Application form IBB-NeuroBiobank: Human Material Transfer request

Request to be sent to: neurobiobank@uantwerpen.be

Applicant - Principal Investigator 1 (liable recipient):

Name:

Address:

Applicant - Legal representative 1:

Title:

Name:

Address:

Applicant - Principal Investigator 2:

Name:

Address:

Applicant - Legal representative 2:

Title:

Name:

Address

If more applicants, please provide information of other PI / LR

Date of application:

Is your study approved by a medical ethical committee? ○ yes ○ no ○ not applicable

If yes: date: where:

send this document together with the application form

Study title:

Study design:

study design and/or abstract

Please define your study groups.

Be as detailed as possible. Who are your study objects? Which pathologies must be included or excluded per study group? If a control group is included, please define what meets your criteria for the control group. Which pathologies may still be involved? Please be aware that copathologies do occur quite often.

Sample selection based on neuropathology or protein markers?

Please clarify the sample criteria. Disclaimer: Neuropathologically confirmed samples are scarce and limited. Therefore, extra argumentation is mandatory to acquire these samples. It is likely that the quantity of samples available will fall short of the quantity that is desired. In case of brain tissue, please refer accordingly: www.uantwerpen.be/brainlocalisations

The materials - Sample type: which type(s) is required?

- ☐ CSF (frozen)
- ☐ Blood plasma (frozen)
- ☐ Blood serum (frozen)
- ☐ Formalin-fixated paraffin- embedded brain tissue (FFPE slides)
- ☐ Untreated frozen brain tissue
- ☐ Untreated frozen muscle tissue
- ☐ Untreated frozen nerve tissue

In case of multiple sample types:

- Should they be matching the same study objects: ○ Yes ◉ No ○ Partially
- In terms of selection criteria, is presence of the additional sample type ○ Mandatory ◉ Facultative

The images

- ☐ Digital histological image – read only shared via https://neuropath.uantwerpen.be platform
- ☐ Digital histological image – read + write shared via https://neuropath.uantwerpen.be platform
- ☐ Digital histological image – transfer of high resolution image file (*.MRXS)

Research method:

The materials

- ☐ Histological (frozen or FFPE tissue)
- ☐ Molecular (frozen or FFPE tissue)
- ☐ Biomarker analysis (liquids)

the Images

- ☐ AI assisted target discovery
- ☐ AI assisted software development

Quantity

Please define the desired number of samples per study group and the minimum required quantity or volume per sample (µL or mg or number of microscopy slides).

Sample selection criteria and background information

Disclaimer: It is possible not all demanded data is present. Please choose only data that is relevant for your study. Keep in mind your cohort size will go down by adding more selection criteria.

	Selection criteria	Background info	Remark
Age at sampling	☐	☐	
Age at death	☐	☐	
Sex	☐	☐	
Possible clinical diagnose	☐	☐	
Neuropathological diagnose	☐	☐	
Protein markers	☐	☐	
Collection tube (PP/PS)	☐	☐	
Freeze-thaw cycles	☐	☐	
Hemolysis present	☐	☐	
Brain hemisphere L/R	☐	☐	
Brain mass	☐	☐	
Post mortem delay	☐	☐	
Duration of formol fixation	☐	☐	
Muscle fraction/region	☐	☐	
MMSE score: … /30	☐	☐	
Other:	☐	☐	

Declares to agree with the following:

◯ Yes ◯ no If no, please state your suggestions:

Representations and undertakings of the Applicant(s) and co-Applicant(s):

The Applicant(s) and co-Applicant(s), principal investigator(s), represent(s) as follows and acknowledges that if IBB biobank agrees to supply the Materials or the Images to the Applicant, such representations shall become terms of the contract with IBB:

A. the Materials

A1. The Applicant shall use a courier with suitable skill and experience to safely transport the Materials in accordance with all applicable laws including General Data Protection Regulation (GDPR). The Applicant Institution will bear the cost of carriage and any necessary insurance. (€)

