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

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

Research method:

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

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:	☐	☐	

Declaires to agree with the following:

○ Yes ◉ no If no, please state your suggestions:

Representations and undertakings of the Applicant:

The Applicant represents as follows and acknowledges that if IBB biobank agrees to supply the Materials to the Applicant, such representations shall become terms of the contract with IBB:

1. The Applicant Institution shall use a courier with suitable skill and experience to safely transport the Material 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.

2. The Materials is 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 Material. Risk in and responsibility for the Material shall pass to the Applicant Institution once it is loaded onto transport as organized by the Applicant Institution. The Applicant Institution shall provide IBB with written confirmation of the safe receipt of the Materials promptly after their delivery to the Applicant Institution's laboratory.

3. The Materials will be used in accordance with the laws and regulations of the country and locality where the Studies are to be performed, and in accordance with all applicable guidelines and ethical principles. The Applicant has adequate training and facilities to study the Materials and will directly supervise the Studies. The Recipient Institution will use the Material in accordance with good laboratory practice standards, all due skill and care and with dignity, sensitivity and respect.

4. Restrictions on use. Recipient agrees (i) to use the Material only for the Study, (ii) to restrict the analysis and/or modification of the Material solely to that needed to carry out the Project, and (iii) that the Material may not be used in humans or for any diagnostic or therapeutic purposes. Recipient will not use the Material (i) for any commercial purposes, including commercial screening, (ii) for sale or otherwise transferring Material 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.

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

6. The Materials will not be transferred or made available to any individual not under the supervision and control of the Principal Investigator without the prior consent in writing of IBB.

7. Approvals and licenses. Provider warrants that the Material has 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 Material (or, in the absence of such explicit consent, a presumed consent or ethical approval) allows for the use of the Original Material for the Study, and (ii) if the Project implies a secondary use of the Original Material, a valid ethical approval covers such use. Recipient represents that it has obtained all other regulatory and ethical approvals and licenses that are needed for the use of the Material in the Project. Recipient will comply with all

laws, regulations and guidelines applicable to the handling, use, storage and/or destruction of the Material.

8. 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 Applicant; 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 Agreement, 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 so that IBB may seek a protective order or other remedy. In any event, Applicant 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 Applicant, or (ii) the Confidential Information is or becomes part of the public domain, through no breach of this Agreement by the Applicant (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 Applicant, without use of IBB's Confidential Information; or (v) is approved for release by prior written authorization of IBB.

9. The Studies will be conducted under the 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 Institution understands that the Materials may have hazardous properties, contain infectious agents or pose other health and safety risks. The Applicant assumes all liability for duly evidenced damages which may arise from its use, storage or disposal of the Material. IBB will not be liable to Applicant for any loss, claim or demand made by Applicant, or made against Applicant by any other party, due to or arising from the use, storage or disposal of the Material by the Applicant. IBB shall not be liable for any damages resulting from the use, application, storage, or disposal/destruction of the Materials by Applicant, except to the extent such damage result directly from IBB's gross negligence or willful misconduct.

10. The Materials are supplied to Applicant with no warranties, express or implied, or merchantability or fitness for a particular purpose or otherwise. In particular, 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.

11. This Agreement 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 Agreement shall first be discussed in good faith between the Parties in order 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.

12. This HMTA is effective when signed by both Parties and terminates on completion of the Applicant's research with the Materials as described in the section Study Design and Studies performed by Applicant.

13. Transferred Material that will not be used by the Applicant has to be listed in detail and returned to the IBB biobank after completing the studies at the cost of the Applicant.

14. Acknowledgment. In all oral presentations, written publications or press releases relating to the use of the Material, Applicant and Applicant Scientist will acknowledge IBB's contribution of the Material. 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.

15. Enrichment. Upon written request of IBB, the acquired information/data following the analyses on the samples from the NBB-IBB shall be shared, in confidence with IBB by the Applicant for the purpose of internal scientific noncommercial research of the NeuroBiobank only.