Bundesministerium
für Bildung
und Forschung

Leitfaden für die Antragstellung
zur Förderung einer nationalen Biomaterialbankeninitiative

Anträge zu Biomaterialbanken sind entsprechend den Vorgaben dieses Leitfadens zu erstellen (DIN A4, maximal 20-seitig incl. Literaturverzeichnis, in englischer Sprache). Anträge, die den Vorgaben des Leitfadens nicht entsprechen, können nicht berücksichtigt werden. Zur Erstellung Ihrer Vorhabensbeschreibung benutzen Sie bitte die Formatvorlage auf der Internetseite des BMBF bzw. des Projektträgers.

Die Antragstellung erfolgt elektronisch über das Internet-Portal (http://www.pt-it.de/ptoutline/cbmb). Dort ist die Vorhabenbeschreibung im PDF-Format hochzuladen. Im Rahmen der elektronischen Antragstellung wird ein PDF zur Authentifizierung der Antragsteller/in generiert. Damit die elektronische Version der Vorhabenbeschreibung Bestandskraft erlangt, muss dieses Dokument nach erfolgter elektronischer Antragstellung zusätzlich in Papierform mit rechtsverbindlicher Unterschrift des Antragstellers beim Projektträger eingereicht werden.

Es wird empfohlen, die einschlägigen internationalen Standards der OECD (www.oecd.org/dataoecd/41/47/44054609.pdf, www.oecd.org/dataoecd/7/13/38777417.pdf) und die Empfehlungen des Europarates über Forschung mit humanbiologischem Material zu berücksichtigen (www.coe.int/t/dg3/healthbioethic/texts_and_documents/Rec_2006_4.pdf) sowie die Dokumente und öffentlich verfügbaren Ressourcen des TMF e.V. (www.tmf-ev.de/produkte) zu Rahmenbedingungen von Biomaterialbanken einzusehen.

Die Vorhabenbeschreibung kann **bis spätestens 15. September 2010** beim Projektträger elektronisch eingereicht werden.

Application for the Funding of a Centralised Biomaterialbank (cBMB)

Please prepare your application in English **not exceeding 20 pages for the headings 1. to 12.**, including a maximum of 1 page of references (DIN A4, at least 11 point Arial). Structure your application using the headings listed below. Make an entry (n.a. = not applicable, if appropriate) under **every** heading and a comment to **every** sub-heading (bullet point).

Note: Applications that fail to comply with these requirements will be considered incomplete and will be rejected without peer review.

1. BIOMATERIALBANK SYNOPSIS

<table>
<tr><td>APPLICANT/
COORDINATING
INVESTIGATOR</td><td>Please name one person (Name, employment status, institution and department)</td></tr>
<tr><td>ORGANISATION</td><td>Please mention the name of the institution presenting this application (hosting institution).</td></tr>
<tr><td>TITLE</td><td>The title of the project (not exceeding 140 characters) should be as precise as possible.</td></tr>
<tr><td>BIOBANKS TO BE INCORPORATED</td><td>Example:
<table>
<tr><th>Name of Biobank</th><th>Biobank Operator and Affiliation</th><th>Contribution besides Samples (if applicable)</th></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
(Only list BMBs to be included in your cBMB and fulfilling ALL of the following criteria: international publications in peer reviewed journals, national/international grant acquisition including material/data to third parties AND documented quality assurance, for details see appendix C)</td></tr>
<tr><td>ADDITIONAL MAJOR PARTICIPANTS</td><td>Example:
<table>
<tr><th>Name</th><th>Affiliation</th><th>Contribution/ Role</th></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
(List participants e.g. persons responsible for data protection concept, central IT infrastructure or already established centralised databases NOT all persons involved in the cBMB concept)</td></tr>
</table>

2. EXISTING RESOURCES AND DEVELOPMENTAL CONCEPT

2.1 SUMMARY

Shortly present your institution, main research fields and the activities planned to establish a cBMB. Summarize the aims of your project:

- ...
- ...
- ... (up to 8)

2.2 INTERNATIONAL PERSPECTIVE

Set your cBMB into perspective. Do related (systematic) collections exist nationally and/or internationally?

2.3 CONCEPT FOR SETTING UP A CENTRALISED BMB

- Local prerequisites: Describe the existing infrastructure and "handling" of BMBs at your institution. Which relevant resources and centralised processes in terms of BMBs are already in place and will be integrated into the process?
- Specify measures to be taken to develop and/or expand towards a cBMB.

