



Leitfaden für die Antragstellung „Biomaterialbanken“

Application for the Funding of a Biomaterialbank (10 pages max.)

Please prepare your application in English **not exceeding 10 pages for the headings 1. to 7.**, including a maximum of 1 page of references (DIN A4, at least 10 point Arial, publication listings in numerical order). Structure your application using the headings listed below. Make an entry (n.a. = not applicable, if appropriate) under every heading. Signatures of principal / coordinating investigator and responsible bio-statistician/data manager are mandatory.

Note: Applications that fail to comply with these requirements will be considered as not eligible and rejected without peer review.

1. SYNOPSIS

APPLICANT / COORDINATING INVESTIGATOR	<p>Name, address, telephone, fax, e-mail</p> <p>In case of multiple applicants the principal investigator / coordinating investigator of the project who will take responsibility for conducting the entire project should be listed first.</p> <ul style="list-style-type: none"> • First name, last name, academic title • Institution and department (complete name) • Postal address • Telephone • Fax • E-mail address 															
TITLE	The title of the project (not exceeding 140 characters) should be as precise as possible. In case of funding this title shall be quoted in the annual reports of the funding organisation. Acronym is optional.															
CONDITION/TOPIC	The medical area being addressed (e.g. Parkinson, depression, asthma).															
OBJECTIVE(S)	Please specify the relation of the project within the network or to single subprojects. Comment on the correlation/connection to the entire consortial research.															
KEY WORDS	Maximum 6															
PROJECT DURATION	In month															
SUMMARY	Please give a summary of the main goals of the project (max. 1600 characters). The project summary serves two main purposes: i) It will inform the multidisciplinary review committee of the principal aims of the project. ii) If your project is funded the summary will be published on the internet through an electronic information system. (It should therefore be concise as well as comprehensible to a lay public). Please avoid abbreviations.															
DESCRIPTION OF THE CONSORTIUM	<p>Example:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">Subproject No.</th> <th style="width: 15%;">Partner</th> <th style="width: 30%;">Titel of Subproject</th> <th style="width: 20%;">Function in the consortium</th> <th style="width: 25%;">Contribution</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td>xyz GmbH</td> <td>Identification of pharmacogenetic polymorphisms by high-throughput screening</td> <td>Coordination</td> <td>Monitoring, evaluation and processing of results</td> </tr> <tr> <td style="text-align: center;">2</td> <td>University of...</td> <td>Significance of CYP2C9 polymorphism for oral anti-</td> <td>Preclinical partner</td> <td>Establishing pharmacogenetic assays</td> </tr> </tbody> </table>	Subproject No.	Partner	Titel of Subproject	Function in the consortium	Contribution	1	xyz GmbH	Identification of pharmacogenetic polymorphisms by high-throughput screening	Coordination	Monitoring, evaluation and processing of results	2	University of...	Significance of CYP2C9 polymorphism for oral anti-	Preclinical partner	Establishing pharmacogenetic assays
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			<i>diabetica</i>		

2. AIM OF THE PROJECT

Which medical area/disease entity is to be addressed? Does the biomaterial bank relate to a specific disease(s)? What are the novel aspects that will be studied by the proposed biomaterial bank itself or within the network and/or subprojects? Which principal research questions/hypotheses to be addressed, if applicable in cooperation with subprojects? Bring them into order indicating major and minor motivations/starting hypotheses of the investigation(s) planned.

2.1 EVIDENCE

Set your BMB into perspective. Do related (systematic) collections exist? In which context were these collections sampled (basic and/or clinical research, treatment context)? Have relevant results been drawn? Give references to any relevant (systematic) BMB(s) and/or (own) publications, if applicable. What are the novel aspects of the planned BMB?

2.2 THE NEED FOR A BMB

What impact will potential results provide for the clinical practice or understanding the disease? Why is a (systematic) collection necessary? How will the society/science benefit from the BMB?

2.3 STRATEGIES FOR THE EXPLOITATION/DISSEMINATION OF RESULTS AND MATERIALS

What will be your strategies for the dissemination of results? Indicate how the expected results of the BMB will be used; discuss dissemination of results, especially beyond regular journal publication, describe potential sustainability measures (i.e. open to scientific community or non-academic research). If applicable, how is the scientific community in general informed of the availability of samples?

