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| **Biobank Application Form** | | | | | | | | | | | | |
| Biobank approval is required for any research project collecting and/or using human bodily material (HBM). Please submit this fully completed form electronically to the Scientific Biobank (wbb@uzleuven.be - tel. 016 34 61 93). This document, signed by the biobank manager, is required to be enclosed with the initial submission of the dossier to the Ethics Committee Research UZ / KU Leuven (EC).  Please refer to the ‘Definitions & abbreviations’ section of this application form (page I) if clarification on the biobank-specific terms used throughout this document is required. | | | | | | | | | | | | |
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| Study Details | | | | | | | | | | | |  |
| S-number: | | | | S-number | |  | | |  | | | |
| Submission type: | | | | Initial submission | Amendment1 | | | |  | | | |
| PI | | | | Name | | *e-mail:* | | | Email | | | |
| UZ Leuven physician2: | | | | Name | | *e-mail:* | | | Email | | | |
|  | | | | | | *phone:* | | | Phone | | | |
| Study coordinator/CRA: | | | Name | | | *e-mail:* | | | Email | | | |
|  | | | | | | *phone:* | | | Phone | | | |
| Expected date at which the first sample will be collected: | | | | | | Sampling start date | | | | NA | | |
| Expected date at which the last sample will be collected: | | | | | | Sampling stop date | | | | NA | | |
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| Biobank application type | | | | | | | | | | | |  |
| Indicate which of the following categories apply to the concerning research project. Multiple answers are possible (e.g. established cell lines obtained from an external provider). Please complete the sections of the application form, indicated in the table below, for each applicable application type3. Section 3 until section 0 should be completed for all applications. | | | | | | | | | | | | |
| **Application type** | | | | | | | | | | | **Section** | |
|  | Clinical trial 4 | | | | | | | | | | [Complete section](#CT) 2.1 (2.3/2.4/[2.55)](#Section7) | |
|  | Externally obtained human bodily material | | | | | | | | | | [Complete section 2.2](#External) (2.3/2.4/[2.5](#Section7)5) | |
|  | Primary use of human bodily material | | | | | | | | | | [Complete section 2.3](#Prim) | |
|  | Setup a collection - Primary use of HBM (umbrella) | | | | | | | | | | [Complete section 2.3](#Prim) | |
|  | Setup a collection - Use of residuary material (umbrella) | | | | | | | | | | [Complete section 2.4](#Sec) | |
|  | Secondary use of remaining HBM after Primary use | | | | | | | | | | [Complete section 2.4](#Sec) | |
|  | Secondary use of Residuary Material | | | | | | | | | | [Complete section 2.4](#Sec) | |
|  | Production of cell lines/in vitro models/animal models from HBM for primary use | | | | | | | | | | [Complete section 2.3](#Prim) | |
|  | Production of cell lines/in vitro models/animal models from HBM for secondary use | | | | | | | | | | [Complete section 2.4](#Sec) | |
|  | Use of established cell lines/in vitro models/animal models | | | | | | | | | | [Complete section](#Cell) 2.5 | |
|  | Export of HBM | | | | | | | | | | [Complete section 2.3](#Prim)/[2.4](#Sec)/2.55) | |

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| Clinical trials | | | | |
| Please complete the following fields for any clinical trial regardless of the intended use of the HBM. | | | | |
| EudraCT nr: YYYY-NNNNNN-CC | | | | |
| Can any of the human samples collected within this clinical trial be used for a purpose other than what was provided in the submitted dossier?6 | | | | Yes  No |
| If not, the remaining part of section 2 and section 3 may be omitted.  If the previous question was answered affirmatively, the concerning samples fall within the scope of the Law on Human Bodily Material as referred to in Article 22 (cfr. Art. 3 §3 f, Law on HBM dd 19 December 2008). Therefore, a biobank will have to obtain the concerning samples in accordance with the provisions of this Law. If so, please specify in which biobank the HBM will be registered: | | | | |
| UZ/KU Leuven Biobank | |  | | |
| A notified Belgian Biobank other than UZ/KU Leuven Biobank, | |  | | |
| Please specify: | Biobank: Biobank name  FAMHP notification number: BB###### | |  | |
| If the HBM, available for future use, will be registered within the UZ/KU Leuven Biobank, this application form should be completed for those samples, and only those samples, which can be used for a purpose other than what was provided in the submitted dossier. Please complete [Section 2.3](#Prim) (primary use), [Section 2.4](#Sec) (secondary use) and/or [Section](#Cell) 2.5 (established cell lines /in vitro models/animal models). | | | | |