2.4 ETHICAL CONSIDERATIONS AND DATA SAFETY

Please comment on ethical considerations and data safety aspects relating to the cBMB.

- Describe how existing legal requirements for data protection are currently met.
- Do experiences exist with networking BMB-projects? If yes, please document details.
- Describe the current situation regarding informed consent and sample ownership. Is the use of material collected in studies / trials possible beyond the original research aims?
- If applicable, comment on future strategies to allow broad / expanded use of material. Describe the project plan to obtain positive opinions of ethical committees and data protection officers.

3. ORGANISATION AND SCOPE OF INTENDED CENTRALISED BMB

3.1 STRUCTURE OF cBMB

- Organisational model of your intended cBMB (e.g. centralised collection vs. decentralised collection)
- If applicable, services provided by the cBMB (e.g. RNA/DNA extraction, immunohistology / TMA, PCR, Affymetrix Chips)

3.2 DATA AND MATERIAL ACQUISITION AND STORAGE

Describe the concept of a centralised data and material acquisition and storage. Please comment on the following points:

- Type of data to be sampled and stored (data of patient, data of the sample(s), data of sample analysis?)
- Type of equipment used for data recording and material storage (including IT-solutions)
- Information contained within the database (e.g. clinical, genetic, pathological information). Who will provide the input?
- Management concept for updating and maintenance of the database

4. DEVELOPMENT OF DATA SAFETY CONCEPT

Depending on organisational model of the cBMB, describe key elements of the future data protection concept:

- Technical and organisational instruments
- Data recording and storage
- Data and material transfer

5. QUALITY ASSURANCE

Describe the current and future organisational and technical measures for quality assurance and quality control (e.g. coding of data, second control of coding, documentation of data corrections). Describe key elements of the future quality management system:

- Development and implementation of Standard operation procedures (SOPs)
- Quality manual (Workflow)
- Feedback strategies concerning material and data quality
- Implementation of GLP guidelines
- External quality assurance/monitoring

6. CBMB OPERATORSHIP AND MANAGEMENT

Is there a strict policy for centralised operation and management of any local specimen collection? Describe your concept for operation and management of the cBMB including comments on the following aspects:

- Operator of the cBMB
- Legal status of the cBMB
- Organisation of access to the cBMB (roles and rights, independent board, material transfer agreements)
- Intellectual Property Rights (e.g. rules for authorship and secondary usage)
- If applicable, usage fee (i.e. amount, difference between internal and external usage)

7. INTERNATIONAL COOPERATIONS

Describe collaboration with organisations / institutions in other countries.

8. INFRASTRUCTURE AND SPATIAL CONCEPT

Describe current facilities and other resources available for conducting the cBMB. Describe the future spatial concept for your cBMB including information on location of the cBMB, equipment and size.

9. SUSTAINABILITY

Comment on the sustainability of the cBMB after BMBF funding. Describe how the established infrastructure and services (if applicable) will be maintained after the termination of BMBF funding. Please provide a declaration of the host institution (cf. appendix A) assuring to maintain the cBMB beyond BMBF funding

10. MILESTONES

Please provide a table showing planned implementation of the cBMB; give milestones. What will be completed at what points in time?

11. REFERENCES

12. FINANCIAL DETAILS

12.1 FINANCIAL SUMMARY

The overall expenditure should be summarised in the table below. Please, provide both man months and Euros for employment costs and state the requested funds separately for each year of the project.

Please list all requested instrumentation/ consumables with price information in the table below.

12.2 OTHER FUNDING

In case you have already submitted the same request for financial support or parts hereof to other institutions, please mention this here. Indicate those third parties which will provide funds, free services or consumables for the BMB.
If this is not the case please declare:
"A request for funding this project has not been submitted to any other addressee. In case I submit such a request I will inform the Federal Ministry of Education and Research immediately".