2.4 ADDED VALUE

Comment on the interaction within the consortium and other potential roles within the network.

3. ORGANISATION AND BREADTH OF INTENDED BMB

3.1 TYPE OF BMB

What organisational model does apply to your intended BMB? Is the BMB itself performing research? Is the purpose of the BMB exclusively the collection and distribution of biomaterials and data without own research projects? Will the BMB project provide services (RNA/DNA extraction, immunohistology/TMA, PCR, Affymetrix Chips, etc) on assignment of other projects in the consortium?

- Centralised collection (multiple providers, primary storage in one place and limited access for third parties) or
- decentralized collection (multiple providers, primary storage in one place, broad access for and investigations by third parties different from the holder) or
- decentralized collection of cooperative nature (storage and/or investigation of collected materials primarily decentral)

What biological material is intended to be sampled (nature [tissue or sample type] and numbers)?

Comment on the primary goal of the material collection:

- Is the material primarily stored for routine diagnostic or therapeutic purposes and can additionally be used for research questions? If applicable, in which amount yet? Is the treatment context embedded in a clinical study (purpose commitment)? If applicable, in which amount yet?
- Is the material only sampled and stored for research question(s)?

What is the planned duration for the BMB?

3.2 POPULATION TO BE STUDIED

Describe and justify the (patient) population to be studied (inclusion/exclusion criteria). Include reflections on generalisability.

3.3 DATA AND MATERIAL ACQUISITION AND STORAGE

Describe the concept of data and material acquisition and storage.

- Which data are intended to be sampled and stored (data of patient, data of the sample(s), data of sample analysis)?
- Describe, if applicable, yet obtained numbers and comment on data protection.
- Does the database, or is intended to contain clinical, genetic or pathological information?
- Who does or will provide that input and where?
- Who is responsible for update and maintenance of the data base?
- Which instruments will be used to record the data? Are the instruments validated and reliable?
- How will the personal responsible for data acquisition be trained?
- How will the patients be selected and recruited for the BMB?
- Which standards will be used to classify diagnoses and stages of the disease(s)?
- Comment on the potential accessibility of related resources (if applicable, cf. 2.1) and on the possibilities to use or integrate already existing sources or data.

3.4 FEASIBILITY OF COMPREHENSIVE SAMPLING

What is the evidence that the intended recruitment rate and total number of samples/patients for the BMB is achievable? In case of existing (systematic) collections, which publications of the last 2 years are based on this material bank?

3.5 INTERNATIONAL COLLABORATIONS

If the proposed BMB includes non-German centres or collaboration with organisations in other countries please give full details of funding arrangements agreed or under consideration.

4. ETHICAL CONSIDERATIONS

Specify the ethical considerations relating to the BMB (informed patient consent, purpose commitment declaration, interest in property, personal rights). Do you/did you ask for permission to use the clinical/genetic/pathological data for research purposes? At best, a 'Letter of Intent' (LOI) from respective partners/institutions is provided.

5. BMB OPERATORSHIP AND MANAGEMENT

5.1 OWNERSHIP

Who will be the operator of the BMB? What will be the legal form of the BMB? Where is the ownership defined?

- Is the acquisition of ownership intended or the concession of life estate (w/o acquisition of ownership) on the samples? If any of these, by what means can the different regulations be met?

According to your organisational model, what measures are intended to support potential long-term usage?

- How is access to the BMB organised? Are potential co-founders informed? If yes, how?
- How is the co-authorship regulated?

- How are formal aspects, e.g. ethical review and/or rationing with scarce material taken into account? If applicable, how many material/data applications did you receive in the last 2 years? If applicable, how were/are material/data applications reviewed (e.g. independent board?)
- Do scientists pay for samples? (how much)? Is there a fee difference between internal and external usage?

5.2 MAJOR PARTICIPANTS *(please indicate roles of major participants according to your organisational model)*

#	Name	Affiliation	Responsibility / Role	Signature
			Principal/Coordinating Investigator	
			...	
			

Who is responsible for statistics? Professional background/expertise should be given.

#	Name	Affiliation	Responsibility/Role	Signature
			Responsible for Statistics	

Who is responsible for quality assurance and the data documentation?

