BioMedBridges

Deliverable D1.6

Project Title:	Building data bridges between biological and medical infrastructures in Europe	
Project Acronym:	BioMedBridges	
Grant agreement no.:	284209	
	Research Infrastructures, FP7 Capacities Specific Programme; [INFRA-2011-2.3.2.] “Implementation of common solutions for a cluster of ESFRI infrastructures in the field of "Life sciences"	
Deliverable title:	The Ethical Governance Framework for BioMedBridges	
WP No.	1	
Lead Beneficiary:	1: EMBL	
WP Title	Management	
Contractual delivery date:	30 June 2013	
Actual delivery date:	30 June 2013	
WP leader:	Janet Thornton	1: EMBL
Contributing partner(s):	n/a	

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Contents

1 Executive summary

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.

The BioMedBridges Ethical Governance Framework sets out policies for the project that specifically relate to ethical and regulatory issues with regard to the access of data used within the project. The aim of the 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 based on a common ethical framework focussing on specific issues that are key to the development and operation of BioMedBridges

The BioMedBridges Ethical Governance Framework as presented in Annex 1 to this report was developed by the Independent External Ethics Advisor and the Ethical Governance Committee and was approved by the Executive Steering Committee of the project.

2 Project objectives

With this deliverable, the project has reached or the deliverable has contributed to the following objectives:

No.	Objective	Yes	No
1	Manage the BioMedBridges project from Year 1-4		x

2	Organise the management meetings for all the project including: the Annual General Meeting for all partners; the Executive Steering Committee meetings (up to twice per annum) and the regular meetings of the Technical Coordination Committee (up to 3 times per annum)		x
3	Organise the Scientific Advisory Committee and their annual meeting, including reporting back to all partners		x
4	Provide good communication between all partners, through a professional web site		x
5	Ensure timely and appropriate reporting to the commission and completion of deliverables in all Work Packages		x
6	Develop metrics to assess the progress of the grant and its impact on the BMS community		x
7	Develop with all partners a plan for sustainability of the infrastructure built during the project, following completion of the grant		x
8	Ensure that ethics issues are addressed	x	

3 Detailed report on the deliverable

3.1 Background

As part of the evaluation of the BioMedBridges proposal by the Commission, an Ethics Review was conducted in May 2011 and some issues were raised that need to be coordinated across all of the BioMedBridges partners and countries.

The Ethics Review Report stated the following requirements for the project:

1. Reporting. Prior to the commencement of each relevant WP, and where applicable, copies of ethical approvals, opinions or notifications by the competent legal local or national ethics boards, bodies or administrations must be submitted to the European Commission and reported as a deliverable.

2. Legitimacy of Data Samples. Applicants must confirm that all data samples used in this project are either legitimately available commercially or have been obtained following appropriate ethical approval.

3. Data Controller. In compliance with Directive 95/46/EC and with article 29 working group 8/2010 opinion, a data controller dedicated to the project should be designated.

4. Independent External Ethics Advisor. Given the extent and complexity of the ethical issues involved, an external independent Ethics advisor must be appointed, and a report by the Ethics Advisor must be submitted to the European commission REA together with the Periodic Reports.

5. No new data. Confirm that no additional new data will be collected, e.g. related to animal studies.

6. Data management. Applicants should provide detailed information on procedures that will be implemented for data collection, storage, access, sharing policies, protection, retention and destruction. Confirmation that they comply with national and EU legislation should also be included. More specifically, applicants should provide more information on the use case of personalised medicine, specification of content requirements and of sharing and access procedures.

7. Unforeseen usage. Applicants must address the potential for unforeseen usage of the massive data centre envisaged by the proposal and the possibility for ‘mission creep’.

Additionally, the progress of compliance with these requirements should be described in the periodic and final reports. The BioMedBridges Ethical Governance Framework is intended to address these points.

4 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

In addition, WP5 Secure access is involved in the implementation of the infrastructure enabling secure and ethical use of data.

4.1 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.

The Independent External Ethics Advisor is Carol Smee, Wellcome Trust Sanger Institute.

4.2 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.

Committee:

- Janet Thornton, Chair
- Ruth Chadwick, University of Cardiff and ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) (nominated by BBMRI)
- Christian Gluud, Copenhagen Trial Unit, Centre for Clinical Intervention Research, Copenhagen University Hospital (nominated by ECRIN)
- Kimmo Pitkänen, Institute for Molecular Medicine Finland (FIMM) (nominated by EATRIS)
- Maurizio Ribera d'Alcala, Stazione Zoologica Anton Dohrn (nominated by EMBRC)

4.3 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.