FINANCIAL PLAN

Personnel												
	Organizational Segment	**Institution/ Participant**	**Job Specification**	**Qualification of staff**	**TVöD/ BAT**	**Full Time Equivalents**	**Total (T€)**	**y1 (m/T€)**	**y2 (m/T€)**	**y3 (m/T€)**	**y4 (m/T€)**	**y5 (m/T€)**
1	*e.g. Scientific cBMB Management*											
2	*e.g. Technical cBMB Management*											
3	*e.g. Data (Security) Management*											
4	*e.g. IT*											
5	*e.g. Quality Assurance*											

Equipment / Consumables									
	Type of Equipment/ Consumables	**Justification**	**No of items**	**Total (T€)**	**y1 (T€)**	**y2 (T€)**	**y3 (T€)**	**y4 (T€)**	**y5 (T€)**
1									
2									
3									
	TOTAL			€	€	€	€	€	€

APPENDICES

A. INSTITUTIONAL COMMITMENT

Please provide a declaration of the host institution assuring to maintain the cBMB beyond BMBF funding. Specify resources that will be put at the disposal of the cBMB (staff, housing, etc.), indicate amounts in Euro.

B. DECLARATION OF COMMITMENT BY BMB OPERATORS AND OTHER MAJOR PARTICIPANTS INVOLVED

Provide a declaration of commitment of all operators of BMBs to be incorporated into the cBMB and, if applicable, of additional persons crucial for the cBMB and its operational aspects as listed under "1. Study Synopsis".

C. DESCRIPTION OF BMBs TO BE INCORPORATED

Please fill in one form for each relevant BMB (as listed under "1. Study Synopsis") fulfilling at least ALL of the following criteria:

- Usage of the BMB (material and/or data) to scientific aims shown by international publications in peer reviewed journals AND
- Documented conduct of projects granted national / international funding having used material / data from the BMB AND
- documented quality assurance.

Make an **entry** (n.a. = not applicable, if appropriate) in every cell, **replace** comments in italics and **delete** all items that do not apply where appropriate. Column width is to remain constant and total length of the table is **not to exceed two pages.**

BIOMATERIALBANK SUMMARY

1. GENERAL BMB INFORMATION	
Complete Name	
Acronym	
Website	
Operator (name and affiliation)	
Organizational Format	Stand alone BMB (delete items that do not apply) Single BMB integrated in a network Network with several sites/providers Other, please specify Centralised collection (multiple providers, storage in one place) Decentralised (multiple providers, storage in several places)
Financial Support (last 5 years)	Institutional funding: – *in EURO* Public funds: – *in EURO* Funds from industry: – *in EURO* Funds from charity/foundations: – *in EURO* Access/Usage fees: – *in EURO* Other (specify): – *in EURO*
2. OBJECTIVES AND CHARACTERIZATION	
Background	*two sentences on the background of the BMB (clinical, population)*
Topics of Interest	*Disease entity 1* *Disease entity 2* *....*
Origin and Use of Samples	(delete items that do not apply) Origin: research, diagnosis, therapeutics, other *(specify)*: Use: research, diagnosis, therapeutics, other *(specify)*:
Sample Type and Number of Samples (number of people and samples, not aliquots, having been collected)	*Sample Type 1 (e.g. DNA, fluids, serum) – Donors/ Samples* *Sample Type 2 – Donors/ Samples* *....*
3. MANAGEMENT AND INFRASTRUCTURE	
Governance List all boards governing the BMB	
IT Technology being used e.g. for sample/ data administration	
Automation of processing steps	Sample processing (delete items that do not apply) Pipetting/ aliquots Storage Retrieval Biomolecule extraction Analysis Other (specify):
Research Services provided by the BMB	
Access to Data and Samples and/or reagents/methods	is granted to: *e.g. academia, industry*
Consent (Type of consent being obtained in relation to future use of the samples)	Broad consent (delete items that do not apply) Specific consent Presumed consent Please give details on type of content:
4. SAMPLE STORAGE AND QUALITY ASSURANCE	
Storage Conditions	*specify storage conditions – short-term vs. long-term for all samples* *Sample type 1 – Storage Condition* *Sample type 2 – Storage Condition* *.....*
Quality Management	*list steps/features for which a quality framework is established e.g. sampling, shipment, storage, data management, IT, alarm for storage temperature, back-up system, biosecurity measures, other*
5. PUBLICATIONS / GRANTS / SAMPLES REQUESTED	
Relevant Peer Reviewed Publications	*List Relevant Peer Reviewed Publications derived from material / data of the BMB*
Relevant grant acquisitions	*List projects granted national / international funding having used material / data from the BMB*
Samples Requested	*Indicate number of requests for samples that have been submitted to the BMB within the last 3 years*