Euro-BioImaging
European Research Infrastructure for Imaging Technologies in Biological and Biomedical Sciences

WP 2 Legal, Governance and Ethical Issues

Task 2.2
Establish an appropriate organizational and governance model

Deliverable 2.4
Draft Ethics Policy

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Contents

Abbreviations

BBMRI	Biobanking and Biomolecular Resources
DoW	Description of Work
EATRIS	European Advanced Translational Research Infrastructure in Medicine
ESFRI	European Strategy Forum on Research Infrastructures
ECRIN	Pan European infrastructure for clinical trials and biotherapy
ELIXIR	European Life-Science Infrastructure for Biological Information
ERINHA:	European Research Infrastructure on Highly Pathogenic Agents
ICT	Information and Communication Technologies
IMI	innovative medicines initiative
Infrafrontier	Infrastructure for phenotyping and archiving of mammalian genomes
INSTRUCT	An integrated Structural Biology Infrastructure for Europe

1 Executive summary

From the scope of Euro-BioImaging it is obvious that a wide variety of possible ethical issues needs to be addressed. D2.4 Draft Ethics Policy will outline: a) specific approaches to establish an ethics policy for the operation of Euro-BioImaging and b) possible interfaces with other biomedical ESFRI projects (BMS ESFRI RI) and relevant initiatives.

Concepts developed by other BMS ESFRI RI projects were analysed. None of the already proposed solutions was directly applicable for Euro-BioImaging. Furthermore it became clear that ethical issue policies within the different BMS ESFRI RI projects are not yet harmonised across Europe. A possible solution seems to emerge from the BioMedBridges project, which is a joint effort of ten ESFRI BMS RI projects and aims to develop the shared e-infrastructure—the technical bridges—to allow interoperability between data and services in the biological, medical, translational and clinical domains and thus strengthen biomedical resources in Europe.

After the analysis of the other BMS ESFRI RI projects a first proposal to address ethical issues within Euro-BioImaging is given. This proposal does not aim to replace or double local or national ethics committees, which in turn have to comply with the European existing ethical rules and guidelines for biomedical research. The FP7 ethics checklist (http://cordis.europa.eu/fp7/ethics_en.html#ethics_cl) can serve as a basis.

Accordingly in a first step Euro-BioImaging will seek ethical advice from local and national boards responsible for respective permissions during implementation.

In a second step it is proposed that Euro-BioImaging should install an ethics advisory committee comprising external experts. The scope of its activities will be:

- a continuous evaluation of the activities of Euro-BioImaging relevant to ethical issues
- providing regular reports on ethics issues to the Euro-BioImaging Board
- coordination of ethical issues
- analysis of the requirements from the ethics review report
- overseeing the delivery of the progress of compliance with ethics requirements reports
- providing advice on ethical governance and related matters to the Euro-BioImaging Board ensuring that Euro-BioImaging operates to appropriate ethical standards and complies with relevant aspects of the ethical governance framework
- confirming legitimacy of data samples, i.e. collect documentation showing that data used in this project are either legitimately available commercially or have been obtained following appropriate ethical approval.

In parallel Euro-BioImaging will cooperate with other BMS ESFRI RI projects -starting with the BioMedBridges project- to harmonise ethical standards for life science research infrastructures across Europe. Changes to the structure and composition of the ethics advisory committee can be performed, as changes are emerging and seem to be appropriate for incorporation. During our analyses of the ESFRI activities it became clear, that besides establishing an ethics advisory committee there is also a considerable need for providing teaching and training on ethical issues. This will be especially addressed by WP13 of the Euro-BioImaging project.

More details on an ethics advisory committee will be provided in the final business plan.

2 Introduction

Euro-BioImaging aims at ensuring access to cutting edge imaging technologies to all European scientists. During the preparatory phase (2010-2013) a concept of construction and operation of the pan-European distributed infrastructure will be created. The advanced imaging technologies used in biological and medical research require extremely diverse technologies. Thus a framework and roadmap for relevant ethical issues needs to be developed. This concept will be an integrative element of the future pan-European biomedical imaging infrastructure and will be included in the Euro-BioImaging business plan.

A respective concept has to be developed in close cooperation with the other BMS ESFRI RI projects.

It is obvious from the scope of Euro-BioImaging that a wide variety of possible ethical issues need to be addressed. In a first approach the current general ethics check list provided by the European Commission for FP7 projects (http://cordis.europa.eu/fp7/ethics_en.html#ethics_sd) was used as a guideline:

- Research on humans involving
  - children
  - patients
  - persons not able to give consent
  - adult healthy volunteers
- Research on Human Embryo/ Foetus
  - human Embryonic Stem Cells (hESCs)
  - derivation of cells from Embryos
- Research involving Human genetic material
  - human biological samples
  - human data collection
- Privacy
  - processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?
- Research on animals involving
  - transgenic small laboratory animals

Thus in this deliverable we outlined:

a) specific approaches to settle Euro-BioImaging-specific ethical issues and
b) possible interfaces of ethics policies of other BMS ESFRI activities.

3 Objectives of WP2 (according to description of work [DoW]): establish an appropriate organizational and governance model taking ethical issues into consideration

According to the DoW Euro-BioImaging will establish a governance and legal structure for the construction and operation allowing for a sustainable and long term infrastructure. A governance structure will be developed addressing issues such as coordination and integration, location and sites, control of member states, management structure, finance and tax issues, scientific quality assurance, user access, IPR and **ethical issues**.

