Bundesministerium
für Bildung
und Forschung

Förderrichtlinie

„Ertüchtigung deutscher Biobank-Standorte zur Anbindung an BBMRI“

LEITFADEN FÜR DIE ANTRAGSTELLUNG

1. VERFAHREN

Einreichende
Im Rahmen der o.g. Förderrichtlinie können formlose Skizzen eingereicht werden von

A der Kontakt- und Vermittlungsstelle für Biomaterialbanken als „Nationaler Knoten“ (engl. German Biobank Node, GBN) für BBMRI und
B Einrichtungen, die sich an einem Verbund von Biobank-Standorten beteiligen möchten.

Arbeitsprogramm
Ziel des o.g. Verbundes ist die Erarbeitung, Erprobung und Anwendung von übergreifenden, generischen Standards, Produkten und Lösungen zur Integration deutscher Biobank-Standorte mit humanen Proben und Daten in BBMRI. Der Verbund wird durch den GBN koordiniert.

Ein Konzept für das Arbeitsprogramm des Verbundes und ein erster Ressourcenplan werden vom GBN erstellt.

Die Einrichtungen, die sich am Verbund beteiligen möchten, schlagen maximal 3 Biobanken zur Teilnahme am Verbund vor. Ferner erläutern sie ihre Expertise und Qualifikation im Hinblick auf die Förderziele. Mögliche Lösungswege im Hinblick auf die Ziele sollten skizziert werden. Ein Arbeitsprogramm ist nicht vorzulegen.

Begutachtung
Die formlosen Skizzen werden von einem international besetzten Expertenkreis begutachtet. Hierbei werden das Arbeitsprogramm und der Ressourcenplan des GBN sowie die Profile der Biobank-Standorte im Hinblick auf die Förderziele bewertet. Die Bewertungskriterien sind in der Förderrichtlinie unter Punkt 4. aufgeführt.

Workshop
Die Einrichtungen / Koordinierende, deren Skizzen positiv bewertet wurden, sollen auf einem Workshop das Arbeitsprogramm und die Ressourcenplanung konkretisieren und die förmliche Antragstellung vorbereiten. Hierbei sind ggf. Auflagen aus der Begutachtung zu berücksichtigen.

Förmliche Antragstellung
Der DLR Projektträger wird zur Einreichung von Formanträgen schriftlich auffordern.

2. ERSTELLUNG DER FORMLOSEN SKIZZEN

Die einzureichenden Unterlagen sind nach den Vorgaben dieses Leitfadens zu erstellen. Teil A ist ausschließlich vom GBN einzureichen. Teil B ist von jedem der sich bewerbenden Biobank-Standorte einzureichen.

Teil A: Vorgaben für die Kontakt- und Vermittlungsstelle für Biomaterialbanken, GBN (DIN A4, maximal 12-seitig, in englischer Sprache). Die Unterlagen sind nur vom GBN einzureichen.

Teil B: Vorgaben für Biobank-Standorte, die sich um Teilnahme am Verbund deutscher Biobank-Standorte bewerben (DIN A4, maximal 8-seitig (ohne Anhänge), in englischer Sprache).

Bitte benutzen Sie die Formatvorlagen auf der Internetseite des DLR Projektträgers http://www.dlr.de/pt/Portaldata/45/Resources/Dokumente/GF/Formatvorlage_Skizze_BB-Allianz.docx und http://www.dlr.de/pt/Portaldata/45/Resources/Dokumente/GF/Formatvorlage_Biobank_profile_BB-Allianz.xlsx. Dokumente, die den Vorgaben des Leitfadens nicht entsprechen, können nicht berücksichtigt werden.

Das Einreichen der Unterlagen erfolgt elektronisch über das Internet-Portal (https://www.pt-it.de/ptoutline/application/BBALLIANZ). Bitte übersenden Sie zeitnah ein Druckexemplar der Projektskizze an:

DLR Projektträger - Gesundheitsforschung
Frau Dr. Isabell Hahn
Heinrich-Konen-Str. 1
53227 Bonn

Die Unterlagen können **bis spätestens 28. Januar 2016** eingereicht werden.

