



**Material and Data Access Policy
Netherlands Heart Tissue Bank**

Policy and conditions for access to Material and Data

Contents

1. Introduction	3
2. Definitions	3
3. Ethical principles	4
4. Request procedure for access to Material and Data.....	5
5. Costs	6
6. Publication and Authorship	6
7. Open Access	6
8. Composition of the Data Access Committee (DAC)	6

1. Introduction

The Netherlands Heart Tissue Bank (NHTB, Nederlandse Hartenbank) is a biobank that collects and stores high-quality cardiac tissue from donors. The tissue and related clinical data will be available for cardiovascular researchers to study pathophysiological mechanisms in heart diseases, to improve diagnostics and yield novel (drug) therapies. This Material and Data Access Policy describes the framework and practical procedures to guide access to and use of Material and Data. This policy is a binding document for Requesters, who are seeking access to Material and Data from the NHTB.

2. Definitions

Data

The data collected by the NHTB in the context of collected heart tissue.

Data Access Committee (DAC)

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

Material

The heart tissue collected by the NHTB, obtained from the donors that are registered for the NHTB.

Material and Data Transfer Agreement (DTA)

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

Metadata

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

Provider

The NHTB. The NHTB provides Material and Data to a Requester. The NHTB is part of the Netherlands Heart Institute (NLHI). Biobanking, data management and quality management are performed by the Durrer Center of the NLHI.

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](#) and the "[Ethische en juridische verklaring](#)" of the NHTB 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 NHTB 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

- Check whether a [request](#) for the desired Material and Data set already exists.
- Check the [data dictionary](#) on the website for an overview of the available variables.
- 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 info@hartenbank.nl.

Step 2: Assessment by Data Access Committee (DAC) and ethics committee for biobank

- The request form will be assessed by the DAC. Within eight weeks you will receive notice of the DAC 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 NHTB data set is suitable for answering the research question.
- When the request is approved by the DAC the request for tissue will be assessed by the ethics committee for biobank (BTC, Biobank ToetsingsCommissie) of Amsterdam UMC. Within three weeks you will receive notice of the BTC assessment.

Step 3: Feedback from the DAC

- When the DAC and BTC 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.
- The Data will be sent with SURF FileSender.

Step 5: Feedback to the NHTB

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

5. Costs

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

6. Publication and Authorship

- Publications based on Material and Data from the NHTB 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 DAC. The aim is to finalize analysis and publication within nine months.
- For each publication resulting from the NHTB Material and Data:
 - The DAC 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 NHTB will be mentioned in the acknowledgements.

7. Open Access

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

8. Composition of the Data Access Committee (DAC)

The DAC consists of the members of the Scientific Advisory Board of the NHTB.