mitoBANK– Biosample request

Project-#: _____ (assigned centrally)
Date: _____

RECIPIENT	
Title, full name	
Organisation, institute	
Street	
Zip code, city, country[1]	
Phone	
Fax	
E-Mail	
Time period for use	from until

Project description

Title of the project		
Is there a previous proposal on the same topic?	☐ No	☐ Yes, previous project #:
Are Data from mitoREGISTRY also requested[1]?	☐ No	☐ Yes
Scientific background (max. 1000 characters without empty spaces)		
Scientific objectives and project aim(s) (max. 1000 characters without empty spaces)		

1 Please note, that the biosamples can only be transferred to recipients with its offices located in the EU, EEA or countries with an adequacy decision. Otherwise, a separate agreement has to be concluded, in particular with contractual data protection clauses.

Aims on publication

Anticipated title of the planned publication		
Anticipated journal(s)		
Planned submission date:		
	Name(s)	Institute(s), E-Mail
Leading author(s)		
Co-authors or other involved scientists without Co-authorship[2]	**Please note:Any publication must comply with the mitoBANK and mitoREGISTRY Publication Policy (see Annex 1)!** **The draft publication, together with MTA Annex I has to be submitted to the management of the mitoNET before it is submitted to the journal.**	
Acknowledgments[3]	The mitoBANK has been funded by the Deutsche Forschungsgemeinschaft within the SFB1216 from 2015 till 2019 BMBF: PerMiM 01KU2016A and GENOMIT 01GM1920A are funded by BMBF from 01.07.2020-to 30.06.2023	
Further citations to be added to the manuscript		

[2] Depending on the type of project and the requested biosamples, the involvement of particular investigators or other contributing sites as Co-Authors, Contributors or Collaborators could be requested by the Management of mitoNET in this section.

[3] In the manuscript, RECIPIENT has to acknowledge the funding sources using the exact language, as provided in this section.

Ordering Form

SAMPLE AND PROJECT DESCRIPTION

Material	□ DNA □ RNA □ Fibroblasts	□ Plasma □ Urine
Description of the cohort / Samples requested		
Plan for analyzing the samples		
Analytical methods		
Responsible site		

EXPENSE ALLOWANCE

Charge per sample[4]		**Number of Samples**	**Total costs**
Fibroblast cell line	€ 60.00	☐ _____	_____
Distribution of iPS cell	€ 2,500.00	☐ _____	_____
DNA/RNA (less or equal to 48 aliquots)	€ 6.00	☐ _____	_____
DNA/RNA (more than 48 aliquots)	€ 5.00	☐ _____	_____
Establishment of cell line from skin biopsy	€ 90.00	☐ _____	_____
Extraction of DNA	€ 12.00	☐ _____	_____
Extraction of RNA	€ 24.00	☐ _____	_____
Urine	€ 22.00	☐ _____	_____
Plasma	€ 22.00	☐ _____	_____
			TOT. _____[5]

BANK ACCOUNT

Holder of account	Klinikum rechts der Isar
Bank	Bayerische Landesbank
IBAN	DE82 7005 0000 0000 0202 72
BIC	BYLADEMM
Reference No.	8890003079

SHIPPING DETAILS

Shipping address	
Courier name	
Courier Account Number	

[4] Transportation costs have to be covered by the recipient (also for former mitoNET partners and mitoNET recruiting centers)

[5] Total amount/charges are subject to VAT, if applicable.

Project-#: _____

With the conclusion of this agreement for the PROVISION OF BIOLOGICAL SAMPLES following terms have been agreed upon:

