



Belgian Association of
Research Ethics Committees

EC SUBMISSION FORM FOR BIOBANKS

Purpose of the document

This document aims to harmonise the process related to the initial submission of a biobank to the ethical committee as required in the Royal Decree on the biobanks dd. Jan. 09, 2018. The document serves as a guideline to the Biobank (Professional) Manager and as an evaluation checklist to the Ethical Committees. The document is however not a list of strict (legal) criteria and can be deviated from in order to most adequately inform the evaluating ethical committee.

Authors

Ann Bracke, Hilde Debois, Aernout De Raemaeker, Anne Gabriel, Pieter Moons (coordinator), Marianne Paesmans, Angélique Rézer, Robert Rubens, Ruth Storme, Kimberly Vanhees, Christel Vansteenkiste, Audrey Van Scharen, Steven Van Wortswinkel, Peter Vermeulen

With revisions and input from:

- The Belgian Ethical Committees
- The compendium working group
- BBMRI.be
- BAREC



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Information Biobank

Biobank

Name

Address

Manager (“uitbater”¹ “exploitant”) of the Biobank (responsible for)

Name

Address

Email address

Professional manager² (“beheerder” “gestionnaire”) biobank

Name

Address

Email address

Institution

Number of “Orde van Artsen”/ “Ordre des Médecins” (if applicable)

Please provide the CV

In order to enable to evaluate the operational capacity of the biobank, please provide a brief description of other biobank associated staff and their role in operating the biobank. This can take the form of text, table or organigram

¹ As defined in art. 1, 4° of the Royal Decree dd. Jan. 09, 2018

² As defined in art. 2, 28° /1 of the HBM Law dd. Dec 19, 2008 and art. 11 Royal Decree dd. Jan 09, 2018



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Biobank quality management systems

Although quality management systems are not a legal requirement, having a quality management system in place inspires confidence to the EC that the biobank operates according to certain standards. Please indicate whether you adhere to (this is **no legal requirement** and has no impact on the evaluation!)

- ISO 9001 date of last accreditation dd/mm/yyyy
- ISO 20387 date of last accreditation dd/mm/yyyy
- Other..... date of last accreditation dd/mm/yyyy
- Internal QMS
- None

Description of HBM in the Biobank

Please provide a general description of the (future) material in your biobank:

.....

Examples of material include

- Body fluids (blood, urine, feces, vaginal wash,...)
- Tissues (FFPE, Fresh frozen,...)
- Derived material (DNA, RNA, proteins,...)
- Cell lines

Aims and activities Biobank

Please provide a general, but specific, description of the aims and objectives of your biobank:

.....

Please indicate which research domains and types of research will be supported by your biobank:

Examples of research domains include:

- Ageing, cardiology, immunology, infectious diseases, gynaecology, oncology

Examples of types of research include:



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- Genomics, metabolomics, biomarker studies, development of diagnostic test or procedure³,...

Activities

Please indicate the type of activities that will be performed by your biobank:

Storing HBM

For indefinite period of time (long term biobank)

For limited period of time (temporary biobank):

Timeframe:

For own institution only⁴

Acting as the biobank for another institution/organization/company :

Import and/or collection of HBM

Territorial

From Belgium

From other country in EEA

From outside EEA

Source

Industry (biobank / lab)

Academia (university (hospital) / biobank / lab)

Other: ...

Donor

From living donor

³ If the activity is limited to technical validation this should not be part of this application as technical validation does not fall under the scope of the Belgian Law d.d. 19 December 2008 regarding the procurement and use of human biological material intended for human medical applications or for scientific research purposes.

⁴ HBM will not be made available to third parties outside your own institution.



“Prospectively collected” HBM: Research HBM obtained in the setting of a research project/study approved by the Medical Ethical Committee (MEC) (“Primary use”)

“Residual” HBM (art.2, 33° Belgian Law d.d. 19 December 2008 regarding the procurement and use of human biological material intended for human medical applications or for scientific research purposes (“HBM law”): HBM primarily obtained for diagnostic purposes or for therapeutic interventions but not (longer) needed for additional diagnosis and as such may be discarded

“left-over” HBM: remaining after the scope / objectives of the primary use for a research project/study have been accomplished

From deceased donor

Collection of material after decease for scientific research purposes (art. 12 HBM law)

Making HBM available

To whom

- To industry (commercial biobank / lab)
- To academia (university (hospital) / biobank / lab / investigators)
- To own institution only

To where (export)

- HBM remains in Belgium
- HBM goes to another country in EEA
- HBM goes outside EEA

In support of the above, it is mandatory to provide the following documents. These documents should cover at least all checked boxes which thus serve as a guidelines to what should be included in the SOP. These SOPs target procedures that are legally imposed.

