## INTRODUCTION

The Netherlands Brain Bank (NBB) provides human brain tissue and/or other biological Material for scientific research obtained on the basis of informed consent. The Material will only be supplied subject to conditions stated in this Material Transfer Agreement (MTA).

The MTA is concluded with the legal entity (named Recipient in the MTA) and signed by the person who was granted the power of representation thereto. The applicants employed by or affiliated with the Recipient organization can keep on filing applications for Material required for a certain research project. The MTA functions as a framework agreement and remains in effect for an indefinite period of time.

The Recipient has the responsibility to make sure that the applicants of NBB Material, are familiar with the contents of the MTA. Nevertheless, the NBB has drawn up a clear summary of the MTA, called the Material Transfer Statements (MTS), which is always sent to the applicant together with the Implementing Letter.

The terms and conditions of the MTA are non-negotiable. We kindly request you to carefully read, sign and return the signed MTA. The NBB accepts either electronic signatures, or a scan of the signed MTA sent by e-mail.

# The Netherlands Brain Bank, a department of the Netherlands Institute for Neuroscience

and

# Organisation

Material Transfer Agreement of tissue and/or fluid of human origin for research purposes.

#### THE UNDERSIGNED.

Royal Netherlands Academy of Arts and Sciences (KNAW) acting for and on behalf of The Netherlands Brain Bank (NBB), a department of the Netherlands Institute for Neuroscience (NIN), whose registered office is at Meibergdreef 47, 1105 BA AMSTERDAM Z.O, The Netherlands, represented by the managing director of the NIN, Dr. ir. J.C. Huijser, Hereinafter referred to as "Provider";

## And

<Name organisation>, established at <address>, represented in this matter by <name representative>, who was granted power of representation by the Executive Board, Hereinafter referred to as "Recipient"

Hereinafter collectively referred to as the "Parties".

#### WHEREAS:

The Provider has human biological material available, which has been obtained on the basis of informed consent that restricts the use of the material to **research purposes only.** 

The Recipient is interested in conducting research with this Material. The Provider is willing to provide Material to the Recipient, under the conditions set out in this agreement hereto:

#### **Article 1. Definitions**

1. "Original Material" The description of the Material being transferred, specified in the Implementing Letters covered by this Agreement. 2 "Material" Original Material, Progeny and Unmodified Derivatives. Modifications, or any substances the Recipient makes using the Original Material that are not Modifications. Progeny, or Unmodified Derivatives will not be considered Material. 3. "Progeny" The unmodified descendant from the Material, such as DNA from DNA, cell from cell. 4. "Unmodified Substances created by the Recipient which constitute an Derivatives" unmodified functional subunit or product expressed by the original material. Examples include: purified or fractionated subsets of the Original Material, such as cells, DNA and RNA. 5. "Modifications" Substances created by the Recipient which contain/incorporate the Material, such as immortalized cells. 6. " Pseudonymized Pseudonymized coded information concerning the donor of the human Material: Donor Information" I. Clinicopathological information of the donor including postmortem time, age and sex of the donor, pH as measure for agonal state, clinical information and recent drug history. Ш Neuropathological diagnosis The information provided does not allow identification of the donor without disproportionate efforts. 7. "Implementing Letter" The document containing the summary of Original Material that will be transferred under this agreement, financial contribution and administrative information. "NBB Code" 8. The Netherlands Brain Bank (NBB) code of the Material which allows reidentification of the donors by the Provider through the use of this code. The key to the code shall remain under the sole control of the Provider. "Material Transfer 9. The document containing the summary of conditions and Statement or MTS" obligations of the material transfer laid down in this MTA. The MTS is signed by the Applicant prior to actual transfer of the Material. 10. "Applicant" The scientist employed by working for or working under auspices of the Recipient requesting for Material required for a research project specified in the Application Form. An NBB form filed by the Applicant requesting for certain 11. "Application Form" Material and/or Pseudonymized Donor Information and describing the research use.