1) The biological material (hereinafter "biosamples") will be provided by Klinikum rechts der Isar der TU München, represented by its Commercial Director Dr. Elke Frank, Institute of Human Genetics, Ismaninger Str. 22, 81675 München Germany (hereinafter "mitoBANK") as requested above. The project coordinator is Dr. Holger Prokisch ("Coordinator") as an employee of the Provider. The RECIPIENT has to cover the portion of the expense allowance as agreed above. Biosamples will only be transferred to Recipients within the EU, EEA or countries with an adequacy decision.
2) RECIPIENT shall keep complete and accurate records of the results of the Project and shall make them available in confidence to the mitoBANK in a final report that shall include results relevant to the health of patients, if any.
3) For any projects where it is planned to generate modified derivatives of the biosamples, RECIPIENT could be requested to send an aliquot of such modified derivatives to the mitoBANK, if interested. The mitoBANK, at its own complete discretion, will decide to include them in the mitoBANK.
4) The samples sent to the RECIPIENT are and remain without any exceptions and for an unlimited period of time the property of the mitoBANK. Any unused biosamples must be returned to the biobank after completion of the study, unless otherwise agreed. Biosamples will be used exclusively for research and testing purposes as agreed herein and not for commercial purposes. Biosamples are to be used only at the Recipient organisation and will not be transferred to any third party without the prior written consent of the mitoBANK. Biosamples may not be transferred to countries outside the EU, EEA and countries without an adequacy decision.
5) The biosamples and additional data are labelled with a pseudonym. In accordance with the requirements of the German Data Protection Act, RECIPIENT commits to take technical and organizational measures to appropriately safeguard the biosamples and its additional data from misuse and loss. RECIPIENT will not attempt to re-identify or contact individuals who originally provided the samples. The coordinator of the mitoBANK has to be informed without any delay in case of suspected privacy violations (e.g. if a re-identification is possible or could be possible) or if other irregularities in the processing of samples are detected. RECIPIENT will keep all received information confidential. RECIPIENT undertakes to, at mitoBANK's discretion, destroy or return the biosamples in case the data subject (cf. Art. 4 No 1GDPR) withdraws his or her consent. For avoidance of doubt, the withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal.
6) The biosamples shall not be used for clinical trials, tests in humans or for treating humans.
7) The RECIPIENT acknowledges that the biosamples include biological material and therefore may have inherent defects or can even be infectious in individual cases. The mitoBANK provides the biological material without any warranty of usefulness for the intended purpose. The RECIPIENT shall indemnify the mitoBANK from all claims raised by his staff or third parties against the mitoBANK in connection to the use of the requested biosamples. Except to the extent prohibited by law, RECIPIENT assumes liability for damages which may arise from its use, storage or disposal of the biosamples. The mitoBANK will not be liable to the RECIPIENT for any loss, damage, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the biosamples, except when caused by the gross negligence or wilful misconduct of the mitoBANK. The limitation of liability shall not apply for material breaches, contractually foreseeable damages or any violations of life, body or health.
8) mitoBANK confirms the exclusive authorization for the use of the biosamples for the proposed research and for the requested time period. After expiry of the time period the biosamples can be shared with other scientists by the mitoBANK.
9) The RECIPIENT shall not obtain any property rights, especially patents, for the biosamples or for any information that has been achieved in connection with the use of the biosamples without the prior written approval of a scientific committee formed by clinical and basic scientific experts of mitoNET, represented by the management of mitoNET and the responsible scientist of the mitoBANK.
10) The respective corresponding author commits to adhere to the described publication goals in all internal and external publications as agreed on page 2 and annex 1.
11) Any manuscripts, resulting from the analysis of the requested biosamples have to be provided to the management of mitoBANK prior submission. The manuscripts will be reviewed in respect of its formal compliance with this Agreement within 5 days of receipt. Once published, a pdf file of the publication (or dissertation) is to be sent to the management of mitoBANK
12) The recipient has to assure that its employees comply with all obligations under this Agreement as if they were imposed on themselves.
13) The recipient assures that IRB approval has been or will be obtained for each individual research project involving the use of the requested biosamples.
14) The RECIPIENT agrees to use the Biosamples in compliance with all applicable laws, regulations, and guidelines, including National Institutes of Health (NIH) guidelines such as, for example, those relating to research on humans and/or involving the use of animals or recombinant DNA.

15) The Parties undertake to comply with all applicable regulatory requirements, in particular, the German Data Protection Act, the Data Protection Acts applicable at Federal State level and the General Data Protection Regulation (EU) 2016/679.
16) These terms shall be construed, governed, interpreted, and applied according to German law without regard to its conflicts of laws rules or principles. The exclusive place of jurisdiction is Munich, Germany.
17) By signing below the recipient approve and agree on the proposal and the terms of this MTA.