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| HBM – Externally obtained | |
| Please complete the following section for all HBM obtained from an external provider (i.e. any provider of HBM not related to UZ Leuven or KU Leuven such as a vendor,or foreign collaborating researchers ): | |
| Please select the purpose with which the HBM will be obtained below: | |
|  | Analysis only & destruction/return of remaining HBM (including derivatives) 7 |
|  | Analysis & storage of remaining material (including derivatives) for future use 8 |
|  | Set-up of a collection of HBM 8 |
| Please complete section 2.2.1 for all HBM obtained from external providers with the sole purpose of sample analysis after which any remaining HBM will be returned or destroyed. For those samples for which this is the case section 2.3 until 2.5 may be omitted. For all samples obtained from an external provider with the intention to store the HBM for future use [Section 2.3](#Prim) (primary use), [Section 2.4](#Sec) (secondary use) and/or [Section](#Cell) 2.5 (established cell lines/in vitro models/animal models) should be completed. | |

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| Externally obtained HBM for analysis only | | | |
| Please indicate for each external provider, which HBM will be obtained. Indicate whether the intended use is allowed within the scope of the previously obtained approvals from the Ethics Committee and confirm that the rights of the patients with regard to their consent were respected. Clarify what agreements exist regarding the destination/fate of the material after analyses. | | | |
| **Origin - Provider** | **Type/Quantity of HBM** | **Use** | **Destination/Fate of HBM** |
|  | All info equal to 1st row | All info equal to 1st row | All info equal to 1st row |
| Select origin  Name institution:  Institution  Address:  Address  HMTA available:  Yes  No  NA | HBM type ### Unit  HBM type ### Unit  HBM type ### Unit  HBM type ### Unit | Collection protocol approved by EC9   Yes  No  NA  ICF allows the intended use :  Yes  No  NA  If not: - New ICF will be obtained  Yes  No  NA  - EC waiver will be requested  Yes  No  NA | Select destination of remaining material |

To add an additional cell line, please click on the table and select the  sign which will become visible at the bottom right corner of the table.

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| HBM - Primary use |
| Please complete the following sections for all HBM that is part of the current application and for which the donor has explicitly and specifically given written consent in the context of the removal, storage and/or use of the material subsequent to being informed about all aspects of the research project to which this appertains. |

|  |  |  |
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| Origin of the HBM | | |
| List all samples that will be obtained using the table below. Complete one row per sample type. Indicate the sample origin as well as the collected quantities. | | |
| **Type of HBM/Donor** | **Origin/collection site** | **Quantity** |
|  | All info equal to 1st row | All info equal to 1st row |
| HBM type:  HBM type  Donor type  Select item. | Select origin  Name institution:  Institution  Address:  Address  HMTA available (import):  Yes  No  NA | Number of donors: ###  Number of time points: ###  Samples/donor/time point: ###  Quantity/sample: ### Unit  Total quantity/per donor: ### |

*To add an additional sample type, please click on the table and select the  sign which will become visible at the bottom right corner of the table*

|  |  |  |  |
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| Processing and storage of HBM | | | |
| Please list all derivatives that will be obtained from the samples mentioned above in the table below. Indicate where these samples will be stored, for which period of time and at which condition as well as the intended quantities that will be obtained per derivative type. Complete the shipment details if you intend to store/analyze these samples at a site other than UZ/KU Leuven. | | | |
| **Type of HBM** | **Quantity** | **Storage** | **Shipment** |
|  | All info equal to 1st row | All info equal to 1st row | All info equal to 1st row |
| Primary sample:  Enter HBM type  Derivative  Enter HBM type  no derivatives obtained10 | Number of aliquots/parent 11  ###  Aliquot quantity  ### Unit | Samples stored:  Yes  No  Condition: Select condition  Institution: Institution  Address:  Address  Period (during research project): ### | Samples shipped:  Yes  No  Institution: Institution  Consignee Name:  Consignee  Consignee Phone: Phone  Consignee Email: Email  HMTA available (export):  Yes  No  NA |