Committee:

- Janet Thornton (Chair)
- BBMRI: Kurt Zatloukal, Jan-Eric Litton
- EATRIS: Gerrit Meijer, Jan Willem Boiten
- ECRIN: Jaques Demotes, Christian Ohmann
- ELIXIR: Søren Brunak
- EMBRC: Wiebe Kooistra
- EU-OPENSCREEN: Ronald Frank
- Euro-BioImaging: Jan Ellenberg, Antje Keppler
- ERINHA: Hervé Raoul, Caroline Carbonelle
- Infrafrontier: Martin Hrabé de Angelis, Michael Räss
- INSTRUCT: David Stuart, Lucia Banci

4.4 WP5 "Secure access"

Work Package 5 "Data security" will:

> *[…] address regulations, requirements and design aspects as well as security implementation. It will analyse the legal and ethical situation concerning sharing and transfer of data and access to data in a trans-European context for all e-Infrastructures. The legal implications and corresponding data exchange strategies will be analysed on the European, national, regional (e.g. data protection law in Scotland) and local (e.g. hospital law) level. Legal implications for different types of data and linking of data have to be considered, including biobank data, genetic data, stem cell research data, data originating from children and vulnerable populations, and the special situation of clinical trials data (Directive 2001/20/EC and GCP). Specific attention will be*

paid to personal data (Directive 95/46/EC) and the roles of data controller and data processor for the data bridges[1].

The WP5 deliverables are:

No.	Name	Due month
5.1	Report on regulations, privacy and security requirements	18 (Jun 2013)
5.2	Tool for assessment of regulatory and ethical requirements, including supportive documents	24 (Dec 2013)
5.3	Report describing the security architecture and framework	30 (Jun 2014)
5.4	Implementation of a pilot for the security framework	48 (Dec 2015)

5 Specific items addressed in the framework

5.1 Scope and rationale of the framework

- The framework covers only the work done within the BioMedBridges project.
- It is a broad terms document. It is not feasible or within the scope of the project to investigate and include detailed legal requirements from each of the BioMedBridges or biomedical sciences research infrastructure (BMS RI) partner countries. Instead, data should only be made available within the project for which all national regulatory requirements have been fulfilled.
- No new data will be generated within the BioMedBridges project.
- No data will be stored in conjunction with the project. Data is stored by the data providers and made accessible/linked from there.
- Novel ways of combining data or datasets within the project can proceed as long as the data is linked or unlinked anonymised and the responsible research ethics committee (NB: not the project's Ethical Governance Committee) has granted approval.

[1] http://www.biomedbridges.eu/workpackages/wp5

— Responsibility for all data that is made available, linked or accessed via the services provided by the project remains with the data providers. Permission to use the data must have been obtained in accordance with all applicable laws and regulations.

5.2 Data access and feedback to participants

— The project is concerned with building data bridges—constructing the tools and technology to link up different types of data—not with processing and analysing data. Issues surrounding feedback of results and incidental findings to participants is the responsibility of the researcher(s) using the tools provided by the project.

— Given the extreme heterogeneity of data included in the BioMedBridges project expertise in existing data access committee has to be utilised. Data approval will run through existing committees.

— The framework stipulates that each data provider complete a data provider form, the intention of which is to ensure that all ethical aspects of making data available within the BioMedBridges project have been addressed.

5.3 Participant consent

— Participant consent must cover all aspects of making data available and/or accessing it in a country that is different from that in which the original consent was given.

— It must cover the implications of linking new and different types of data and the resulting potential new discoveries.

— It must cover the fact that direct feedback of research results to participants is not planned.

— It must cover the fact that it will be impossible to remove unlinked anonymised data (i.e. data that cannot be identified for removal) if a participant wishes to withdraw.

6 Updates to the framework

As the project evolves and the specific needs of the use cases – and the hurdles involved in setting up the data bridges and pipelines – are defined in more detail, adjustments may be made to this framework. Adjustments may also be necessary based on changing regional, national and/or European regulations or based on the technical feasibility of different approaches towards data integration in a secure and ethical manner. Any necessary adjustments will be developed and agreed by the Ethical Governance Committee and approved by the Executive Steering Committee.

7 Looking forward

- The implications of the new EU Directive on data protection, which will enable participants to ask to be completely "forgotten", must be examined.
- It should be examined how external data (i.e. data that is not contributed by one of the BioMedBridges partners or BMS infrastructures) should be treated if it is introduced into the project.

8 Delivery and schedule

The delivery is delayed: ☐ Yes ☑ No

9 Adjustments made

No adjustments were made.