A GUIDELINE FOR THE GERMAN BIOBANK NODE

1. APPLICANT

Indicate the name of the institution (legal person) submitting the application.
Name one person (Name, position, institution, department) that will assume coordination activities.

2. EXPERTISE WITH REGARD TO THE FUNDING SCHEME

Indicate active national and / or international co-operation (what was your contribution, in which context, what was the output?).

2.1. Literature

Only list major publications with regard to your achievements in developing and testing generic standards, products, and solutions.

3. DRAFT WORK PROGRAMME FOR A BIOBANK ALLIANCE AND LINKING TO BBMRI

The focus of the funding scheme is on developing and testing generic standards, products, and solutions. Present a draft work programme on

- *link to BBMRI,*
- *national networking,*
- *IT-integration,*
- *quality management,*
- *quality of data and samples,*
- *public accountability, public relations, public outreach,*
- *ELSI,*
- *counselling biobanks, and*
- *education and training.*

Prioritise the issues and describe the work programme. Comment on coordination with BBMRI and indicate third parties' expertise needed for each work package. Define each work package (WP) in detail and use the template below to specify the work package's time frame and deliverables.

WP no. 1	Milestone / Deliverable(▼)	year 1	year 2	year 3
1		▼		
1.1		▼		
1.2		▼		
…				▼
…				▼

4. RESOURCES REQUESTED

Use the table below to indicate requested resources for each work package needed at (a) the German Biobank Node and (b) the local biobanks.

WP no.	Description	GBN		All Local Biobanks	
		Person Months	EUR (total)	Person Months	EUR (total)
1	*Scientists: Brief description of the activity with respect to the work programme*				
	Technical staff: Brief description of the activity with respect to the work programme				
	Itemize material expenses, e.g. consumables, contracts, travel; use one line per category *Specify the work to be contracted. Why does it have to be commissioned and cannot be done by the applicant?* *Provide calculation of travel expenses and*				

	consumables.				
2	*Scientists: Brief description of the activity with respect to the work programme*				
	Technical staff: Brief description of the activity with respect to the work programme				
	Itemize material expenses, e.g. consumables, contracts, travel; use one line per category *Specify the work to be contracted. Why does it have to be commissioned and cannot be done by the applicant?* *Provide calculation of travel expenses and consumables.*				

B GUIDELINE FOR BIOBANKS APPLYING TO PARTICIPATE IN THE BIOBANK ALLIANCE

1. APPLICANT

Indicate the name of the institution (legal person) submitting the application.
Name one person (Name, position, institution, department) that will assume the local coordination.

2. INSTITUTIONAL PROFILE

Shortly present your institution. Regarding biobanking: Comment on collection strategies and main collection foci. How many biobanks exist at the institution? Please specify the type of biobank(s) and the type of materials stored. How many samples do they store?

3. ORGANISATION / GOVERNANCE OF LOCAL BIOBANK(S)

Describe the existing local infrastructure with regard to biobanking. Include information on organizational structures. Is there a global governance for the local biobank(s)? If yes, briefly summarize governance; give details in a separate table (if applicable: appendix 4).

Are there comprehensive local organizational strategies in biobanking? If yes, give details.
Have biobanking activities been centralised? If yes, to what extent? Describe the general local situation regarding data integration and quality management.

4. BIOBANKS PROPOSED BY THE INSTITUTION TO BE INCLUDED IN THE BIOBANK ALLIANCE

The willingness to cooperate and share is central to the funding scheme. Please submit a declaration on the willingness and ability to cooperate and share (appendix 2).
Note that only one application is to be submitted per site. A thorough local clearing process is expected taking into consideration the expertise of the local biobank(s) with respect to the aims of the funding scheme. Centralised biobanks embedded into comprehensive local biobanking concepts will be favoured. In certain instances stand-alone biobanks may be considered. These cases will need to be convincingly justified. The number of biobanks proposed by an institution is limited to a maximum of three. In case you propose more than one biobank: Every heading should contain the information on all proposed biobanks (do not duplicate headings 4.1 to 4.8).