*To add an additional sample type, please click on the table and select the  sign which will become visible at the bottom right corner of the table.*

|  |  |
| --- | --- |
| Use of HBM | |
| Indicate the intended sample usage in the table below. | |
| **Type of HBM** | **Sample use** |
|  | All info equal to 1st row |
| HBM type  All HBM types | Quantity immediately used within project without biobank storage: ### samples  Quantity stored for use within the scope of the project: ### *samples*  Quantity stored for future use outside the scope of this project: ### samples |
|

*To add an additional sample type, please click on the table and select the  sign which will become visible at the bottom right corner of the table.*

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| --- | --- | --- | --- |
| Destination/Fate of remaining material | | | |
| Clarify what will happen to the samples after the study has been completed | | | |
| **Type of HBM** | **Destination/Fate of remaining material** | | |
|  | All info equal to 1st row | All info equal to 1st row | |
| HBM type    All HBM types | Select destination of remaining material | If stored for future use:  Name institution:Institution  Period (years): ### | Address: Address  FAMHP notification number12: BB###### |

*To add an additional sample type, please click on the table and select the  sign which will become visible at the bottom right corner of the table.*

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| HBM - Secondary use |
| Please complete the following sections for all use of HBM for which the donor has not given explicitly and specifically consent in the context of the removal, storage and/or use of the material. This includes the use of residuary material and the use of HBM that was obtained within a research specific context other than the project that is the subject of the current application. |

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| Origin of the HBM | | | |
| List all samples that will be obtained using the table below. Complete one row per sample type. Indicate the sample origin and the obtained quantities. Clarify whether the sample originates from an established - research specific - collection of HBM, has been obtained through an external provider or has initially been collected with a diagnostic and/or therapeutic purpose (i.e. residuary material). Indicate whether the intended use is allowed within the scope of the previously obtained approvals from the Ethics Committee and biobank and confirm that the patient's rights with regard to their consent were respected. | | | |
| **Type of HBM** | **Origin/collection site** | **Residuary/research specific material** | **Quantity** |
|  | All info equal to 1st row | All info equal to 1st row | All info equal to 1st row |
| HBM type:  HBM type  Donor type  Kies een item. | Select origin  Name institution:  Institution  Address:  Address  HMTA available (import):  Yes  No  NA | Select Origin Type  If originating from an established collection:  - ID of the collection protocol: S#####  - Collection protocol approved by EC13  Yes  No  - Collection protocol approved by biobank14  Yes  No  - If ICF does not allow the intended use  - New ICF will be obtained  Yes  No  - EC waiver will be requested  Yes  No | Number of donors  ###  Number of samples/donor  ###  Sample quantity  ### Unit |

*To add an additional sample type, please click on the table and select the  sign which will become visible at the bottom right corner of the table.*

|  |  |  |  |  |
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| Processing and storage of HBM | | | | |
| Please list all derivatives obtained from the samples mentioned above in the table below. Indicate where these samples will be stored, for which period of time and at which condition as well as the intended quantities that will be obtained per derivative type. Complete the shipment details if you intend to store/analyze these samples at a site other than UZ/KU Leuven. | | | | |
| **Type of HBM** | | **Quantity** | **Storage** | **Shipment** |
|  | All info equal to 1st row | | All info equal to 1st row | All info equal to 1st row |
| Parent sample:  HBM type  Derivative  HBM type  no derivatives obtained15 | | Number of aliquots/parent16  ###  Aliquot quantity  ### Unit | Samples stored:  Yes  No  Condition: Select condition  Institution: Institution  Address:  Address  Period (during research project): ### | Samples shipped:  Yes  No  Institution: Institution  Consignee Name:  Consignee  Consignee Phone: Phone  Consignee Email: Email  HMTA available (export):  Yes  No  NA |

