 

PROTOCOL ONLY for TRANSFER OF ARTIFICIALIZED[[1]](#footnote-2) OR EXTRACTED[[2]](#footnote-3) HUMAN BODY MAterial TO A THIRD PARTY[[3]](#footnote-4)

**Template instructions**

* Blue info bars represent instructions and information – to be deleted from the final protocol version
* <Red text> to be edited to protocol specific language and changed to black font in the final version.
* Black text represents text that, if applicable, should by default be incorporated without editing
* If a particular section is not relevant to the study, include it, but indicate that it is not applicable.

**Delete this text !**

**<Protocol Full Title>**

**Version number:** v <Number> **– Date** <Version Date>

**Internal ref. nbr: SXXXXX[[4]](#footnote-5)**

**Sponsor[[5]](#footnote-6)/Recipient**

Institution:

Address:

**Recipient-Scientist**

Name:

Department:

Address:

Telephone:

Emai:

**Provider-Scientist on behalf of UZ/KU Leuven**

Name:

Institution:

Department:

Address:

Telephone:

Emai:

**Confidentiality Statement**

The information in this document is strictly confidential and is available for review to Investigators, potential Investigators and appropriate Ethics Committees, Institutional Review Boards or Competent Authorities. This protocol may be added as an appendix to a material transfer agreement between the parties (if applicable). No disclosure should take place without written authorization from the Sponsor, except that this protocol may be disclosed for both internal and external auditing purposes.

SIGNATURES

The undersigned Recipient-Scientist(s) confirm(s) that the above referenced protocol has been acknowledged and accepted, they agree to conduct the Study in compliance with the approved protocol, and will adhere to the applicable laws.

**Recipient-Scientist(s)**

………………………… ………………………… …………………………

Name & Title Signature Date

List Of Abbreviations

|  |  |
| --- | --- |
| **Abbreviation** | **Definition** |
|  |  |
| HBM | Human Body Material |
| EC | Ethics Committee |
| <insert other> | <insert other> |
|  |  |
|  |  |

Information about FUNDING AND SUPPORT (to be completed by recipient-scientist and to be submitted to the EC/IRB of the receiving institution)

|  |  |
| --- | --- |
| **Funder** | **Type of Financial or Non-Financial Support** |
| <insert name of company/fund> | <describe type and extent of funding/financial support > |
|  |  |

# Background and Rationale (to be completed by Recipient-Scientist)

Briefly explain the background, issues and medical relevance for why the artificialized or extracted HBM should be transferred.

<insert>

# Study Objective(s) (to be completed by Recipient-Scientist)

Outline the objective(s) for the use of certain artificialized or extracted HBM. Indicate if the recipient intends to use the artificialized or extracted HBM for genetic research.

Objective(s) for the use of the HBM or research description: <insert>

The HBM will be used by the Recipient-Scientist for genetic research: yes / no

* Type of genetic research: <insert>
* Genetic or genomic data (e.g. sequencing) of the HMB will be generated: yes / no
* Genetic or genomic data of HMB are intended to be deposited in a data repository: yes / no

# References

<insert>

# Details about the artificialized or extracted HBM or related data to be transferred (to be completed by Provider-Scientist)

in case the artificialized or extracted HBM has been self-modified, please provide clear information on the type of modification.

Instructions: in the case of multiple choice: strike through what is incorrect

Description/name of the HBM: <insert>

Was the original HMB obtained from UZ Leuven patients, healthy volunteers, residual material, third party: <insert>

In case the HBM is a modification from material that was obtained from a third party:

* the identity and name of the original source (e.g. third party, company, cell culture collection, …): <insert>
* type of modification: <insert>

Is the HMB pseudonymized, e.g. with a code or data that allows re-identification of the donor(s) (even only by UZ/KU Leuven if not by Recipient) or anonymized? <insert>

Description of related data to be transferred, if applicable:

* code: yes / no
* does UZ/KU Leuven have the key to link the code to the donor: yes / no
* will any other (clinical or pathological) personal data be transferred? If so, provide a clear description of these data (eg age, diagnosis, ...): <insert>

Status of the donor of the HBM: alive / deceased / unknown

## The original study of the artificialized or extracted HBM

Indicate the S-number under which the HBM was originally collected and/or created

<insert>

## Sample size

Specify the type and quantity of the artificialized or extracted HBM that will be transferred.

<insert>

## Informed Consent

Provide a brief description in case artificialized or extracted HBM and associated data were collected through informed consent on how the initial consent will be complied with. If artificialized or extracted HBM is anonymised, this paragraph can be completed with “Not Applicable”..

<insert>

1. Any human body material produced or cultivated outside the human body, such as cell lines or cell cultures, in which the “original” cells from a human donor have been completely replaced by “cultivated” or “produced” cells. [↑](#footnote-ref-2)
2. Material that has been extracted from human body material, which, however, no longer contains cells, such as organelles, ribosomes, mitochondria, etc. [↑](#footnote-ref-3)
3. UZ/KU Leuven will not be involved in the research conducted by the third party with the human body material provided by UZ/KU Leuven. [↑](#footnote-ref-4)
4. The S-number can only be filled in after EC Research UZ Leuven provides you with this number at submission. [↑](#footnote-ref-5)
5. The Sponsor of the study is the party who took the initiative for the study and designed the study concept. This is not necessarily the party providing funding for the study. [↑](#footnote-ref-6)