A2. The Materials are provided subject to the reimbursement by the Applicant Institution to IBB for its costs – as specified elsewhere in the HMTA – of biobanking, extracting from storage and preparing the Materials. Risk in and responsibility for the Materials shall pass to the Applicant Institution once it is loaded onto transport as organized by the Applicant Institution. The Applicant shall provide IBB with written confirmation of the safe receipt of the Materials promptly after their delivery to the Applicant Institution's laboratory. (€)

A3. The Materials will be used in accordance with the laws and regulations of the country and locality where the Study is to be performed, and in accordance with all applicable guidelines and ethical principles. The Applicant(s) and co-Applicant(s) have adequate training and facilities to study the Materials and will directly supervise the Study. The Applicant(s) and co-Applicant(s) Institution(s) will use the Materials in accordance with good laboratory practice standards, all due skill and care and with dignity, sensitivity, and respect.

A4. Restrictions on use. The Applicant(s) and co-Applicant(s) agree(s) (i) to use the Materials only for the Study, (ii) to restrict the analysis and/or modification of the Materials solely to that needed to carry out the Study, and (iii) that the Materials may not be used in humans or for any diagnostic or therapeutic purposes. The Applicant(s) and co-Applicant(s) will not use the Materials (i) for any commercial purposes, including commercial screening, (ii) for sale or otherwise transferring Materials to a third party, (iii) to generate scientific data or information that is directly or indirectly conveyed to any third party against compensation, or (iv) in research that is subject to consulting, licensing, or similar obligations to commercial entities.

A5. The Materials will not be used, analyzed, or modified other than necessary for the purpose of the Studies.

A6. The Materials will not be transferred or made available to any individual not under the supervision and control of the Applicant(s) and co-Applicant(s) without the prior consent in writing of IBB.

A7. Approvals and licenses. IBB warrants that the Materials have been collected and is transferred in compliance with all applicable statutes and regulations, such as, without limitation, those involving human tissue samples and General Data Protection Regulation (GDPR), and that (i) the explicit consent provided by the donors of the Materials (or, in the absence of such explicit consent, a presumed consent or ethical approval) allows for the use of the Materials for the Study, and (ii) if the Study implies a secondary use of the Materials, a valid ethical approval covers such use. The Applicant(s) and co-Applicant(s) represent(s) that all other regulatory and ethical approvals and licenses that are needed for the use of the Materials in the Study have been obtained. The Applicant(s) and co-Applicant(s) will comply with all laws, regulations, and guidelines applicable to the handling, use, storage and/or destruction of the Materials.

A8. All unpublished information provided by IBB with respect to the Materials within the scope and purpose of the Study and which is (i) disclosed in tangible form and marked "Confidential" or "Proprietary" or similarly marked by IBB before disclosure to the Applicant(s) and co-Applicant(s); or (ii) disclosed in intangible form such as electronically, orally or by visual inspection, identified as confidential at the time of disclosure and summarized in writing by IBB within thirty (30) days of disclosure ("Confidential Information") will be held strictly confidential and will not be disclosed to any third party, except to its own employees who have a reasonable need to know the Confidential Information for the Study and who shall be bound by confidentiality obligations at least as stringent as the one provided for in this Human Materials Transfer Agreement (HMTA), unless it needs to be disclosed by law or court order. In this case IBB will be informed to the extent legally permissible or reasonably practicable prior to disclosure by the Applicant(s) and co-Applicant(s)so that IBB may seek a protective order or other remedy. In any event, the Applicant(s) and co-Applicant(s) shall disclose only that portion of the Confidential Information that is legally required to be disclosed and will exercise reasonable efforts to ensure that any information so disclosed will be accorded confidential treatment by the court or administrative agency through protective orders, filings under seal and other appropriate means. However, Confidential Information shall not include any information of which can be shown by written evidence that (i) at the time of first disclosure the Confidential Information was already in the possession of the the Applicant(s) and co-Applicant(s), or (ii) the Confidential Information is or becomes part of the public domain, through no breach of this HMTA by the the Applicant(s) and co-Applicant(s) (iii) the Confidential Information has been received from a third party which did not acquire it directly or indirectly from IBB or any of its Affiliates (iv)is subsequently independently developed by the the Applicant(s) and co-Applicant(s), without use of IBB's Confidential Information; or (v) is approved for release by prior written authorization of IBB.

