Belgian Association of
Research Ethics Committees

EC FORM FOR BIENNIAL EVALUATION OF BIOBANKS

Purpose of the document

This document aims to harmonise the process related to the biennial evaluation of a biobank by the ethical committee (EC) 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. Preferentially, this form is submitted to the same EC that performed the initial or previous evaluation of the biobank.

Authors

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With revisions and input from:

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

Information Biobank

Biobank

Name

Address

Manager ("uitbater"[1] "exploitant") of the Biobank (responsible for)

Statute Exploitant: [natuurlijk persoon - personne morale / rechtspersoon - personne physique]

Name:

Official Address

Contact person exploitant:

Email address contact person:

Professional manager[2] ("beheerder" "gestionnaire") biobank

Name

Address

Email address

Institution

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

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

Biobank quality management systems

Although quality management systems (QMS) 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

In the document "EC SUBMISSION FORM FOR BIOBANKS", or previous version of the "EC FORM FOR BIENNIAL EVALUATION OF BIOBANKS" a general description of material kept in your biobank and/or provided to end users/other biobanks was provided:

Examples of material include

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

Please indicate whether the range of materials has expanded/reduced since your last submission to the EC and list the material types that have been added/removed.

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Overview of HBM stored in the biobank and/or made available (The registry)

Please provide a copy of the register (preferentially in electronic form), listing the HBM that was additionally stored in the biobank since your last submission to the EC.

This overview should at least contain the information that needs to be registered by law as listed in Annex I to the Law of 2008 on Human Materials:

- Type of material
- Date of receipt
- Source (contact details of the hospital, physician, biobank or third party from which the HBM was obtained
- whether the material is traceable or non-traceable, and if traceable the ID-number

Please provide a copy of the register, providing an overview of the HBM that was provided by the biobank since your last submission to the EC.

This overview should at least contain the following information that needs to be registered by law as listed in Annex I to the Law of 2008 on Human Materials.

- Type of material
- Date of shipment
- Contact details recipient
- whether the material is traceable or non-traceable and if traceable the ID-number
- Every application of article 11 of the law (incidental findings)

To enable the verification that the purpose and finality of the intended research use of a sample correspond to the purpose for which the biobank was accredited, the purpose should be listed when applicable.

Aims of the Biobank

In the document "EC SUBMISSION FORM FOR BIOBANKS", or previous version of the "EC FORM FOR BIENNIAL EVALUATION OF BIOBANKS" a specific description of the aims and objectives of your biobank was provided

Please indicate whether the aims and objectives of your biobank were expanded/reduced since your last submission to the EC and indicate which aims and objectives were added/removed:

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Activities of the Biobank

Activities may include collection, handling, conservation, storing, distribution, use and research, including import, export of HBM.

Please indicate whether the activities of your biobank will be expanded/reduced as compared to your last submission to the EC and indicate which activities were added/removed:

……

Traceability

The biobank contains

☐ Traceable HBM (pseudonymised)

☐ Non-traceable HBM (anonymised)

Additional documents

Please provide the following:

- Update of the floor plan of the premises of the biobank
- Copy of the previous EC approval
- The initial EC submission form and last biennial evaluation forms (if any), exclusive of the registry
- 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.
- CV of the professional manager if changed since last submission
- Comprehensive list of major non-conformities received in the framework of ISO20387 audits or during inspections from the FAMPH since the initial submission or last evaluation by the EC

SOP's and/or other documents, as listed below, form an integral part of this evaluation procedure. The SOPs as required under the initial submission of the Biobank to the EC should be provided to the extent that substantial amendments were made or if additional SOP's have been put in place. In such case, please clearly indicate which substantial amendments were made to existing SOP's/documents and/or which new SOP's/documents were added to the submission. More details about the potential content of such SOPs can be found in the document "EC SUBMISSION FORM FOR BIOBANKS". If the biobank is ISO 20387 accredited, the submission of these SOPs to the EC is not required as the accreditation process replaces the SOP evaluation process by the EC.

- SOPs describing sample collection and import for storage in biobank, including guarantees related to ethical approval, consent status and privacy laws.
- SOPs describing how HBM is made available to (i) another biobank or (ii) a third party end user.
- SOPs documenting the data fields recorded in the data management system.
- SOPs describing the donor identification system (only when the biobank handles traceable materials).
- SOPs documenting the rules related to traceability, patient withdrawal and incidental findings.
- SOPs detailing how non-conformities are handled
- An overview of the financial compensations requested by the biobank (no profit on the material as such can be made) when deliveries are made to third party end-users or other biobanks.
- SOP detailing the termination procedure of the biobank

Signature

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.