#	Name	Affiliation	Responsibility/Role	Signature
			Responsible for Data Assurance	

Please indicate the expertise of all above-mentioned participants by citing own relevant publications and/or specifying major role in ongoing comparable research projects (list max. 5 publications of the last 5 years per person).

5.3 BMB-SUPPORTING FACILITIES

Which BMB-specific facilities and other resources are available for conducting the systematic collection?

5.4 QUALITY ASSURANCE

Describe and justify the concept for quality assurance. Describe the actual organisational and technical measures for quality assurance and quality control (coding of data, second control of coding, documentation of data corrections). Are GLP guidelines implemented? Have quality procedures been developed? Are they formulated in specific manuals (Standard operation procedures, SOPs)?

5.5 DATA PROTECTION CONCEPT

How will the existing legal requirements for data protection be met? Describe the data protection concept applied and the planned data and work flow (diagrams). If applicable, provide positive votes of the data protection organisation in charge. Depending on organisational model and purpose of the BMB, is anonymisation of data applicable? Comment on the following aspects of the data protection concept:

- Technical and organisational instruments
- Central patients list (localisation)
- Patient identification data
- Pseudonymisation and depseudonymisation (localisation, where does this process take place)
- Informed patient consent
- right of withdrawal
- purpose commitment declaration
- Storage time of data
- Workflow for quality assurance
- Safety of data transmission and documentation
- Criteria of material dissemination

- Policy document including all legal regulations and agreements

6. REFERENCES

Publication listing according to numerical appearance in the text.

7. TIMELINE FLOW/MILESTONES

As funding by BMBF will critically depend on the progress according to milestones, please provide a proposal of milestones reflecting planning, recruitment status and data clearing/analysis progress. Include a diagram showing stages and milestones. Comment on the possibility of sustainable establishment of the BMB after BMBF funding.

8. FINANCIAL DETAILS OF THE STUDY

8.1 FINANCIAL SUMMARY

Indicate total duration of the BMB project, the period of time for which funding is requested, and when funding should begin.

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

8.2 EQUIPMENT

In case you apply for instruments which are available where you work, but which are not at the project's disposal, please give detailed information.

Please list all requested instrumentation with price information.

8.3 CO-FINANCING BY INDUSTRY AND/OR OTHER THIRD PARTIES

Co-financing by industry or other third parties is possible if

- the independence of investigators is ensured and
- terms and conditions of the financial commitment are disclosed.

If co-financing is intended the application should briefly describe the type and volume of the intended co-financing, indicating the respective company or other third party.

Details are to be specified:

- Describe the type and volume of support (including any services or consumables provided free of charge).
- Indicate the amount of support to be provided and assure in writing that the third party will render these services, stating their terms and conditions, if any.
- Assure that the coordinating investigator is independent, in particular with regard to the analysis of the BMB and the publication of its results. A statement giving such assurances will be demanded by the funding organizations after the review process is finished.

Please don't make any agreements before a formal notion of award has been received; please contact the funding organisation first! Appropriate agreements on intellectual property, confidentiality, publication of results, property rights should be concluded between all those playing a leading part in the conduct of the BMB.

Reference is made to the legal provisions relevant to cooperation between industry, medical institutions and their staff.¹

¹ Detailed information can be found in particular in the "Gemeinsamer Standpunkt zur strafrechtlichen Bewertung der Zusammenarbeit zwischen Industrie, medizinischen Einrichtungen und deren Mitarbeitern" (Common position concerning the consideration of cooperation between industry, medical institutions and their staff from the aspect of criminal law) published by

8.4 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".

	Organizational Segment	Institution/ Participant/	No of items/ Kind of equipment/ Explanation	Qualification of staff	TVöD/ BAT	Total months	Total years	Total (€)	y1 (m/€)	y2 (m/€)	y3 (m/€)	y... (m/€)
1	Scientific BMB Management											
2	Organisational BMB Management											
3	Data (Security) Management											
4	Statistical data analysis											
5	Quality assurance											
6	Meetings/ Travel	no of attendees	no of meetings x €/ p									
7	Documentation payment		documentation per sample/patient hours of staff per sample/patient €/ patient x no of patients									
8	Materials		Consumables, laboratory expenses									
9	Equipment											
10	<i>Other</i>											
	TOTAL							€	€	€	€	€

m = staff indicated in months; € = other expenditures indicated in Euro; ./p = per person