12. "Commercial The sa Purposes" purposes

The sale, lease or license of the Material. Commercial purposes shall also include uses of the Material to produce

or manufacture products for general sale.

13. "Collection"

All Material remaining after completion of the research project as specified in the Application Form, retained by the Recipient subject to this MTA.

#### **Article 1. Scope of this Agreement**

- 1. This Agreement contains the terms and conditions under which the Material shall be transferred to the Recipient and subsequently made available to the scientists employed by or working for the Recipient.
- 2. This Agreement and the resulting transfer of the Material constitute an authorization to use the Material solely for the purpose of the research as specified in the Application Form of this Agreement.

#### **Article 2. The Material Provided**

- 1. The "Original Material" that is covered by this Agreement is or will be specified in the Implementing Letters covered by this Agreement including Pseudonymized Donor Information and available associated know how.
- 2. The Provider represents and warrants:
  - a. the Material has been collected and maintained in full compliance with the applicable national laws and the international regulations described in BrainNet Europe's Code of Conduct for Brain Banking<sup>1</sup> including requirements for informed consent;
  - b. it is not aware of any defects in the Material or of any other circumstances that would limit the intended use and value of the Material to Recipient under this Agreement.
- The Material accompanied by Pseudonymized Donor Information when provided will be transferred coded with an NBB Code. Under no circumstances shall the identity of the donor be provided to the Recipient or the key to link the NBB Code to the donor's personal information.

# **Article 3. Rights to the Material**

- 1. At all times the Provider retains the ownership rights to the Material, including Progeny and Unmodified Derivatives and any Material contained or incorporated in Modifications.
- 2. Neither Recipient nor the scientists employed by the Recipient, nor any other third party

<sup>&</sup>lt;sup>1</sup> Klioueva, N. M., Rademaker, M. C., & Huitinga, I. (2018). Design of a European code of conduct for brain banking. In I. Huitinga & M. J. Webster (Eds.), *Handbook of Clinical Neurology* (Vol. 150, pp. 51–81). Elsevier. https://doi.org/10.1016/B978-0-444-63639-3.00005-0

shall have rights in the Material other than as provided for in this Agreement.

- 3. At all times the Provider retains the right to recall the Material on reasonable grounds. Upon a notified request from the Provider, the Recipient shall discontinue the use of the Material and return it to the Provider. The use of research data resulting from research using the recalled Material will be permitted. Reasonable grounds to recall the Material shall include the following:
  - a. The Applicant or scientists employed by the Recipient fail to comply with conditions of this Agreement;
  - b. The Recipient fails to fulfill the obligations laid down in art. 9 of this Agreement;
  - c. The family of the donor insists on withdrawing the consent to the use of the Material in research;
  - d. Other reasonable grounds substantiated for by the Provider. Examples of such grounds include, but are not limited to, a change in Dutch legislation or a breach of donor anonymity.

The Recipient shall be indemnified for the financial contribution paid subject to art. 9 of this Agreement and the costs of the transport of Material in cases where the Material is recalled on the grounds mentioned under c and d.

