Contact: Management team of the mitoNET
Friedrich Baur-Institute, Klinikum der Universität München
Fax: +49 (0)89 4400 57402
E-Mail: boriana.buechner@med.uni-muenchen.de

mitoREGISTRY – Data request

Project-#: _____ (assigned centrally)
Date:

Proposer	
Title, full name	
Organisation, institute	
Street	
Zip code, city, country	
Phone	
Fax	
E-Mail	

Project description

Title of the project			
Is there a previous proposal on the same topic?	☐ No	☐ Yes, previous project #:	
Are Samples from mitoBANK 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)			
Funding available?			

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[1] If yes, please complete the mitoBANK Material Transfer Agreement

Project-#: _____

Date:

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[1]	**Please note:** **Any publication must comply with the mitoNET Publication Policy.** **Once the publication is accepted by a journal, please send the completed Annex I of the DUA to the management team of the mitoNET.**	
Acknowledgments[2]		
Further citations to be added to the manuscript[3]		

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[1] Depending on the type of project and/or the requested data, the mitoNET management team will inform PROPOSER on the clinical sites, who collected the data.

[2] In the manuscript, PROPOSER has to acknowledge the mitoREGISTRY funding sources and any involved scientists without Co-authorship, as well as to add citations using the exact language, as provided in these sections.

Project-#: _____

Date:

Data specification

RECIPIENT	☐ same as proposer ☐ other person / address	
Title, full name		
Organisation, institute		
Street		
Zip code, city, country		
Phone		
Fax		
E-Mail		
Time period for use	from until	
Data format	☐ .CSV *(semicolon separated)* ☐ .xlsx	☐ other:
Description of the cohort / Data requested *(i.e. diagnosis, genetic mutation etc.)*	The following patients / data / sections from the Data-specification List Version No. are requested:	
Responsible for statistical analysis	Name / Institute:	
Issuance of data **Charge per data set[1]** **(double pseudonymized by a data trustee)**	☐ until April 2022: free of charge for mitoNET members and recruiting clinical sites. ☐ after April 2022: 10 € per complete visit[2] for former mitoNET members and recruiting centres. Recruiting centres will not be charged for own patient entries. ☐ 50 € per complete visit[2] for external academic sites	
Total costs for project **(to be filled in by the management team)**		
Additional notes **(if necessary use a separate sheet)**		

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[1] Transportation costs (i.e. shipment of Data-CD) have to be covered by the proposer

[2] At least the core data set and - where available - the clinical scores (Newcastle Score, SARA) will be provided.

mitoREGISTRY Data Use Agreement (V04-DEC-2019)

Project-#: _____

Date:

With the conclusion of this data use agreement the following terms have been agreed:

1) The data would be provided as requested above. The proposer has to cover the portion of the setup costs as agreed above.
2) Data use by the PROPOSER is allowed providing that there is NO transfer of ownership. All intellectual property rights and other rights to the requested data set remain with the mitoREGISTRY and the mitoNET scientific steering committee (DATA OWNER).
3) The requested data set refers to a defined status of the mitoREGISTRY. Since subsequent data modifications are possible, the data set is backed up and archived at the KUM for 10 years.
4) Prior to the transfer to PROPOSER the data will be coded by a pseudonym, so that under no circumstances will PROPOSER and RECIPIENT be supplied with the identity of the patient. In accordance with the requirements of the German Data Protection Act and the General Data Protection Regulation (GDPR) PROPOSER and RECIPIENT commit to take technical and organizational measures to appropriately safeguard the data from misuse and loss. PROPOSER and RECIPIENT will not attempt to re-identify or contact individuals who originally provided the data. The Principal Investigator (PI) of mitoREGISTRY has to be informed without any delay – no later than 36 hours of the PROPOSER becoming aware of the event - 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 the data are detected and will cooperate with the mitoREGISTRY requests for information regarding such security incident as necessary to enable the mitoREGISTRY to determine and comply with its notification obligations under Applicable Law. PROPOSER and RECIPIENT will keep all received information confidential and comply with all relevant national and international data protection regulations, in particular the GDPR.
5) The PROPOSER agrees to use the provided data exclusively for the research purposes as agreed herein and not to share / provide the data to third parties.
6) The PROPOSER agrees to inform the mitoNET management team about any noticed errors in the provided data.
7) In accordance with Good Scientific Practice after publication of the results the data sets and the analysis program should be archived for a longer period (at least 10 years according to the "DFG recommendations on good scientific practice", 1998). For this purpose, the data PROPOSER commits to archive the data and analysis programs that were used to create the publication accordingly.
8) The PROPOSER agrees to comply with the mitoNET Publication Policy. The respective corresponding author commits to adhere to the described publication goals in all internal and external publications as agreed on page 2.
9) Annex I is to be completed for any manuscripts resulting from the analysis of the requested data and has to be provided to the mitoNET management team with the acceptance of the manuscript. PROPOSER will update Annex I once the manuscript has been published.
10) During the implementation of this proposal, the parties guarantee to maintain scientific accuracy and to adhere to the accepted rules of science and technology.
11) Except to the extent prohibited by law (or, alternatively, to the extent permitted by law), the PROPOSER assumes all liability for damages to the extent due to or arising from the use, storage or disposal of the Data by the PROPOSER. mitoREGISTRY will not be liable to the PROPOSER for any loss, claim or demand made by the PROPOSER, or made against the PROPOSER by any other party, to the extent due to or arising from the use, storage or disposal of the Data by the PROPOSER.
12) If a data subject turns to the mitoREGISTRY and Biobank with the request for the deletion of this data, the mitoREGISTRY will reject this with reference to the public interest in the data processing for the traceability of research results within the meaning of Art. 17 para. 3, Art. 89 GDPR and the fact that the affected rights are sufficiently protected by the double-pseudonymization. PROPOSER and RECIPIENT will support him as necessary. If a refusal due to a different jurisprudence, due to a law or a binding instruction of the supervisory authority responsible for the parties is not possible or becomes not possible, in this case the mitoREGISTRY may require PROPOSER and RECIPIENT TO DELETE THE DATA WITHOUT COMPENSATION.
13) THE DATA ARE PROVIDED "AS-IS" AND THE mitoREGISTRY MAKES NO REPRESENTATIONS AND EXTENDS, NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, TRADE SECRET OR OTHER PROPRIETARY RIGHT. IN NO CASE WILL THE mitoREGISTRY BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES OR FOR ANY LOST PROFITS OR LOST REVENUES DUE TO, OR ARISING FROM, THE PROPOSER'S USE, STORAGE OR DISPOSAL OF THE DATA.
14) The Project shall be carried out under the direct supervision and responsibility of the principal investigator nominated by PROPOSER as identified on page 1 of the mitoREGISTRY Data Request. PROPOSER hereby declares that the Project has been approved by the responsible Local Ethics Committee on _____. The PROPOSER agrees to provide a copy of this approval to the mitoNET management team prior data transfer.
15) By signing below the PROPOSER agrees on the above mentioned terms.
16) On behalf of the mitoNET Scientific Steering Committee this agreement will be approved by the PI of the mitoREGISTRY, Prof. Dr. Thomas Klopstock, KUM.

Proposer	Name/Institute	
	Place, date	_____ Signature
For the mitoREGISTRY	**Klinikum der Universität München (KUM)**	
	Place, date	_____ Signature, Prof. Dr. med. Thomas Klopstock
	Place, date	_____ Signature, Pia Budian, Legal Counsel, Commercial Direction

Please complete and send the following table for each accepted manuscript to the management team prior proof-read.

Title of the publication	
Accepted by Journal	
	Copy and paste from the submitted file
Author(s)	
Acknowledgment(s)	
If applicable: Please confirm by activating the checkbox, that citations have been added to the manuscript as requested on page 2 of the DUA: ☐	

After publication, please update the following table and resend Annex I[1] to the mitoNET management team

Published on:	
Pubmed link:	
Link to free text:	

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[1] If allowed by the journal, please send Annex I together with the final PDF-version or a preprint of the published manuscript.

mitoREGISTRY and mitoBANK - Publication Policy

Introduction

Sharing of data and bio-specimens with the scientific community is a major objective of the mitoNET Registry (mitoREGISTRY) and 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.
8. 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.
9. 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.

   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.

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[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.

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.

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 of 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