*To add an additional sample type, please click on the table and select the  sign which will become visible at the bottom right corner of the table*

|  |  |
| --- | --- |
| Use of HBM | |
| Indicate the intended sample usage in the table below. | |
| **Type of HBM** | **Sample use** |
|  | All info equal to 1st row |
| HBM type  All HBM types | Quantity immediately used within project without biobank storage: ### samples  Quantity stored for use within the scope of the project: ### *samples*  Quantity stored for future use outside the scope of this project: ### samples |
|

*To add an additional sample type, please click on the table and select the  sign which will become visible at the bottom right corner of the table.*

|  |  |  |  |
| --- | --- | --- | --- |
| Destination/Fate of remaining material | | | |
| Clarify what will happen to the samples after the study has been completed. | | | |
| **Type of HBM** | **Destination/Fate of remaining material** | | |
|  | All info equal to 1st row | All info equal to 1st row | |
| HBM type  All HBM types | Select destination of remaining material | If stored for future use:  Name institution:Institution  Period (years): ### | Address: Address  FAMHP notification number17: BB###### |

*To add an additional sample type, please click on the table and select the  sign which will become visible at the bottom right corner of the table.*

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| HBM – Use of established cell lines/in vitro models/animal models |
| Please complete the following section for all use of established cell lines/ in vitro models/ animal models. These include commercially obtained cell lines/in vitro models/animal models, as well as previously created or obtained from an external, non-commercial, provider. No distinction is made based on whether cells are immortalized or not. |

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| Origin of the HBM | | | |
| List all cell lines/ in vitro models/ animal models that will be used in the research project that is the subject of this application using the table below. Complete one row per cell line. Indicate the origin as well as the obtained quantities and storage location, period and conditions. | | | |
| **Cell lines - In vitro/Animal model** | **Origin** | **Storage** | **Quantity18** |
|  | All info equal to 1st row | All info equal to 1st row | All info equal to 1st row |
| Name - ID  ID - Name  ICF available:  Yes  No  NA  Unknown  Ethical declaration available:  Yes  No  NA  HMTA available (import):  Yes  No  NA | Origin  Name institution or vendor:  Name  Address:  Address  ID of the protocol under which the cell line was created (if applicable): S##### | Condition: Select condition  Name institution:  Institution  Address:  Address  Period (years): ### | Number of cells  ### |

*To add an additional cell line, please click on the table and select the  sign which will become visible at the bottom right corner of the table.*

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| Sample and donor coding | |
| Describe the method that will be applied to code the samples and donors19: | |
|  | Anonymization20 |
|  | Pseudonymisation |
|  | Fully identifiable donors and samples |
| In case of pseudonymisation, control over the identification key and the responsibility to communicate any information to the donor, in the event that the analyses of the samples generate findings that have a significant impact on his/her health status, rests on:   * Name: *Name* * Contact details: Contact | |
| Documents | | |
| In order to allow the UZ/KU Leuven biobank to perform an informed assessment of the content of the research project, we ask you to include the following documents with your application if applicable.  Required for all dossiers:   * + The biobank application form (BB-GEN002-FO03)   + A copy of the study protocol   + A copy of the CTC registration form   + A model of the informed consent form if required according to the applicable regulation * Additionally, in case of:   + HBM obtained from an external provider:     - A collection protocol approved by an EC /IRB and model of the informed consent form.     - An ethical declaration from the provider or manufacturer stating that the concerning HBM was obtained in accordance with the legislation in force in the country of origin and in accordance with international standards of ethics and protection of privacy and personal data when obtained from a commercial vendor.     - HBM Transfer Agreement in case the HBM originates from outside Belgium, if available. * Optional:   + Lab manual, HBM Transfer Agreement or any other relevant information with regard to the HBM. | | |