4.1. Expertise with regard to the funding scheme

The focus of the funding scheme is on developing and testing generic standards, products, and solutions. In this context please detail expertise and experience concerning the issues indicated in the funding scheme (the main areas being IT-integration, quality management, quality of data and samples, public accountability, and integration in BBMRI). Indicate active national and / or international co-operation (what was your contribution, in which context, what was the output?).
List the biobank(s) you propose to include in the activities of the alliance of biobanks (biobank alliance) to be established; give details in appendix 1. What is their particular expertise?
What contribution in terms of development and / or testing could be envisaged? Indicate possible approaches to developing and testing generic standards, products, and solutions.

4.2. Resources

Indicate type of samples stored; give order of magnitude using the following sample type categories: Whole blood, plasma, serum, cryo tissue, FFPE tissue, cell lines, urine, saliva, other (e.g.: serum: 50.000; FFPE tissue: 220.000).
Give information on dedicated (a) total biobank staff, (b) IT staff, (c) QM staff (d) technicians, and (e) managerial staff. Comment on spatial situation and technical equipment for storage.
Does the biobank have the possibility to host collections including comprehensive data (e.g. enabling researchers to lodge collections once the initial study is complete)?

4.3. Funding

Is there institutional long-term funding of the biobank(s)? If yes, provide amount per year and an institutional statement on the funding available for the biobank(s) (if applicable: appendix 2). Does the

institutional long-term funding fully cover running costs? Indicate details about other funding available (e.g. through grants); specify amounts.

4.4. Quality management

Describe the current situation concerning quality management. Do you have a quality management manual describing quality policy, quality objectives, an organizational chart, and a process map? If yes, on which norms or guidelines is it based (e.g. ISO 9001, OECD guidelines[1], other: specify). Please provide the table of contents of your QM manual (appendix 5).
Have the biobank or biobank-relevant processes been certified / accredited (specify norm)? Which processes have been certified / accredited? Has the biobank been audited (internal / external audits)?
List the dedicated QM staff; give their qualification and duties.

4.5. IT infrastructure

Please describe the current situation of your IT-infrastructure. Does your IT infrastructure supports an access possibility for your users (e.g. scientists, clinicians) to self-manage part of the materials stored in your biobank? Comment on the IT support of management of identification data like names, birthdates or addresses (e.g. pseudonymisation). Can you link or merge data from different origins like e.g. clinical or laboratory data gathered during the routine health care processes by the help of an IT system? Are you able to locate samples using data not primarily belonging to the sample, but to the donor patient or proband (e.g. diagnosis, therapies)? Does your IT infrastructure supply concepts or solutions for the semantic comparability of data? Comment on data interchange interfaces within your IT infrastructure and for communication with external IT systems and/or IT infrastructures. List the dedicated IT-staff; give their qualification and duties (e.g. operation, development).

4.6. Services provided

Give information on services provided (e.g. tissue micro arrays, virtual microscopy, DNA / RNA extraction).

4.7. Sharing data and samples

Describe the current situation concerning informed consent, sample ownership, and sample access. Is there a broad, generic consent (since when)? If yes, in which context (e.g. for samples issued from routine care, specific projects). Describe access policies and practical arrangements for access (e.g. roles and rights, access committees). Comment on the possibility of secondary use of samples collected in specific projects. Is there an access plan for samples collected during primary studies? Indicate the approximate percentage of samples / data usable for research (e.g. through broad consent). Is there a fee for access to samples / data? Give key data on samples accrued, issued, and results in appendix 3. Are you able and willing to share samples and data with external partners at the national and European level?

4.8. Public accountability

Comment on the policy concerning public accountability, especially with regard to the recommendations of the German Ethics Council (Deutscher Ethikrat). Where appropriate: indicate web page where information can be accessed. Note that an entry in the German Biobank Registry is mandatory.

5. LITERATURE

Only list major publications with regard to your achievements in developing and testing generic standards, products, and solutions.

Please note: The amount of funding for participation in the biobank alliance will be determined after (a) the assessment of the draft work programme to be submitted by the German Biobank Node and (b) the evaluation of the biobanks having been proposed by their respective institutions to be included in the biobank alliance.

