

# Ethical Governance Framework

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## Definition of terms used in this document

### *Anonymisation*

Data are considered to be anonymised where they are fully (unlinked) anonymised or linked (coded, pseudo-) anonymised where the linkage code (cipher) is not held by, or accessible to, the researchers/research establishment.

'Anonymised' data do not contain any identifiable information such as, for example, name, address, phone number, full date of birth, national health or social insurance numbers, full postcode, etc., and it is not reasonably possible for the researcher to identify the individual to whom the data relate.

- Linked anonymised (or pseudoanonymised or coded) data are fully anonymous to the researchers who receive or use them, but contain information or codes that would allow others (e.g., the clinical team who collected them or an independent body entrusted with the safekeeping of the code) to link them back to identifiable individuals.
- Unlinked anonymised data contain no information that could reasonably be used by anyone to identify the individuals who donated them or to whom they relate.

### *Data*

The term 'data' in this document may refer to genomic data, anonymised images, metadata, etc. It does not refer to data that contains identifiable information such as name, phone number, or date of birth.

### *Personal Data*

Data which may be used to identify a research participant. (Note: Although in some EU jurisdictions personal data may also be used to

describe human biosamples, in the context of this document, it relates to identifiable data only).

#### *Data provider*

The 'data provider' is the individual researcher or investigator or body of researchers or investigators that makes data available for access and use within the BioMedBridges project. (It does not refer to the participant.)

#### *Participants*

The term 'participant' refers to an individual whose data are accessed within the scope of the BioMedBridges project. Participant in this document is equal to "data subject" in applicable EU legal documentation.

#### *Ethics committee*

The term 'ethics committee' in this document refers to a committee which has given ethical approval for a study which has collected data that will be subsequently made available by the data provider within the BioMedBridges project. (It does not refer to the BioMedBridges Ethical Governance Committee.)

#### *Project*

'Project' refers to the BioMedBridges project (funded by the European Commission within Research Infrastructures of the FP7 Capacities Specific Programme, grant agreement number 284209).

#### *Project coordinator*

'Project coordinator' refers to the European Bioinformatics Institute, which coordinates the BioMedBridges grant.

#### *Research Infrastructures*

The ten Research Infrastructures (RIs) involved in the BioMedBridges project include:

- Biobanking and Biomolecular Resources research infrastructure (BBMRI)
- European Advanced Translational Research infrastructure in Medicine (EATRIS)
- European Clinical Research Infrastructures Network (ECRIN)
- European Life Science infrastructure for Biological Information (ELIXIR)
- European Marine Biological Resource Centre (EMBRC)
- European Infrastructure of Open Screening Platforms for Chemical biology (EU-OPENSSCREEN)
- European Biomedical imaging infrastructure (Euro-BioImaging)
- European Research infrastructure on Highly Pathogenic Agents (ERINHA)
- European Infrastructure for Phenotyping and Archiving of Model Mammalian Genomes (Infrafrontier)
- Integrated Structural Biology Infrastructure for Europe (INSTRUCT).

# 1 Introduction

## 1.1 Project aims

This document sets out policies for the BioMedBridges project that specifically relate to ethical and regulatory issues with regard to the storage and access of data.

The objective of the BioMedBridges project is to better enable researchers to access data, increasing its utility with the ultimate goal of benefiting society, for example by facilitating new discoveries in health research and by allowing re-analysis of expensive, rare or unrepeatable investigations, while continuing to protect the interests of research participants with regard to their privacy and confidentiality.

## **1.2 Background for the Ethical Governance Framework**

The aim of this Ethical Governance Framework is to enable the BioMedBridges project to operate within agreed terms with respect to participant consent, ethics committee approvals and national regulations, ensuring researchers supply and access data whilst working under a common ethical framework. The framework has been written so that very different datasets can be utilised in an ethically-coherent manner to maximise research benefit, while acknowledging the responsibilities and obligations that are owed to research participants.

Data providers have a number of responsibilities and obligations, such as the obligation to respect participant confidentiality. Researchers accessing the data have a custodian role, to ensure the careful and responsible management of the information. They have an obligation to operate in conformity with the requirements of their own institution, and fulfil all necessary national and international regulatory and ethical requirements. They also have obligations to the BioMedBridges project, as well as the funders and the wider research community, to carry out high quality, ethical research.

The purpose of this document is to provide a framework for the project and to focus on specific issues that are key to the development and operation of BioMedBridges. To achieve this, ethical policy documents established by other large-scale consortium projects, including the Wellcome Trust Sanger Institute's UK10K project, have been drawn upon during the writing of this framework.