SOPs describing sample collection and import for storage in biobank, including guarantees related to ethical approval, consent status and privacy laws including:

- Checks related to the approval of the research protocol and template ICF by an EC/IRB



- Guarantees (provider qualification) that sample collection occurred conform locally applicable legislation and international ethics and privacy standards
- Guarantees that in Belgium collected HBM complies with the Royal Decree d.d. 9 January 2018 concerning the biobanks with regard to who collects the HBM and whether collection occurs in a healthy and safe environment with respect for privacy.
- Evaluation procedure by the professional manager of the consent status of the incoming material including workflows in case of doubt (contacting suppliers, quarantine procedure, approval via EC in case of continued doubt)

SOPs describing how HBM is made available to the end user, including

- Request procedure (template sample request form)
- Request evaluation procedure (eligibility for access to HBM, list of documents that need to be provided in support of the evaluation, criteria, evaluation of consent status)
- Template HBMTA

This document should contain the following minimal items:

- The nature of the research for which the material is provided. This should be in line with the aims and activities of the biobank
- Responsibilities related to the traceability of the HBM
- In case of provision of personal data (from the medical record), a section on the appropriate technical and organizational measures to ensure safekeeping (GDPR)

Template framework agreement with end users and/or other biobanks (if applicable)

This document should contain the following minimal items:

- A general description of the research for which the HBM is provided
- A reference to specific, written agreements covering the specific research purpose of samples within research projects covered by this framework agreement
- Responsibilities related to traceability, personal data and consent
- Workflow related to the transfer of personal data, including the transfer of template consent forms (living donor) or declaration of compliance with applicable laws (deceased donor or residual material)

An overview of the financial compensations requested by the biobank (no profit on the material as such can be made)



Sample and data management system

Traceability

The biobank contains

- Traceable HBM (pseudonymised)
- Non-traceable HBM (anonymised)

Sample management system

- Allows for the registration of samples and corresponding data
- Ensures the traceability of the samples and derivatives thereof (if applicable)
- Allows to generate the minimal data required for the bi-annual evaluation by the EC / for the competent authorities (upon request)
- Allows to shield personal data from users, except for the professional manager
- Allows the professional manager to inform the patient or treating physician in case of incidental findings; if not applicable, please motivate: ...

In support of the above, it is mandatory to provide the following documents. These documents should cover at least all checked boxes.

SOP documenting the data fields recorded in the data management system.

- Minimal requirements incoming material: type of HBM, date of receipt, origin (incl. contact details), anonymized versus pseudonymised (incl. ID-number)
- Minimal requirements outgoing material: date of delivery, contact details receiver, anonymized versus pseudonymised (incl. ID-number), feedback to the donor or treating physician in case of incidental findings (if applicable)

SOP documenting the rules related to traceability, patient withdrawal and incidental findings including:

- procedures related to the removal strategy of samples and all derivatives in cases of patient withdrawal
- procedures related to lifting of traceability.
 - For living donors, lifting of traceability is only possible with donor consent. For deceased donors or in case of residual material, traceability can be lifted by the professional manager, a medical doctor in the involved lab of clinical biology, the



- head physician of the involved hospital or the medical doctor in the involved blood processing centre.
- Once in the biobank traceability can only be lifted with consent of the donor or, if deemed impossible or exceptionally inappropriate, by positive advice from an EC, or upon transformation of the HBM.
 - procedures documenting the flow related to incidental findings
 - The donor has the right to be informed in case clinically relevant and validated information becomes available.
 - Information should occur by the medical doctor responsible for obtaining the HBM or when obtained in a hospital by the head physician of the hospital or when obtained in a blood processing centre by the person liable for the centre.
 - In accordance with the law of 22 August, 2002 concerning the rights of the patient:
 - The communication with the patient should occur in a for him/her understandable language
 - The patient can request a written confirmation
 - The patient can request assistance from a trustee
 - The information will not be provided to the patient
 - Upon his/her explicit request, unless not providing the information would result in serious consequences for the health of the patient or third persons and then only after obtaining a second opinion and after consulting the appointed trustee, if applicable.
 - If the information is deemed to result in serious medical consequences for the patient, but only after obtaining a second opinion.

Termination of the biobank

An SOP should be available documenting:

- The reporting strategy to the FAGG and the EC indicating the destination of the in the biobank available HBM
- The conditions and procedures that apply for the transfer of HBM to another biobank or its destruction in case of non-transferability



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Additional documents that are required for the submission to the FAGG

- FAMHP application form
- Floor plan of the premises of the biobank
- Copy of the EC approval (which cannot be provided as this should result from this submission form)
- Copy of the diploma of the professional manager

Additional documents

Please provide the following:

- Declaration on honor by the DPO or person responsible for the data processing that the biobank operates according, and ensures compliance with, the applicable privacy laws.

Date

Signature of the Professional manager (“beheerder” “gestionnaire”)

As professional manager of this biobank I hereby declare that human body material stored in this biobank shall not be used for financial gain.