<table>
<tr><td rowspan="2">RECIPIENT</td><td colspan="2">Name/Institute</td></tr>
<tr><td>Place, date</td><td>Signature</td></tr>
<tr><td rowspan="3">For the mitoBANK</td><td colspan="2">Klinikum rechts der Isar der Technischen Universität München</td></tr>
<tr><td>Place, date
Munich,</td><td>Signature

……
Dr. Elke Frank</td></tr>
<tr><td colspan="2">Read and acknowledged:

Place, date
Munich,

……
Dr. Holger Prokisch

Place, date
Munich,

……
Univ.-Prof. Dr. Meitinger</td></tr>
</table>

mitoBANK Material Transfer Agreement – Annex I

Project-#.: _____

Accepted publication

Please complete and send the table for each accepted manuscript to the management of mitoBANK prior proof-read

Title of the publication		
	Name(s)	Institute(s)
First author(s)		
Last author(s)		
Co-authors	**Please note:** **Any publication must comply with the Publication Policy (see below)!**	
Other involved scientists without Co-authorship		
Acknowledgments		
Further citations to be added to the manuscript		

mitoBANK and mitoREGISTRY - Publication Policy

Introduction
Sharing of data and bio-specimens with the scientific community is a major objective of the mitoNET Registry (mitoREGISTRY) and the mitoNET Biobank (mitoBANK).

The following publication policies will be included in the mitoREGISTRY data use (DUA) and mitoBANK material transfer agreements (MTA) covering data and sample sharing.

1. mitoNET members take priority over external researchers.
2. The mitoNET primary publication goals (according to the BMBF proposal from 2018) have highest priority and must not be affected by any other research on Data or Biosamples.
3. Key actors on a specific topic precede researchers with less significant contributions.
4. Named authors will have to meet authorship criteria as set out by International Committee of Medical Journal Editors[1]. For many journals, contribution of data is not, by itself, an adequate criterion for authorship, but qualifies mitoREGISTRY and mitoBANK investigators and other key center staff that participated in the collection of the data and specimens for acknowledgement by name as Co-Investigators/Collaborators or as Contributor (see below for definitions).
5. Decisions regarding access to data or samples will be made by the mitoNET Scientific Steering Committee (SSC) [2].
6. Researchers (hereafter named RESEARCHERS) who propose to use the data and/or bio-specimens which have been collected for the mitoREGISTRY and mitoBANK will send a broad outline of the study/data mining proposal to the SSC.
7. The SSC will inform all investigators (members of the Horizontal Clinical Network (HCN) of the mitoNET), who have contributed data to the proposed study of the RESEARCHER on the request and its approval.
8. Members of the mitoNET (incl. but not limited to the members of the HCN), who may have a specific interest in the topic, may contact the RESEARCHERS in order to express an interest in active involvement in the study/data mining project. With agreement, they would work with the RESEARCHERS on the study/data mining project and be involved in the writing and reviewing of the manuscript and thereby qualify for named authorship. Declaration of interest should be received within 4 weeks of the announcement. In the event of a large number of expressions of interest relative to the size of the study/data mining project, the RESEARCHER/S may limit the number of mitoNET collaborators for active involvement to a workable number at an early stage in the process.
9. In case of arbitration each side will select an arbitrator from the SSC-team. Then, those two arbitrators select a third arbitrator, at which point the dispute is presented to the three chosen arbitrators. Decisions are made by majority vote. The decision of the arbitrators cannot be rebutted. In case the RESEARCHERS are not in agreement with the decision of the arbitrators, the proposal of the RESEARCHER could be partly or completely rejected. In the event of any disagreement, a mediation process should be initiated. Mediation should be conducted with a single mediator who does not judge the case but simply helps to facilitate discussion and eventual resolution of the dispute. The mediation should be confidential and non-binding. The parties should agree on who will conduct the mediation. The parties should agree to mediate in good faith until either party reasonably determines that it is fruitless to continue. If the parties cannot reach an agreement, an arbitration process will be initiated.
10. All manuscripts will acknowledge the methods of mitoREGISTRY data and mitoBANK samples gathering using language that is recommended by the SSC and found in the data use and material transfer agreements.
11. All manuscripts will acknowledge the support of the Federal Ministry of Education and Research (BMBF) as well as other entities providing financial support if appropriate, using language that is recommended by the respective funding source and found in the data use and material transfer agreements.
12. In addition to the named authors, all manuscripts will be submitted with (1) an acknowledgement of the mitoREGISTRY and mitoBANK using a corporate acknowledgement phrase followed by an asterisk, (2) a list of Co-Investigators/Collaborators and Contributors (if appropriate) for indexing in PubMed and listing as part of the publication (in print or as an e-content) and (3) as a class, the research participants in the study. The following definitions will be used to assign appropriate acknowledgement:

