

DETECTIN-HF Policy

for Access to and Sharing of

Biological Samples and Data

1. Introduction

DETECTIN-HF is a transnational European research project on DETERmining the role of Clinical and epi-geneTic risk markers IN dilated cardiomyopathies and Heart Failure. The DETECTIN-HF consortium aims at three major tasks:

- 1) Harmonization of existing national registries to foster trans-national research on DCM;
- 2) To investigate the clinical value of selected biomarker candidates, genotypes and gender effects in this large-scale cohort;
- 3) to develop and validate a personalized risk model for development of HF and SCD in DCM patients.

By creating a single portal and harmonization of clinical workflows, an infrastructure arises which facilitates access to human biological samples and associated clinical and research data from the individual national registries.

DETECTIN-HF will encourage and expedite effective and ethical access to samples and data from this consortium, preferably in the context of high-level research collaboration between providers (e.g. registries with their biobanks, including scientists and physicians who contributed to these registries and biobanks) and requesters. At the start of this project, 5 European countries collaborate in DETECTIN-HF: Heidelberg (Germany), Utrecht (Netherlands), Paris (France), Warsaw (Poland) and Tartu (Estonia).

This access policy presents three areas of guidance:

- i) ethical principles;
- ii) governance procedures; and
- iii) practical procedures for access.

Together with existing legal frameworks, these three areas provide the ethical and legal framework and practical procedures to guide access to and use of biological samples and associated data. This policy is a binding document for requesters, who are seeking access to samples/data from DETECTIN-HF.

2. Definition of Terms

Samples/Data

Biological samples or data stored in, and under stewardship of, one of the individual registries collaborating in DETECTIN-HF, as well as data derived through the use of the requestor.

Consortium Partner

Registries participating in the DETECTIN-HF consortium as mentioned in the granted proposal vor DETECTIN-HF. Please note that the individual registries remain in control over ultimately granting / denying access to potential users/requesters.

Requester

A qualified person requesting samples/data. Needs to be registered as specified in Step-1 and -2 of paragraph 6.

Bona Fide Researcher

A researcher with:

1. an intention to generate new knowledge and understanding using rigorous scientific methods;
2. an intention to publish the research findings and share the derived data in the scientific community, without restrictions and with minimal delay, for wider scientific and eventual public benefit; and where
3. the intended activities are not inconsistent with legal and ethical requirements or widely recognised good research practice; and
4. they have a bona fide research project: in practical terms, a research project or proposal that has been approved by a recognised funder, or a researcher that belongs to a research organisation that has the capability to lead or participate in high quality, ethical research should normally be considered bona fide.

Provider

A DETECTIN-HF Consortium Partner providing a registry including samples/data.

MTA

A contract between the requestor and the DETECTIN-HF Consortium specifying conditions under which the biological material and/or data are transferred to a recipient. A data-only transfer agreement is sometimes called a Data Transfer Agreement (DTA) or Data Access Agreement (DAA).

Project Outcome

Can be published in the form research papers, patents, new therapies and other types of commonly acknowledged medical research achievements. This also includes a report on the use of samples and/or data.

Personal Data

'Personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (GDPR Article 4.1).

Pseudonymisation

'Pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person (GDPR Article 4.5).

Human Biological Samples

Constituent parts of the human body, or human biological material, including organs and parts of organs, cells and tissues, and body fluids.

Data and Sample Access Committee (DSAC)

An independent committee with the mandate to review all data and sample access applications to the DETECTIN-HF Consortium. It is composed by one representative of each DETECTIN-HF Consortium Partner. The DSAC makes recommendations for approval/rejection of access requests.

3. Legal Premise

All proceedings related to access and sharing must be compliant with national and European legislation such as the Directive 95/46/EC and, as of 28 May 2018, the EU General Data Protection Regulation and a Code of Conduct (GDPR Article 40). It is the national legislation that applies to the data controller responsible for a biorepository, a registry, or a collection of personal data which, in turn, applies to the processing of samples and data, irrespective of where the samples and data are used. The processing of data and the use of biological samples must be compliant with the provisions of the informed consent form and/or decision of an ethical review board, and/or a data protection authority/officer if applicable. If none of the above is applicable, it must be compliant with national legislation.

4. Governing Ethical Principles

DETECTIN-HF will facilitate and support access to samples and data from participating registries according to the following principles:

1. Scientific integrity:
Requesters and providers are expected to act in an honest, transparent, equitable manner and uphold the highest standards of quality in scientific research.