#### Article 4. Terms and conditions

- 1. The Recipient warrants that neither the Material nor any biological materials treated therewith will be used in human beings.
- 2. The Recipient shall not carry out any procedures with which the identity of the donor or its relatives could be derived.
- 3. Recipient shall not distribute or release the Material to any person other than the scientists employed by the Recipient, and shall ensure that no one will be allowed to take or send this Material to a third party. It is however permitted to temporarily send the Material to another laboratory, contractor or a third party to conduct a certain analysis when required for good conduct of the research project specified in the Application Form or explicitly requested by the Applicant and confirmed by NBB. In all other circumstances, when the Recipient wishes to make the Material available to a third party, the third party is required to submit an Application form to the Provider and conclude a separate MTA with the Provider.
- 4. The Recipient shall not use the Material for Commercial Purposes and shall ensure that nobody shall be allowed to use the Material for such purposes. The Recipient may perform research activities using the Material for commercial product development or services to third parties.
- 5. The Recipient takes responsibility to ensure that research performed on the Material supplied by the Provider shall be executed in a safe manner and in accordance with all applicable rules and regulations.
- 6. Findings on individual Material relevant for maintenance and improvement of the collection quality of the NBB should be made available to the Provider. Such findings will only be used to ensure proper handling, preservation and dissemination of NBB Material and will not be published. Such findings may include but are not limited to the results obtained by research procedures such as genotyping. In case these research findings are of confidential nature, the Provider shall enter into a separate non-disclosure agreement with Recipient thereto. In exceptional cases the pressing health

interests of family members of the donor can take precedence above the confidentiality of the findings. Recipient does not make any representation or warranty with regards to such findings, nor shall it be responsible for any use by Provider of such findings.

- 7. The Provider should be mentioned in all publications resulting from research using the Material, under Materials and Methods section, in the following manner: "The brain samples and/or bio samples were obtained from The Netherlands Brain Bank, Netherlands Institute for Neuroscience, Amsterdam (open access: www.brainbank.nl). All Material has been collected from donors for or from whom a written informed consent for a brain autopsy and the use of the material and clinical information for research purposes had been obtained by the NBB".
- 8. Within thirty days after the completion of the research project the Applicant shall report whether all Material has been fully used while conducting research specified in the Application Form. If any Material remains, the Recipient shall consult with the Provider to determine whether it may be retained, returned, or must be destroyed. The agreed course of action shall be confirmed in writing.
- 9. The Recipient may retain the Material remaining after the completion of the research for the purpose of:
  - a. continuation of scientific investigation in the same line of research as specified in the Application form;
  - b. validation of conducted scientific research as specified in the Application Form;
  - c. and/or other purposes explicitly approved for by the Provider, provided that these purposes are research related.
- 10. The Recipient is considered to be responsible for the Collection, unless another person has been explicitly designated by the Recipient. The holder of the Collection is required to consider third party's requests for Material, to encourage optimal use of the Collection. The Material may only be re-used by a third party for other research after said third party has filed a new Application Form with the NBB and signed a separate, new MTA/MTS.
- 11. When Applicant's employment is terminated, the Recipient shall inform the Provider whether the Collection will be retained by the Recipient subject to this Agreement and shall designate a person responsible for the Collection.
- 12. The Collection may not be used for purposes inconsistent with this Agreement.

#### **Article 5. Inventions**

- 1. The Recipient retains ownership of the results obtained through research conducted by the Recipient.
- 2. The Recipient may decide to obtain any protection, such as patent protection of inventions resulting from research performed on the Materials.
- 3. The Recipient is free to decide on all matters concerning the use and commercial exploitation of the results obtained through research on the Material.
- 4. In case the Recipient will file patent application(s) claiming inventions made by the Recipient through the use of the Material, the Recipient will provide written notice to the Provider.

# **Article 6. Safety Measures and Liability**

- 1. The Recipient acknowledges that although the Provider does not knowingly dissect donor material which has been exposed to infectious agents, the Material is not tested by the Provider and may therefore contain potentially hazardous components. Therefore, all Material should be treated by the Recipient as potentially hazardous. The Provider can provide samples for pathogen testing on request and at the costs of the Recipient.
- 2. Recipient understands that all appropriate precautions to minimize any health risk become fully its responsibility, after signing of this Agreement.
- 3. In no event shall the Provider or its staff (directors, representatives, employees, students or assignees) be liable for any use, handling, storage or disposal of the Material by the Recipient, or any loss, claim, damage, or liability of whatsoever kind or nature which may arise from or in connection with this Agreement, except if it is caused by Provider's gross negligence or willful intent.