Co-Investigator/Collaborator: A person who does not meet the criteria for authorship of the study, but who acted as an investigator or study coordinator for the mitoREGISTRY and mitoBANK. Co-Investigators may be listed in the appendix (or online – depending on the journal) and are indexed in PubMed. This will include a listing of Co-Investigators/Collaborators under the name "The mitoNET Consortium"; this name will be included on the authorship line. The number of individuals each site is permitted to include on the list for "The mitoNET Consortium" will be proportionate to the number of subjects recruited at their site. This number will be determined and approved by the SSC. The list of collaborators will be maintained by the PIs of the mitoREGISTRY and mitoBANK and distributed to the lead author.

Contributor: A person who does not meet the criteria for authorship, but has contributed in other ways, including collection of data; technical help; acquisition of funding; supervision of key personnel; contribution of drugs, reagents, equipment or patients; or editing the manuscript for non-intellectual content. Contributors will be notified and are listed in the Acknowledgement section of the manuscript. The list of contributors will be maintained by the PIs of the mitoREGISTRY and

mitoBANK and distributed to the lead author. To the extent possible, names and centers should be listed for online review and appropriate indexing.

If there are any disputes in respect to authorship of a publication or the Investigator Listing, a mediation / arbitration process should be initiated as described under 9).

13. Prior publications (as long as changes are still possible) as well as AFTER publication RESEARCHERS will inform the SSC on any manuscripts, as a result of the research project according to the rules as stated in the data use and material transfer agreements. The SSC will ensure that all the above requirements are met and inform RESEARCHERS if any changes are needed.
14. If permitted by the journal, a copy of every manuscript should be provided to the mitoNET SSC upon publication and a version of the article or link to the article may be published at the mitoNET's website (mitoNET.org). In case of not open access and depending on each journals' publication policy, a preprint (the first draft of the paper, which has been initially submitted to the journal) or a postprint (the final reviewed and accepted version, but not the published version) can also be provided for online publication on the website in accordance with the embargo period of the journal.

Sub-studies and Ancillary Studies

For future sub-studies and ancillary studies, members of the sub-study/ancillary study PI and team will be given one year after the end of the respective study to submit for publication; after this period, the data will be released for data sharing (mitoREGISTRY DUA). The mitoREGISTRY and mitoBANK publication policies described above apply to all sub-studies and ancillary studies that use Registry data. The one exception is that only the mitoREGISTRY recruitment sites that participate in the specific sub-study or ancillary study and other sites contributing to the respective study will be cited.

Checklist

If mitoREGISTRY data and/or mitoBANK specimens are used in a publication, please ensure the following:

- ✓ Provide the outline of the proposal to the mitoNET SSC
- ✓ Add the mitoREGISTRY and/or mitoBANK acknowledgements as well as full listing of Contributors as agreed within the DUA / MTA
- ✓ Include any recommended language that describes the mitoREGISTRY data and mitoBANK specimen collection methods as agreed within the DUA / MTA
  Cite the BMBF as the source of support for mitoNET and the mitoREGISTRY and mitoBANK as well as other entities providing financial support if appropriate
- ✓ Provide information on any accepted manuscripts as agreed within the DUA / MTA
- ✓ Provide information on any published manuscripts as agreed within the DUA / MTA
- ✓ If allowed, send a copy, preprint or postprint of the manuscript to the SSC

1 http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

2 Until April 2022, the mitoNET SSC will be composed of the PIs of the Registry, the Biobank, and the research projects, the scientific project manager, one representative of the pediatric clinical sites, one representative of the adult clinical sites and one representative of the patient organization. After May 2022, only the PIs of the research projects may be replaced by in total two other experts for mitochondrial diseases.