10 Efforts for this deliverable

Institute	Person-months (PM)		Period
	actual	estimated	
1: EMBL	1	1	April 2012 – March 2013
Total	1		

11 Attachments

- The BioMedBridges Ethical Governance Framework (Annex 1)

Background information

This deliverable relates to WP1; background information on this WP as originally indicated in the description of work (DOW) is included below.

WP1 Title: Management
Lead: Janet Thornton, EMBL
Participants: n/a

The objectives of WP1 are the management of the BioMedBridges project, including organization of the management meetings such as the Annual General Meeting for all partners, the Executive Steering Committee meetings (up to twice per annum) and the regular meetings of the Technical Coordination Committee (up to 3 times per annum), and the meetings of the Scientific Advisory Committee, including reporting back to all partners. Among the tasks is also the provision of tools to ensure good communication between all partners, timely and appropriate reporting to the Commission and completion of deliverables in all Work Packages, development of metrics to assess the progress of the grant and its impact on the BMS community, the development of a plan for sustainability of the infrastructure built during the project and ensuring that any ethics issues that arise are addressed appropriately.

Work package	WP1	**Start date or starting event:**	month 1

number						
Work package title	Management					
Activity Type	MGT					
Participant number	1: EMBL	2: UOXF	3: KI	4: STFC	11: HMGU	13: VUMC
Person-months per participant	48	0	1	1	1	1

Objectives

1. To manage the BioMedBridges project from Year 1-4
2. To organise the management meetings for all the project including: the Annual General Meeting for all partners; the Executive Steering Committee meetings (up to twice per annum) and the regular meetings of the Technical Coordination Committee (up to 3 times per annum)
3. To organise the Scientific Advisory Committee and their annual meeting, including reporting back to all partners
4. To provide good communication between all partners, through a professional web site
5. To ensure timely and appropriate reporting to the commission and completion of deliverables in all Work Packages
6. To develop metrics to assess the progress of the grant and its impact on the BMS community
7. To develop with all partners a plan for sustainability of the infrastructure built during the project, following completion of the grant
8. To ensure that ethics issues are addressed

Description of work and role of participants

The project will be coordinated by Professor Janet Thornton at EMBL-EBI. The management structure will consist of an Executive Steering Committee, made up of the coordinators of the individual ESFRI BMS projects, and a Technical Coordination Committee, consisting of the Chairs and Co-chairs of the work packages. Janet Thornton will chair both committees. The Technical Coordination Committee will report to the Coordinator and Executive Steering Committee on a regular basis.

The tasks for this WP are as follows:

Task 1: Overall Coordination of the project The coordinator of BioMedBridges has full responsibility for managing this project and achieving its objectives, including infrastructure construction, project reporting and impact assessment and finance. The coordinator will be supported by a full time project manager, whose role will be

to provide day-to-day support and implementation of all management and organisational tasks, including taking charge of accounting for all financial aspects of the project. The project manager will be responsible for the content management of the web site.

An Executive Steering Committee, consisting of all the coordinators of the 10 BMS Infrastructures, which are contributing to this grant. This committee, which is chaired by the BioMedBridges coordinator (who also coordinates the ELIXIR infrastructure), will play a strategic role in the management of the project and be responsible for decisions on the financial management. They will measure progress against the specific objectives, milestones and deliverables of each work package, developing metrics to measure the impact of the work. They will also ensure good coordination with the members of their own the infrastructure. They will oversee the consolidation of the data-infrastructure needs of the different projects, and develop a joint policy on these issues. They will monitor the sustainability of the components of the infrastructure being developed and develop a plan for support following the completion of this grant. The Executive Board will meet twice in the first year: a kick-off meeting and an ordinary Board meeting. In subsequent years, there would be annual meetings, as well as conference calls every two to three months. It is anticipated that the meetings would be held in connection with the Annual General Meetings where possible.

The Technical Coordination Committee will comprise the coordinator of the grant and scientists in charge of different aspects of the construction work with responsibility for coordinating one work package (ie the chairs and co-chairs of the different construction Work Packages 1 - 5). The use case chairs will join this group as appropriate, during the tenure of their use case. This committee will therefore include technical experts taken from each infrastructure. This Committee has the responsibility to assess and report to the Executive Steering Committee on the progress of the work packages and to identify and prioritise future tasks for the following year. The chair for this committee will be the coordinator of the project. The Technical Coordination Committee will focus on the day-to-day and technical issues involved in achieving the planned deliverables and constructing the infrastructure. The Technical Coordination Committee will meet up to twice per year, in addition to the Annual General Meetings, and have monthly conference calls to deal with routine issues and resolve any urgent problems which may arise. The chairs and co-chairs of each Work Package will manage their own WP, ensuring good communication both within the WP and with the rest of this project, through this committee. This is described in more detail in the management section 2.1 below.