## **1.3 Background of the Research Infrastructures involved in the project**

Concerning the issues involved in data security and ethical governance of the BioMedBridges project, it is essential to define the roles and responsibilities of the ten biomedical sciences research infrastructures (RIs) involved in the project:

1. RI that hold and/or provide data (e.g. Infrafrontier, Elixir, ECRIN)
2. RI that provide only metadata (e.g. BBMRI)
3. RI that have no data or are users/consumers of data (e.g. ECRIN, EATRIS).

Data security and full consideration of ethical issues are not only relevant to RIs that hold data, but are also the responsibility of all RIs that intend to use the data.

### **1.4 Project-specific considerations**

Consideration should be given for handling data within the project with respect to

- Trans-border/international access to data
- Establishment of new links between data or types of data that were not linked before.

## **2 Project bodies involved in ethical governance**

The bodies involved in ethical governance of the project are:

- The Independent External Ethics Advisor
- The Ethical Governance Committee, which is comprised of experts whose backgrounds cover the different areas of the project
- The Executive Steering Committee.

### **2.1 Independent External Ethics Advisor**

The Independent External Ethics Advisor:

1. Monitors and reports on the progress of compliance with requirements of the Ethics Review Report and reports on this to the Commission *via* Periodic Reports
2. Oversees the development and preparation and implementation of the Ethical Governance Framework
3. Advises the Ethical Governance Committee, the Executive Steering Committee and the project coordinator on all ethical issues
4. In consultation with the Ethical Governance Committee and the project coordinator, ensures that the project operates to appropriate ethical standards.

## **2.2 Ethical Governance Committee**

The Ethical Governance Committee:

1. Monitors the compliance of the project beneficiaries with the Ethical Governance Framework
2. Provides an ethics management report to each meeting of the BioMedBridges Executive Steering Committee (every three months)
3. Supports the External Independent Ethics Advisor in monitoring and reporting on the progress of compliance with the requirements of the Ethics Review Report and Ethical Governance Framework
4. As necessary, prepares updates of the Ethical Governance Framework, to be approved by the project's Executive Steering Committee.

## **2.3 Executive Steering Committee**

The Executive Steering Committee:

1. Is responsible to ensure that there is no scope-creep within the project with respect to unforeseen use of the mechanisms, processes and infrastructure developed during the project to facilitate the transfer and use of data where Ethical, Legal and Social Issues (ELSI) pertain
2. Approves the Ethical Governance Framework and any updates thereof
3. Ensures that suitably qualified individuals are appointed for the role of Independent External Ethics Advisor and the Ethical Governance Committee.

## **3 General provisions**

### **3.1 Regulatory approvals**

Responsibility for all data that is made available, linked or accessed via the services provided by the project remains with the data providers and must have been obtained in accordance with the laws and regulations in operation in the country in which the data provider resides. This includes any requirement for approval from an appropriate ethics committee or other regulatory body.

Depending on the type of consent given by the participant, there may be joint data custody between the participant and the data provider. It is the responsibility of the data provider to ensure that such joint custody is not in conflict with the provisions of this framework and that the data may be used within the project.

Data providers should determine whether, with respect to the use in the project, any additional approvals may be required for the data they have collected.

Where data providers have collected data from participants in countries outside of their own (another data 'source country'), they must ensure that approvals have been given by appropriate ethics committees and/or other regulatory bodies in the source country of the data to be used in the project.

Data obtained *via* the use of animals in research can only be made available for the BioMedBridges project if the work has taken place within the requirements of national regulations and with appropriate licences or authority permission as required by national law, and with due consideration given to animal welfare and care.

### **3.2 Documentation**

Using the form provided in Appendix 1 to this document, data providers must certify that they will abide by this Ethical Governance Framework and its stipulations, and that appropriate ethical approval and/or consent are in place prior to use of the data within the project.

The data provider forms will be collected by the project coordinator and stored centrally.

### **3.3 Updates to the framework**

As the project evolves, adjustments may be made to this framework. Any adjustments shall be developed and agreed by the Ethical Governance Committee and approved by the Executive Steering Committee.

## **4 Human participants**

### **4.1 Data providers**

The project has been designed to enable maximal benefit from research by making data as accessible as possible to the research community,

while protecting the interests of participants from whom the data originate with regard to their privacy and confidentiality, and within the scope of their consent.