A9. The Studies will be conducted under the Applicant's) and co-Applicant's exclusive responsibility and IBB will not be liable for any consequences thereof. The Materials are to be used and handled with caution and prudence in any experimental work, since not all characteristics of the Materials are necessarily known. The Applicant(s) and co-Applicant(s) Institution(s) understands that the Materials may have hazardous properties, contain infectious agents, or pose other health and safety risks. The Applicant(s) and co-Applicant(s) assume(s) all liability for duly evidenced damages which may arise from its use, storage, or disposal of the Materials. IBB will not be liable to the Applicant(s) and co-Applicant(s) for any loss, claim or demand made by the Applicant(s) and co-Applicant(s) or made against the Applicant(s) and co-Applicant(s) by any other party, due to or arising from the use,

storage, or disposal of the Materials by the Applicant(s) and co-Applicant(s). IBB shall not be liable for any damages resulting from the use, application, storage, or disposal/destruction of the Materials by the Applicant(s) and co-Applicant(s), except to the extent such damage result directly from IBB's gross negligence or willful misconduct.

A10. The Materials are supplied to the Applicant with no warranties, express or implied, or merchantability or fitness for a particular purpose or otherwise. IBB does not represent or warrant that the use of the Materials will not infringe or violate any patent or proprietary rights of third parties.

A11. This HMTA is governed by, and construed in accordance with the laws of Belgium, except as they relate to the conflict of laws. All disputes between the Parties in connection to this HMTA shall first be discussed in good faith between the Parties to try to find an amicable solution. If no solution can be found to settle the dispute within forty-five (45) days after giving notice of the dispute to the other Party, then the Parties will refer the matter to their higher management (executive level: CEO, President, Rector,....) who are at least authorized representatives for the Parties and who will meet and negotiate in good faith in an effort to resolve the dispute within thirty (30) calendar days after the referral. If the matter has not been resolved within such period, each Party is entitled to submit the dispute to the sole competent courts of Antwerp, Belgium, without restricting any right of appeal.

A12. This HMTA is effective when signed by all Parties and terminates on completion of the Applicant's and co-Applicant's research with the Materials as described in the section Study Design and Studies performed by the Applicant(s) and co-Applicant(s).

A13. Transferred Materials that will not be used by the Applicant(s) and co-Applicant(s) must be listed in detail and returned to the IBB biobank after completing the studies at the cost of the Applicant. (€)

A14. Acknowledgment. In all oral presentations, written publications or press releases relating to the use of the Materials, the Applicant and co-Applicants will acknowledge IBB's contribution of the Materials. In the Methods' and Acknowledgments' section of the article: report the use of "NeuroBiobank of the Born-Bunge Institute (IBB-Neurobiobank), Wilrijk (Antwerp), Belgium; ID: BB190113". If relevant, specify the number of samples and type of biospecimens.

A15. Enrichment. Upon written request of IBB, the acquired information/data following the analyses on the Materials from IBB shall be shared, in confidence with IBB by the Applicant(s) and co-Applicant(s) for the purpose of internal scientific noncommercial research of the NeuroBiobank only.

A€ COSTS AND REIMBURSEMENTS: If more than one Applicant is named in this HMTA, Applicant(s) and co-Applicant(s), principal investigators, must mutually agree on how the costs and reimbursements will be settled and make this known to IBB prior to the transfer of the Materials - neurobiobank@uantwerpen.be

B. Digital Histological High Resolution Images

The Parties must explicitly select one of the alternatives by checking the box in (4), (7), (15).