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| Terms and conditions |
| The principle investigator:   * confirms that the data provided in this application form is complete and correct. * confirms that the collection, processing, storage and/or use of the HBM within the context of this research project will remain limited to what is described within this application form and the accompanying study documents. * agrees that the removal of HBM from living donors intended exclusively for procurement by a notified biobank is carried out by a healthcare professional as defined in the coordinated Law of 10 May 2015 on the exercise of healthcare professions (i.e. physicians, dentists, nurses, midwives, pharmacists and chemists authorized to conduct clinical biology analyses or medical laboratory technicians). * agrees to maintain traceability as described in Article 22 of the Belgian Law on Human Bodily Material of 19 December 2008 using any inventory management system or documenting system such as a(n) (electronic) lab notebook. * agrees that, in case that Art. 11 of the Belgian Law on Human Bodily Material of 19 December 2008 applies, any feedback, in the event that sample analyses generate findings that have a significant impact on the donor’s health status, will be communicated to the biobank. * agrees to register the HBM into the UZ/KU Leuven biobank registry as described in annex BB-TEC002-AN01. All documents related to the registration of the HBM within the registry will be provided after the approval of the research project. * confirms that all required technical and organisational measures are in place in order to guaranty the protection of the donor’s personal data in accordance with the provisions stated in EU regulation 2016/679 and the Belgian Law on the protection of natural persons with regard to the processing of personal data dd 30 July 2018. * agrees that, in case of residuary material, he/she will check whether the subjects, intended to be included in the research project, have not objected against the use of their HBM. * agrees that, if applicable, all long-term storage is located within the central storage facility of the UZ/KU Leuven biobank unless otherwise agreed on a case-by-case basis. * in case the present biobank application concerns the alignment of a (historical/legacy) project to the current biobank regulation and policy, he/she confirms that the necessary steps and approvals, required at the time the project was initiated, were achieved for this study. * agrees to notify the biobank of any substantial amendments that affect the HBM aspects of the research project. |

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| Approval | | | |
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| **Signature Principle Investigator** |  | **Signature Biobank Manager** |
| Name: |  | Name: |
| Date: |  | Date: |
| Signature: |  | Signature: |

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| Definitions and abbreviations | |
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| **Anonymization:** | Process by which personal data is irreversibly altered in such a way that a data subject can no longer be identified directly or indirectly, either by the data controller alone or in collaboration with any other party. The concept is absolute, and in practice, it may be difficult to obtain. (ISO 25237:2017) |
| **Cell lines:** | Cell lines (= cells that are manipulated in such a way that their characteristics differ from the original cell, such as industrial preparations) fall within the scope of the Law on HBM. Art. 21 of this Law describes that any secondary use of HBM (including cell lines, regardless of the degree of their manipulation) requires EC approval before the start of the research. (cfr. Newsletter Ethics Committee Research UZ/KU Leuven Number 6 – June 2019) |
| **Clinical trial:** | Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the goal of ascertaining its (their) safety and/or efficacy. (cfr. Art. 2, 7°, Law on experiments on man dd 07 May 2004) |
| **Collection of material for future use within a clinical trial:** | HBM collected within clinical trials is excluded from the scope of the Law on HBM. This means that there are no additional requirements when the material is collected and used as described in a clinical trial application submitted to the FAMHP and an Ethics Committee. However, in the event of the human bodily material being used within experiments for a different purpose, the human bodily material being distributed for a different purpose or the human bodily material being intended for a different purpose, the concerning samples fall within the scope of the Law on HBM as referred to in Article 22. A biobank will have to obtain the concerning samples in accordance with the provisions of this Law. (cfr. Art. 3, §3, f), Law on HBM dd 19 December 2008) |
| **Commercial material:** | Any HBM originating from a provider which activities are driven by a profit motive, including but not limited to commercial cell lines. |
| **CRA:** | Clinical Research Associate |
| **EC waiver:** | For research that implies no more than minimal risk, the Ethical Committee (EC) may approve a request to waive the required elements of informed consent under specific circumstances. Waivers of informed consent are primarily requested for projects involving secondary analysis in which there are minimal risks to the subjects. |
| **Export:** | All samples exported outside Belgium must first be registered in one (or more) Belgian biobank(s) before being sent abroad. There must be a contract or framework agreement with the end user or biobank abroad. Through this contract or agreement, it is determined how the obligations relating to traceability, the control of the donor's consent and the feedback to the donor of the human bodily material will be respected. (Compendium biobanken/biobanques/biobanks – 20 July 2018, FAMHP) |
| **Externally obtained HBM:** | Any HBM obtained from a provider not related to UZ Leuven, KU Leuven or VIB Leuven such as a vendor, a Belgian biobank different from the UZ/KU Leuven biobank (collaborations between Belgian researchers require a provision of HBM by a Belgian biobank) or foreign collaborating researchers. |
| **Ethical declaration:** | A statement of the vendor providing the necessary guarantees that the sample has been taken in accordance with the legislation in force in the country of origin and in accordance with international standards of ethics and protection of privacy and personal data. |
| **FAMHP:** | Federal Agency for Medicines and Health Products |
| **GDPR:** | General Data Protection Regulation |
| **Human bodily material (HBM):** | Any human biological material, including human tissues and cells, gametes, embryos, foetuses, and substances derived therefrom, and regardless of the degree of their transformation. |
| **HBM transfer agreement (HMTA):** | Before making samples available, a written agreement must be concluded between the biobank and another biobank or an end user. This applies to both the transfer of human bodily material in Belgium and to export. The content of the written agreement includes the following items at the minimum:   * The object of the scientific research for which the human bodily material is made available; * Responsibilities to ensure traceability; * If personal data are provided by a biobank when human bodily material is made available, the description of the appropriate technical and organisational measures; * In the case where the biobank, following the provision of HBM, communicates personal data to another biobank:   + In the case of living donors, a template of the consent form (with the contents of the consent) is attached to the agreement;   + In the case of deceased donors or residual human bodily material, the declaration that the legal provisions have been complied with is attached to the agreement.   (Compendium biobanken/biobanques/biobanks – 20 July 2018, FAMHP) |
| **ICF:** | Informed consent form |
| **ID:** | Identification |