Task 2: Organisation of Management Meetings

The whole consortium will meet once a year at the Annual General Meetings. This meeting will involve all the partners and those employed and working on the grant. Presentations will be made on progress on each work package and the use cases described. In the first year there will be an additional meeting at the start of the grant, to ensure good coordination from the beginning. The AGMs would also be the main opportunity for the Executive Board and the Technical coordination Committee to meet and take joint decisions on the direction of the project, and for the advisory

bodies (see below) to learn about the project and the progress being made, as well as providing strategic advice. The last AGM will be an open meeting, in part to provide outreach to all the members of each infrastructure, and also to ensure good uptake and exploitation of the deliverables of BioMedBridges. This meeting will be coordinated by WP2.

Task 3: Organisation of Scientific Advisory Board

The project will have two advisory bodies. We will construct a Scientific Advisory Board, which will comprise a small number of experts in the biological and biomedical life science infrastructure area. This will include world class biologists, IT experts, ethical and legal experts. In addition, representatives of the large e-infrastructures will be invited to form a Technology Watch e-Advisory Task Force, to keep the project informed on developments in this field and in general guarantee a close association between the ICT e-infrastructures and this project. The e-Advisory Task Force will form the Technology Watch Work Package (WP11), and consequently play a more integral part in the project than a conventional advisory board. It is anticipated that both advisory bodies would meet in connection with the Annual General Meetings.

Task 4: Provision of a professional web site

As well as providing the project with a public face, the project web site is also an important management tool. For this reason, the web site has been included in this work package, and will be based at EMBL-EBI, co-located with the coordinator and project manager. The internal/restricted part of the web site will be used both as a workplace and as a repository of documents. The task here is to provide the technical infrastructure for the website, whose contents will be controlled by the project manager.

Task 5: Reporting on the Project to Commission

The project coordinator will be responsible for reporting to the commission, with help from the project manager. Reports from each work package will be delivered by the chair of that work package to the project coordinator, who will then combine these reports to deliver a coordinated report.

Task 6: Developing and monitoring progress and impact

The management bodies will develop procedures and metrics at the beginning of the grant to measure the progress of the grant and its impact on the biological and medical research communities. These metrics will be reported annually. All the partners involved in this WP will have responsibility for this task.

Task 7: Developing Sustainability Plan

During the course of the project the executive steering committee will monitor the sustainability of the infrastructure under construction. All the partners involved in this WP will have responsibility for this task. In the last year of the project the executive

steering Committee will report on the long term sustainability of each component delivered.

Task 8: Establish an Ethical Governance Committee

The Ethical Governance Committee will:

- provide an ethics management report to each meeting of BioMedBridges Executive Steering Committee
- Analyse the requirements from the Ethics Review Report
- Review the draft Ethical Governance Framework document
- Monitor the compliance of the project beneficiaries with the Ethical Governance Framework
- Prepare new versions of the Ethical Governance Framework for approval by the Executive Steering Committee
- Support the External Independent Ethics Advisor in the preparation of Progress of Compliance with Ethics Requirements Reports.

Subcontracting for Audit Certificates: EMBL (Partner 1), STFC (Partner 4), UDUS (Partner 5), TUM-MED (Partner 7), TMF (Partner 10), HMGU (Partner 11), VUMC (Partner 13), UH (Partner 16).

Deliverables

No.	Name	Due month
D1.1	Website	12
D1.2	Devise metrics to measure progress and impact of construction	12
D1.3	1st Periodic Report	18
D1.4	2nd Periodic Report	36
D1.5	Final Report & Sustainability Plan	48
D1.6	ED1: The Ethical Governance Framework for BioMedBridges	18
D1.7	ED2: Progress of compliance with requirements of the Ethics Review Report	36
D1.8	ED3: External Independent Ethics Advisors Report	48

Ethical Governance Framework

Version 1.1, April 2013

Contents

Definition of terms used in this document

Anonymisation

'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.

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-OPENSCREEN)
- European Biomedical imaging infrastructure (Euro-BioImaging)
- European Research insfrast4ructure 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	
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 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	

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	
10	Please sign to indicate that you have read the BioMedBridges Ethical Governance Framework document and you agree to abide by the conditions contained therein	
11	Please sign to confirm that the donor consent provisions and/or ethical approval, and national laws and regulations, allow the use of the data in BioMedBridges *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*	
	For Office Use Only	
	Signature of BioMedBridges Coordinator representative	
	Date of approval	

∗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.