B1. Transfer

The images will be delivered electronically or via secure data transfer. The Applicant shall ensure adequate cybersecurity, GDPR compliance, and shall bear the costs of the data transfer. The Applicant furthermore undertakes to comply with the Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance) of 13 June 2024, applicable as from 2 August 2026 (whereby Chapter I and II are already applicable as from 2 February 2025 onwards)

B2. Costs and risk

The digital images are made available subject to reimbursement by the Applicant of the costs fordigitalization, storage and preparation. Risk and responsibility pass to the Applicant upon successful data transfer.

B3. Use according to law and ethics

The digital images shall be used in accordance with all applicable laws, ethical principles, GDPR and AI Regulations. The Applicant has sufficient expertise, training and facilities to analyze these images and to develop, train and validate AI models.

B4. Restrictions on use

The Applicant shall use the images exclusively for the agreed research project and AI development. The images may not be used for diagnostic or therapeutic purposes in humans.

☐ No commercial use permitted.

☐ Commercial use permitted only with prior written consent and revenue sharing with IBB.
→ A separate agreement should be concluded with a clear statement of terms and conditions

☐ Commercial use permitted subject to a license agreement with IBB and proportional IP sharing.
→ A separate agreement should be concluded with a clear statement of terms and conditions

B5. Limitation of analysis

The images shall only be analyzed or modified insofar as necessary for the agreed research and AI development.

B6. No transfer without consent

The digital images shall not be shared with third parties without prior written consent of IBB.

B7. Approvals and licenses

IBB warrants that the images have been obtained in accordance with all applicable legislation and that it is in the possession of donor informed consent and required ethical approval. The

☐ Applicant confirms that all additional approvals required for AI research are in place.

☐ Applicant bears full responsibility for secondary use.
Secondary use only with joint ethical approval with IBB.

B8. Confidentiality
All non-public information and digital images provided by IBB shall be treated as strictly confidential.

B9. Liability
The Applicant bears full responsibility for the use, storage and processing of the digital images, including cybersecurity risks. IBB shall only be liable in case of gross negligence or willful act.

B10. No warranties
The digital images are provided "AS IS" without any warranty, including accuracy, completeness or fitness for AI training.

B11. Governing law
This Agreement shall be governed by Belgian law. Any disputes shall be submitted to the competent courts of Antwerp.

B12. Term
This Agreement shall enter into force upon signature and terminate upon completion of the agreed research with the images.

B13. Return
Unused digital images shall at the date of completion of the research by Applicant either be deleted or returned in digital form at the Applicant's expense in compliance with IBB's request.

B14. Acknowledgment
In all publications, presentations and press releases concerning the use of the images, IBB shall be acknowledged as follows: "NeuroBiobank of the Born-Bunge Institute (IBB-Neurobiobank), Wilrijk (Antwerp), Belgium; ID: BB190113".

B15. Enrichment & IP
The Applicant shall, upon written request, share results and metadata with IBB. IBB represents and warrants to treat the results and metadata strictly confidential. In addition, all intellectual property rights arising from AI development based on the images shall be shared.

- ☐ Joint ownership of all IP. → A separate agreement should be concluded with a clear statement of terms and conditions
- ☐ Applicant retains IP, but IBB receives royalties/license income proportionate to contribution. → A separate agreement should be concluded with a clear statement of terms and conditions
- ☐ Applicant retains IP, IBB receives a free non-exclusive license for internal research.

B€. COSTS AND REIMBURSEMENTS:
If more than one Applicant is named in this HMTA, the Applicant(s) and co-Applicant(s), including principal investigators, must mutually agree on how the costs for digitalization, storage, transfer, and any reimbursements will be settled. A copy of this duly signed agreement shall be transferred to IBB (neurobiobank@uantwerpen.be) prior to the transfer of the digital images.