Data providers are responsible to ensure that the responsible ethics committees, data access committees, national regulatory authorities or equivalent bodies have granted approval for the data they provide to be accessed within the project. The data provider must ensure that prior approval is available before any deposition of data which may be accessed by users of BioMedBridges services occurs.

Deposition of data by the data providers will act as assurance to the project that data providers have sought and obtained, where necessary, all appropriate approvals as required by relevant national laws and regulations. Where approvals are necessary, the data provider form included in Annex I to this document must be completed and submitted to the project coordinator.

Where there is any doubt, or where the consent does not foresee the use of data in BioMedBridges, approval from an appropriate ethics committee or national authority as required by law or regulation must be sought before data are deposited for use in the BioMedBridges project.

## **4.2 Confidentiality and data security**

All data providers have an obligation of confidentiality and must conform to data protection principles to ensure that data is processed lawfully.

In some areas of the project, the level of detail of data held on a participant may be such that it will be unique to that participant and thus, if linked to other non-anonymised data, could potentially be used to identify the participant. This raises important privacy protection issues. As such, data held within the project must always be linked or unlinked anonymised. Consequently, identification by a third party would only be possible if extra information for a participant were to be made available;

for example, if another dataset was available elsewhere containing data associated with the participant's name, and this was in turn used in conjunction with data that is made available within the project.

Certain data analyses may confer non-intentional stigmatisation of subsets of the population involved. Consequently, any new study within the project that may have the potential to cause stigmatisation through the publication of the results of analyses must be carefully considered and discussed with an appropriate ethics committee in order to obtain further guidance prior to the analyses being undertaken.

### **4.3 Informed consent**

Where the project involves the use of patient data, prime consideration should be given to whether existing consent for the use of this data in the project is sufficient and in accordance with any requirements set down in national guidelines or protocols, which may be upheld by relevant national or local authorities, or by ethical or regulatory bodies. This includes consent given by participants residing in a source country that is different from the country the data is subsequently deposited in. Where this was not initially consented, the responsible authority or research ethics committee should approve the sharing of data across national boundaries. However, in the case of countries using a legal 'opt out' system relating to the use in research of participants' residual human tissue originally taken for medical purposes, rather than a consent process, data from these samples may be included in the project if the 'opt out' system allows for the use and sharing of the data in ways defined by the BioMedBridges project.

Novel ways of combining data or datasets within the project can proceed as long as data is linked or unlinked anonymised and an appropriate ethics committee or national authority has granted approval where required. Where there is doubt that consent provisions adequately cover the combination of datasets, the opinion of an appropriate ethics

committee or national authority should be sought as to whether additional participant consent is required.

4.3.1. Adequate consent available: Where pre-collected participant consent adequately covers the use of data in the project, no further consent will need to be sought.

4.3.2 Adequate consent not available: Where adequate consent has not been obtained, or where there is doubt, a data provider should seek approval from an appropriate ethics committee and, where national requirements dictate, from a relevant regulatory body or authority, before the data can be deposited. An example for this may be pre-collected data where consent or approval was not broad enough to include the use of the data in BioMedBridges.

### Consent forms

Drafting consent forms and obtaining consent for new data collections is entirely the responsibility of the researcher collecting the data, and the responsibility to ensure that appropriate consent and/or ethics committee or other authority approval is in place before data is deposited and/or made available for the project lies exclusively with the data provider.

It is suggested that, going forward, broad and generic consent for the use of datasets may better serve the purposes of the BioMedBridges project, and that consent of this type should be considered, along with advice from appropriate ethics committees and national authorities, where applicable.

It is also suggested that, for future studies and trials, consent should allow for participants to retain control over their data so as to allow for withdrawal up until the data is shared with other researchers or published.

Consent forms should be drafted to adequately cover the BioMedBridges project plans for:

- Access to and linkage of data that is stored in an electronic database
- Sharing of data with other researchers within and outside of the country
- Any decisions made regarding the management and communication of findings of individual clinical significance, including any obligations data consumers may have to communicate findings, and any pre-set time-limits for the feeding-back of results
- Permission for future recontact (if needed).

When drafting consent forms and participant information sheets, it should be ensured that the provisions in these documents do not preclude data sharing, such as by promising to destroy data unnecessarily.

### Re-consent

Re-consent is not required if a broad consent has been obtained, nor if an appropriate ethics committee or relevant authority agrees that the benefit of using the participant's data in the project outweighs any risk to that participant, and local, regional or national regulations allow authorities or ethics committees to make this decision. Ethics committees may decide on alternative methods of informing participants of the uses to which their data may be put, for example, by sending a letter by recorded delivery to the participant's home if they have agreed to be re-contacted, and giving the participant the option to withdraw data that relates to them if not integrated in a dataset or published. Newsletters and websites can also serve as communication tools.