2. Responsibility and accountability:
It is both the requesters' and providers' responsibility to ensure that they have read and understood the relevant policies and procedures and that they act in accordance with them.
3. Respect for responsible governance regarding data and research:
Requesters and providers are expected to take the necessary precautions and safeguards to avoid subjects' privacy breaches. This entails protecting their personal data and putting in place state-of-the-art safety measures for data security.
4. Respectful use of limited resources:
Request for access to biological samples of a limited nature will be granted particularly sparingly. Requesters are expected to request only as much as is required and to obtain results that cannot be effectively achieved otherwise.
5. Accessibility to research results:
Requesters should be willing to make their research results accessible for academic purposes on a royalty-free basis and in a timely manner.
6. Attribution:
The intellectual investment of investigators involved in the creation of data registries and bio-repositories is often substantial, and should be acknowledged. This should be specified in Material and Data Transfer Agreements (MTA/DTA) signed by both parties.
7. Respect for intellectual property:
Sharing of data and biological samples needs to be performed in a way that protects intellectual property rights of the parties involved. It also needs to address the requirements of institutions and third-party funders.
8. Equity and inclusivity of users:
Bona fide researchers who meet the relevant criteria should be granted access based on fair and non-discriminatory terms.
9. Reciprocity:
Stewardship also implies giving something back. Feedback regarding general results should be channelled towards institutions and patients.
10. Confidentiality:
DETECTIN-HF shall treat all the access requests confidentially and will not use them for any purpose other than assessing the availability of the samples/data and access provisions.

5. Procedures Governing Access to and Use of Samples/Data

- A. The samples/data remain under the stewardship of the DETECTIN-HF Consortium Partner as the original source, unless otherwise specified under a separate agreement. Consequently, DETECTIN-HF Consortium only facilitates access, while the DETECTIN-HF Consortium Partners actually grant and provide access. Access should be based on requests for specified research projects.
- B. The quality of data and biological samples shall be ensured by the provider.
- C. The requester needs to ascertain that the samples and data provided are stored in a secure storage and operation facility accompanied by an appropriate access policy, including a

description of who can access the facility, the time-period the samples/data will or need to be stored, and concrete steps for sharing samples/data.

- D. Material Transfer Agreements (MTAs), Data Transfer Agreements (DTAs) or Data Access Agreements (DAAs) should always be used to govern transfer between parties.
- E. Samples/data can only be used for academic or industrial research purposes, depending on the legislation of the Member State or international organisation: The usage and limitations need to be specified in an MTA/DTA between the requester and the DETECTIN-HF Consortium Partner.
- F. All projects using identifiable human biological materials and derived data (beyond the original project for which samples/data were initially collected and provided) are subject to the overarching principle above, i.e., they must also be evaluated by an appropriate and legitimate ethical review board.
- G. The entity which provides biological samples or personal data shall explicitly document any restriction of use or obligation applicable to these biological samples or data (e.g., the limited scope of purpose imposed by the consent form, the obligation to report incidental findings, publication restrictions such as non-discrimination clauses, etc.).
- H. Requests for access to samples/data issued by requesters will be required to follow the request procedure for samples/data via the DETECTIN-HF portal (Section 6).
- I. In order to maximise the value of the registries, DETECTIN-HF requests that provenance data as well as data derived from samples/data are transferred back to the respective DETECTIN-HF Consortium free of charge (so-called 'return of data').
- J. Access will be cost-neutral for requesters. It maybe that the DETECTIN-HF Consortium requires the requesters to partially or fullycover the costs incurred in providing samples and/or data. Cost aspects must be regulated in the MTA/DTA between the requester and the DETECTIN-HF Consortium.

6. Request Procedure for Access to Samples/Data via BBMRI-ERIC IT Services

The basic framework governing the request procedure for accessing samples/data via the DETECTIN-HF portal comprises the following steps.

Step 1: Registration of requester

DETECTIN-HF verifies the identity of each requester and his/her institutional affiliation (employee status).

Step 2: Request of samples/data

A requester files a request for access to samples/data via the DETECTIN-HF portal. The digital form must be filled in. Each request includes information about the approved/proposed research project including its ethical approval status, expected properties of and amount of samples/data and their anticipated use. Data and Sample Access Committee (DSAC) may either request refinement of the request. In compliance with the governing ethical principles in paragraph 4.10, the request is treated as confidential by the DSAC, i.e., it will not be disclosed to other providers. Providers will not use requests for any other purpose than assessing the availabilityof the requested samples/data and providing offers.

Step 3: Access control & samples/data delivery

After receiving feedback from the DSAC, the requester follows up directly with the DSAC in order to provide any additional information needed to assess whether access can be granted. As part of this process, the DSAC must comply with the regulatory and ethical conditions (e.g., data protection regulations, assessment of compliance of informed consent with the approved/proposed project, checking whether the amount of deployable/extraditable samples required is scientifically justified) and transfer liability to the requester by using MTAs/DTAs as deemed appropriate. The DSAC has to decide whether samples/data are released for the project requested. Similarly, access to deliverable/extraditable samples may be subject to prioritisation. For approved requests, the MTA/DTA will need to be executed and access charges paid before samples/data are released to the requester.

Step 4: Return of results

DETECTIN-HF requests that provenance data as well as data derived from samples/data are transferred back to the DETECTIN-HF Consortium free of charge (so-called 'return of data').

Step 5: Request completion notification

For each request obtained via the DETECTIN-HF portal, where Step 3 has been completed, the DSAC needs to be informed whether the request has been completed successfully (whether samples and/or data were provided to the requester and/or whether Step-4 was also completed), or whether it failed. In case a request fails, reasons for failure have to be specified.