# **Article 7. Indemnification**

1. The Material is provided as a service to the research community. It is being supplied to the Recipient with no warranties, express or implied, including any warranty of fitness for a particular purpose. Provider makes no representations that the use of the Material will not infringe any patent or proprietary rights of third parties.

#### **Article 8. Application for the Material and Transfer**

- 1. The Applicant can file an application to the Provider, requesting for certain Material needed for a research project specified in the Application Form. The Applicant will answer questions in the Application Form and disclose all information needed for evaluation of the application by the scientific committee of the NBB. Solely when the Application Form has been evaluated positively, the available Material shall be transferred subject to this Agreement and signing of the Implementing Letter and MTS.
- 2. Except reasonable doubt, the Provider assumes that the person filing the Application Form and signing the Implementing Letter and MTS has been authorized by the Recipient thereto.
- 3. The Recipient has the obligation to inform the Applicant(s) and scientists employed by the Recipient of the provisions of this Agreement.

#### **Article 9. Delivery and Transportation**

1. When application for the Material has been evaluated positively, the Provider shall hold the Material, subject to this Agreement, available for the Recipient for 90 days. The Applicant shall either collect the Material at the address of the Provider or request the Provider to post the Material to Recipient's address. If the Material is posted, the

Provider will take all reasonable precautions to ensure proper packaging of Material for transportation purposes. The Provider however is not liable for any damages to or incurred by the transportation of Material either while en route or once received by Recipient, except to the extent caused by the Provider's negligence or willful misconduct.

- 2. The Provider shall not be responsible for any costs, insurance and liability related to the transportation of the Material. The Recipient shall reimburse the courier with the costs of transportation of the Material either directly or via the Provider.
- 3. Prior to transportation of the Material appointments shall be made regarding the transportation and any special requirements such as the temperature at which it should be maintained. Such requirements and details concerning the Material should be specified in the Application Form and/or the Implementing Letter to this Agreement.

#### **Article 10. Financial Contribution**

1. The Material shall be provided to the Recipient at the amount of the fee indicated in the Implementing Letters. The exact amount of financial contribution shall be determined per Application. The financial contribution shall be paid by wire transfer, in Euros, within 30 days after receipt of the invoice.

#### Article 11. Term

- 1. This Agreement shall enter into force on the date of its signature by the Parties.
- 2. This Agreement is concluded for an indefinite period of time. Either Party may terminate this Agreement at any time and for any reason upon ninety (90) calendar days prior to written notice. Such termination shall not affect any obligations by either Party incurred up to the date of termination, nor shall it affect the ability of the Recipient to complete any research use of Material or Pseudonymized Donor Information transferred hereunder.

#### Article 12. Miscellaneous

- 1. The articles 3, 4.7, 5, 7 will survive termination of this Agreement.
- 2. The Recipient shall ensure that the Material is used in compliance with all applicable laws and regulations.
- 3. This Agreement is not assignable, whether by operation of law or otherwise, without the prior written consent of the Provider.
- 4. This Agreement shall be governed and enforced in accordance with the Laws of The Netherlands. All disputes arising in connection with this Agreement shall be attempted to be resolved amicably. If the dispute persists it shall be submitted exclusively to the competent court in Amsterdam, The Netherlands.

PROVIDER: Royal Netherlands Academy of Arts and Sciences (KNAW) acting for and on behalf of The Netherlands Brain Bank (NBB) a this matter by department of the Netherlands Institute for Neuroscience (NIN), whose registered office is at Meibergdreef 47, 1105 BA AMSTERDAM Z.O, The Netherlands, represented by

RECIPIENT: <name organisation> , established at <address>, represented in this matter by <name representative>, who was granted power of representation by the Executive Board

Name:	Dr. ir. J.C. Huijser	Name:
Job Title:	: Managing director of the NIN	Job Title:
Date:		Date:
Date.		Date.
Signature	<u>a</u> .	Signature: