Material and Data Access Policy
PLN Biobank

Policy and conditions for access to Material and Data

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1. Introduction

The PLN Biobank is an initiative from the PLN foundation to collect and store blood samples from PLN carriers. This biomaterial can be made available to cardiovascular researchers that want to study the pathophysiological mechanisms of PLN cardiomyopathy, improve diagnostics, or want to test novel therapeutic strategies. This Material and Data Access Policy describes the framework and practical procedures to guide access to and use of Material and Data of the PLN Biobank. This policy is a binding document for Requesters, who are seeking access to Material and Data from the PLN Biobank.

2. Definitions

Data

The data collected by the PLN Biobank in the context of collected blood samples.

Scientific Committee (SC)

An independent scientific committee with the mandate to review all applications for access to Data and Material of the PLN Biobank. The composition of the SC is specified in section 8.

Material

The blood samples collected by the PLN biobank, obtained from the blood donors that provide their blood to the PLN Biobank.

Material and Data Transfer Agreement (DTA)

A contract between the Requester and the PLN Biobank specifying conditions under which Material and Data are transferred to Requester.

Metadata

All data describing and documenting the PLN Biobank Material and Data, which is necessary for researchers to interpret the data correctly.

Provider

The PLN Biobank. The PLN Biobank provides Material and Data to a Requester. The PLN Biobank is governed by Netherlands Heart Institute and part of PLaN therapeutics. Biobanking is performed by the Durrer Center of the Netherlands Heart Institute.

Requester

A qualified person requesting data.

3. Ethical principles

When data is provided the Requester and Provider commit themselves to the following principles:

- Scientific integrity: Requester and Provider of the Material and Data are expected to act in an honest and transparent manner and uphold the highest standards of quality in scientific research.
- Responsibility and accountability: It is both the Requester's and Provider's responsibility to ensure that both parties have read and understood the relevant policies and procedures, and act accordingly. The Requester and Provider are aware of the *Privacy statement* of the PLN Foundation and act within the boundaries of the permissions given by the donors.
- FAIR data management: The Provider takes care of sufficient metadata, to enable the Requester to interpret the dataset correctly.
- Open Access publishing: The Requester is considered to publish the results of his research with the PLN Biobank Material and Data open access, to increase the accessibility of the results.
- Respect for responsible governance regarding data and research: Requester and the Provider are expected to take the necessary precautions and safeguards to avoid data breaches. This entails protecting their Data and putting in place state-of-the-art safety measures for data security.
- Material and Data Transfer Agreement (MDTA): Before Material and Data is handed over an MDTA between the Requester and Provider is composed. During the research project the Requester adheres to the conditions stated in the MDTA. The MDTA will be provided by the Provider.
- Respect for intellectual property: Sharing of Material and Data needs to be performed in a way that protects intellectual property rights of the parties involved. It also needs to address the requirements of the Requester's institute and third-party funders.
- Equity and inclusivity of users: Researchers who meet the relevant criteria should be granted access based on fair and non-discriminatory terms.
- Confidentiality: The Provider shall treat all requests confidentially and will not use them for any purpose other than assessing whether the research question can be answered with the Material and Data that is requested and whether the required informed consent is provided to share the Material/Data to answer the research question.

4. Request procedure for access to Material and Data

A Requester can submit a request through the following steps:

Step 1: Fill in the request form

- Fill out the request form.
- Clearly state which tissue samples and variables you wish to receive, which period the data set should concern, and which selection criteria should be applied.
- Email the request form to biobank@plnheart.org.

Step 2: Assessment by Scientific Committee (SC) and ethics committee for biobanks

- The request form will be assessed by the SC. Within eight weeks you will receive notice of the SC assessment.
- The request will be assessed on affiliation, funding source, rationale/background, research question, hypothesis, methodology, involvement of other disciplines and possibly social impact and implementation. At least one person with experience in preclinical research with heart muscle tissue needs to be involved in the request. There will also be a check whether a similar application has been done before (to avoid overlap of analyses) and whether the PLN Biobank data set is suitable for answering the research question.
- When the request is approved by the SC the request for the material will be assessed by the ethics committee for biobank (CTB, Commissie Toetsing Biobanken) of Amsterdam UMC. Within six weeks you will receive notice of the CTB assessment.

Step 3: Feedback from the SC

- When the SC and CTB have assessed the request, you will receive notice of the outcome.
- When the request is approved, an invoice and a Material and Data Transfer Agreement (MDTA) will be sent to the Requester.

Step 4: Provide Material and Data

- After signing the MDTA, the Material and Data will be delivered.
- Customized arrangements will be made for the delivery of Material.

Step 5: Feedback to the PLN Biobank

- At least once every six months the researcher updates the SC on the progress of the analyses.
- At least once every six months the Requester updates the SC on progress of the research and the manuscript. The SC assesses whether the manuscript is in line with the original request within three weeks.
- The PLN Biobank does not require co-authorship, but requests to mention the use of the PLN Biobank Material and Data in the acknowledgements of the manuscript.

5. Costs

There are costs associated with the use of Material and Data of the PLN Biobank. An offer will be made for each specific request that has been approved by the SC.

6. Publication and Authorship

- Publications based on Material and Data from the PLN biobank will be in accordance with international recognized scientific and ethical standards concerning publications and authorship, including the *Uniform Requirements of Manuscripts Submitted to Biomedical Journals*, established by the International Committee of Medical Journal Editors. Copyrights concerning the publications remain with the authors of the publication, regardless of any other provisions regarding intellectual property rights.
- Six months after accessing the Material and Data the Requester will be asked to provide an update to the SC. The aim is to finalize analysis and publication within nine months.
- For each publication resulting from the PLN Biobank Material and Data:
  - The SC must approve the manuscript before publication to assess whether the manuscript answers the intended research question (refer to step 5 in paragraph 4 'Request procedure for access to Material and Data'),
  - The PLN Biobank will be mentioned in the acknowledgements.

7. Open Access

The PLN Biobank emphasizes the importance of accessible research results for anyone, as well to researchers as to patients, companies, and social institutions. Therefore, publications based on PLN Biobank Material and Data should be published open access.

8. Composition of the Scientific Committee (SC)

The SC consists of experts on PLN cardiomyopathy and a board member of the PLN foundation. The members of the Scientific Committee are appointed by the PLN Foundation.