#### **4.4 Feedback to participants**

In general, direct feedback of results and incidental findings within the project to participants is not anticipated or planned. The project is concerned with building data bridges, constructing tools and technology to link up different types of data, not with processing and analysing data. Provisions surrounding feedback of results and incidental findings directly to participants are thus unnecessary and beyond the scope of the project.

Data providers should inform the project coordinator via the data provider form (Appendix 1) if they, or any third party who uses the data, are under any obligation to communicate (feedback) findings of individual clinical significance to participants.

The mechanism of feedback must have been consented to by the participant, agreed with an appropriate ethics committee or national authority and findings must be validated to a diagnostic standard prior to reporting back to the participant. Conversely, participants should be informed during the consent process if no feedback will occur. However, it must be understood before a dataset is used for the project that an open commitment to re-evaluate ad infinitum data from a participant to identify clinically significant findings is not sustainable and, if feedback is considered, there must be an unambiguously predictive relationship between the finding and the disease.

#### **4.5 Participant withdrawal**

Due to the nature of the project, although data may be removed if a participant withdraws their consent, it will be impossible to guarantee the complete withdrawal of individual data from all researchers who have already accessed it.

Where possible, the data held on a participant who wants to withdraw will be removed; however, it will not be possible to remove unlinked

anonymised data. If there is any doubt that participant consent might not allow for the retention of data under the circumstances detailed above, then advice from the responsible ethics committee or national authority should be sought prior to making the data available within the project.

## **5 Use of animal data**

Where the project involves animal data, the data provider must ensure that national guidelines for their welfare and care during collection of the data were followed.

Animal life must have been respected and research work to collect data undertaken within the requirements of national regulations and with appropriate licences or permission by the responsible authorities as required by national law.

## **6 Assurances to third parties**

Assurances made to third parties, such as those found in Material Transfer Agreements, must be included with any accompanying information sent with a dataset prior to its inclusion in the project.

## **7 Time-limited data**

Data providers must make any information about time-limitations attached to datasets by virtue of consent restrictions, ethics committee approval or national regulations, available to the project administration by completion of the relevant section on the data provider form.

# Appendix 1

## Data provider form

**This form must be completed by all parties providing data where there are underlying restrictions on use imposed by consent requirements, ethics committee approvals, national regulations or any other agreements within the BioMedBridges project**

NOTE: Custody of all data made available within the project remains with the provider (and, where applicable, the participants). The data provider has full responsibility for the data when making it available within the project under the terms agreed within the BioMedBridges Ethical Governance Framework.

1	Name of data provider	
2	Name and address of data providers' research institute/university	
3	Name of dataset and URL of dataset or service	
4	Please list the restrictions on use imposed by consent requirements, ethics committee approvals, national regulations or any agreements, such as, research collaboration agreements, material transfer agreements, and data access agreements, including those made with other parties who may have originally supplied the data	
5	Is the research participant data linked or unlinked anonymised*?	
6	If linked anonymised, name the person(s) holding the linkage key	
7	If linked anonymised, please give the name and address of the linkage key holder's research institute/university	
8	If applicable, please state if there is a date by when this dataset must be removed from BioMedBridges	

<p>9 Please state any decisions made regarding the management and communication of findings of individual clinical significance, including any obligations data requestors may have to communicate findings, and any pre-set time-limits for the feeding-back of results</p>	
<p>10 <u>Please sign</u> to indicate that you have read the BioMedBridges Ethical Governance Framework document and you agree to abide by the conditions contained therein</p>	
<p>11 <u>Please sign</u> to confirm that the donor consent provisions and/or ethical approval, and national laws and regulations, allow the use of the data in BioMedBridges</p> <p><i>If you are unsure whether the current consent provisions or ethical approval adequately allow the use of the data in BioMedBridges, we recommend you seek advice from an appropriate ethics committee</i></p>	
<p><b>For Office Use Only</b></p>	
<p>Signature of BioMedBridges Coordinator representative</p>	
<p>Date of approval</p>	

\*Linked anonymised (or pseudo-anonymised) means that the data is coded and can be linked back to the participant by the holder of the linkage 'key', but not by the third party researcher accessing the data. Unlinked anonymised means that no-one is able to identify which participant the data originated from.