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| **Import:** | The procurement of any HBM from an external provider originating from outside Belgium. All samples imported from abroad for use in Belgium, to the extent that they fall within the scope of the Law on HBM, must be registered upon entry into Belgium by a Belgian biobank with which a contract or framework agreement is concluded. This obligation is independent of whether it concerns samples from another biobank, a commercial organization or a hospital. (Compendium biobanken/biobanques/biobanks – 20 July 2018, FAMHP) |
| **Notified biobank:** | An institution recognized by the FAMHP which, in the context of scientific research (excluding research with human medical application), obtains, processes, stores and provides HBM, as well as, if applicable, the data relating to the HBM and the donor. |
| **Parent sample:** | HBM that is the starting point for obtaining derived samples, irrespective of the degree of processing, for which a parent/child-like lineage between the HBM and its derivatives can be established (e.g. whole blood (parent) from which serum (child) is extracted). |
| **PI:** | Principle Investigator |
| **Primary Use:** | Any use of HBM for which the donor has explicitly and specifically given his/her consent in the context of the removal of the material. (cfr. Art. 2, 29°, Law on HBM dd 19 December 2008) |
| **Processing:** | Performing any activity on biological material and associated data during all stages of the consecutive and interlinked processes applied to biological material and associated data from collection, if applicable, acquisition or reception to distribution, disposal or destruction. (ISO 20387:2018 Biotechnology — Biobanking — General requirements for biobanking) |
| **Pseudonymisation:** | Particular type of reducing the association between a set of identifying data and the data subject that both removes the association with a data subject and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms (personal identifier that is different from the normally used personal identifier). (ISO 25237:2017) |
| **Remaining material:** | Any HBM that was collected within the context of a research project that remains after the project has been concluded. |
| **Residuary Material:** | Any HBM that has been removed for the purpose of diagnosis or treatment of the donor that - after a sufficient and relevant part is retained for making, refining or completing the diagnosis or treatment of the donor based on new scientific data - could be destroyed. (cfr. Art. 2, 33°, Law on HBM dd 19 December 2008) |
| **Secondary Use:** | Any use of human bodily material for a purpose other than that for which the donor has given his/her consent in the context of the removal of the material. (cfr. Art. 2, 30°, Law on HBM dd 19 December 2008) |
| **Umbrella:** | An over-arching protocol describing the collection of HBM that shares a common denominator, in order to serve a common, yet specific and relevant scientific research aim concerning a broader spectrum of conditions. Each future use of the included biospecimens requires a new EC and biobank approval of the dossier focused on the secondary use, before the start of the research. |