurse contacts the IBB-NeuroBiobank by calling the general telephone number: +32 3 265 2688 to schedule the controlled transfer of your body materials/data.
- Your body material/data 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.
- 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: PROSPECTIVE SAMPLING 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. In some cases, the IBB laboratory may first carry out a limited preliminary examination. 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:

• I have read the document titled 'INFORMED CONSENT: PROSPECTIVE SAMPLING 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. o I have received an explanation of the purpose and organisation of the storage of my body material/data. o The possible risks and benefits have been explained to me. o I was given the opportunity and sufficient time to ask questions.	*Tick to agree*
• I understand that my participation is voluntary. o I understand that I may request 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. o This will in no way affect my further treatment (in this case, that of the next of kin).	
• I am aware that any scientific research involving my body material/data is subject to prior approval by an independent Medical Ethics Committee. o 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. o This approval has not prompted my decision to consent to storage of my body material/data.	
• 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.	
• 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.

Blood and derivatives	
Cerebrospinal fluid	
Muscle tissue	
Skin tissue	
Nerves	
Fatty tissue	
Stool and/or urine	
Tear fluid	
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 I or my legal representative may be contacted again to provide additional information, e.g. through questionnaires.	
I do want myself or my legal representative to be informed of 'incidental findings' that may have an impact on my 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.