[1] e.g. OECD Guidelines on Human Biobanks and Genetic Research Databases
OECD Best Practice Guidelines for Biological Resource Centres

APPENDICES

1. PROFILE OF BIOBANK(S) PROPOSED TO BE INCLUDED IN THE BIOBANK ALLIANCE

We urge you to use the xls-sheet that can be accessed at http://www.gesundheitsforschung-bmbf.de/Formatvorlage_Biobank_profile_BB-Allianz.xlsx*. Fill it in and*
(a) include it in the application as appendix 1 (to be limited to one page). In addition
(b) submit the excel file as a separate document.
In case of long biobank names use space-saving legends. Note that institutions with one centralised biobank will be favoured.

	Biobank # 1 *Name*	Biobank # 2 *Name*	Biobank # 3 *Name*
General characteristics			
Population biobank, clinical biobank, research / study biobank (P, C, R/S)			
Biobank started sample collection in (yr)			
Samples total (no. of samples, in thousands)			
Governance policies implemented (y, n)			
Centralized biobank (y, n)			
- centralized since when			
- number of biobanks under umbrella organization			
Funding			
Long-term institutional funding (K € / yr)			
Other funding (e.g. grants), mean K €/ yr (last 5 yrs)			
Other earnings (e.g. fees for services / storage) (K € / yr)			
Resources			
Dedicated biobank staff, total including IT + QM staff (FTEs)			
Dedicated IT staff, total (FTEs)			
Dedicated QM staff, total (FTEs)			
Spatial situation (m² for storage and related biobanking activities)			
Total storage capacity (no. samples / aliquots)			
Centralized storage (y, n)			
-180° storage (y, n, automated=a)			
-80° storage (y, n, automated=a)			
+20° storage (y, n)			
Quality management			
Quality management manual available (y, n)			
QM system reviewed (y, n)			
- internal audits (y, n)			
- external audits (y, n)			
- certification / accreditation (y, n, norm)			
IT Infrastructure			
Pseudonymization of data in place (y, n)			
Interfaces to clinical routine data productive (y, n)			
Biobank management system usable for integration of different data sources (y, n)			
IT based sample search /request tools available (y, n)			
Services provided			
DNA / RNA extraction (x)			
other (x)			
other (x)			
Sample / data sharing			
Public accountability according to German Ethics Council implemented (y, n)			
Access policies implemented and publicly accessible (y, n)			
Sample request form publicly accessible (y, n)			
Registered in the German Biobank Registry (y, n)			
Europe-wide sharing possible, provided consent permits			

(y, n, p=partly)			
Samples requested / issued locally in 2014 (n=../n=..)			
Samples requested / issued nationally in 2014 (n=../n=..)			
Samples requested / issued internationally in 2014 (n=../n=..)			
Projects to which samples were issued (no. in 2014)			
Publications originating from samples issued (no. in 2014)			

2. DECLARATIONS

2.1. Willingness to cooperate and share

The institutional applicant and the biobanks proposed by the institution to be included in the biobank alliance shall declare their willingness

- *to co-operate in the biobank alliance,*
- *considering the interests of BBMRI and its Partner Charter, and*
- *to share data and samples across Europe.*

This declaration is to be signed by the competent (legally responsible) persons.

2.2. Long-term Funding

If available: Please provide institutional statement on the long-term funding available, indicate yearly amounts in Euro.

This declaration is to be signed by the competent (legally responsible) persons.

3. KEY DATA ON SAMPLES ACCRUED, ISSUED, AND RESULTS

Please provide one table per biobank. Use the cell highlighted in blue to indicate the total number of samples in 2009. Only indicate the accrual in the years 2010-2014.

Samples stored (total, 2009):	2010	2011	2012	2013	2014
Sample accrual in respective year (n)					
Samples requested (n)					
Samples issued (n)					
Projects (n) to which samples were issued					
Publications (n) originating from samples issued					

4. GOVERNANCE OF THE CENTRALIZED BIOBANK

If applicable

BODIES	RIGHTS and OBLIGATIONS	MEMBERS

5. QUALITY MANUAL – TABLE OF CONTENTS

If available