Especially the medical imaging aspects of Euro-BioImaging will require the development of an ethics policy that determines if and under what circumstances data from patients can be obtained and used for research purposes. Existing policies will be consulted, for example those, that are being developed by other ESFRI projects. Considerations on ethical issues will be included in the final Euro-BioImaging business plan.
Therefore existing activities were assessed for this report.

4 Existing governance structures addressing ethical issues within ESFRI activities and other EC funding activities

4.1 General European Commission statements

All considerations of this report concerning ethical issues take into account the FP7 guidelines outlined by the EC (http://cordis.europa.eu/fp7/ethics_en.html#ethics_sd).

4.2 Ethical issues dealt with by other BMS ESFRI RI

In addition monitor the concepts developed by other ESFRI activities will be monitored (see below). This will include especially:

- BBMRI - Biobanking and Biomolecular Resources Research Infrastructure,
- EATRIS - The European Advanced Translational Research Infrastructure in Medicine,
- ECRIN - Pan European infrastructure for clinical trials and biotherapy,
- ELIXIR - European Life-Science Infrastructure for Biological Information,
- ERINHA - European Research Infrastructure on Highly Pathogenic Agents,
- Infrafrontier - Infrastructure for phenotyping and archiving of mammalian genomes and
- INSTRUCT - An integrated Structural Biology Infrastructure for Europe.

4.3 BBMRI (soon to be published on the website)

Analysis of the **ethical, legal, and societal issues (ELSI)** related to the infrastructure have resulted in the design of i) a coordinated ethical review process ii) a data protection policy for the cross border data transfer issues, both central to the governance of the infrastructure, and iii) in the development of original tools that will facilitate harmonisation. This strategy was based on a conceptual analysis of ethics-related policies for biobanks and biomolecular resources, an analysis of national ethics committee opinions in this domain, and a pilot study (based on research with focus-groups and in cooperation with the 2010 Eurobarometer) on the public perception of biobanks in Europe (Gaskell and Gottweis 2011).

The tools designed consist of a legal Wiki+ platform for disseminating validated existing legal documents in use in EU countries (www.legalpathways.eu), a web based information tool on legal requirements for exchanging biological samples (hSERN; human sample exchange regulation navigator, www.hsern.eu), indicators to promote transparent sharing of biological samples and data and an ELSI transversal platform.

Solutions for secure and efficient trans-national exchange of medical research data is one of the cornerstones for building the European Research Area (ERA) and a knowledge-based economy. For the operation of BBMRI-ERIC various types of data (metadata, pooled data, and object data) will be processed employing Privacy Enhancing Technologies (PETs). Any such approaches will be tested against and based on the common minimum standards set by the European Union for" the protection of individuals with regard to the processing of personal data and on the free movement of such data".

Access to BBMRI-ERIC infrastructure: BBMRI-ERIC shall provide access to samples and related clinical data based on the scientific excellence of the proposed project as determined by an independent peer review and on ethical review of the research project proposal.

Access to human biological samples and identifiable medical data has to be compliant with a variety of ethical and legal requirements, such as the Oviedo Convention (ETS 164), the Helsinki Declaration, the OECD Guidelines for Human Biobanks and Genetic Research Databases (HBGRD) (OECD, 2009), the Recommendation Rec (2006)4 of the Committee of Ministers to member states on research on biological materials of human origin or the Directive 95/46/EC on the Protection of Personal Data (examples of relevant legislation and guidelines are provided in Annex IV). Internationally agreed key

principles relevant to the operation of BBMRI-ERIC are that research on human biological samples and identifiable medical data require informed consent from the sample and data donor, and approval by an ethical review board. Both HBGRD and the Helsinki Declaration foresee that in case informed consent cannot be obtained for practical or scientific reasons, ethical review boards can provide a waiver for informed consent. Alternatively, anonymisation would also waive the requirement for informed consent. Therefore access procedures of BBMRI-ERIC to human biological samples and medical data have to consider the following principles:

- No information related to individuals and their samples can be made freely accessible by internet; only access to coded and aggregated data can be provided through the BBMRI-ERIC web-portal
- Access to samples and medical data can only be provided in the context of a specific research project in accordance with the terms of the consent given by the donor
- The research project has to meet the criteria of scientific excellence (based on scientific review) and has be approved by a ethical review board
- All procedures have to protect privacy of sample donors

The ethical review by BBMRI-ERIC **Ethical Review Board (ERB)** is obligatory for all projects to obtain access to human biological samples or medical data through BBMRI-ERIC. It does not replace the requirement for ethical review at biobank institutions but should support the local ethical approval committees in their decision making process and contribute to the harmonisation of ethical requirements throughout Europe thereby substantially improving efficacy of national/local review processes, particularly in the context of multinational studies.

Assembly of Members: The Assembly of Members shall establish a **Scientific and Ethical Advisory Board (SEAB)** and by two thirds majority any other subordinate bodies as may prove necessary. The decision to establish such bodies shall include provisions concerning the membership, its rotation and terms of reference. The advisory bodies shall agree on their Rules of Procedure. The task of the SEAB is to perform periodical evaluations of BBMRI-ERIC and its different activities. The SEAB shall be composed of distinguished scientists or experts appointed in their own right, not as representatives of Member States. SEAB shall also advise the Assembly of Members with regard to proposals of the Director General on the realization of the Work Programme. The SEAB gives advice to BBMRI-ERIC, but its members are not legally part of it.

Scientific and Ethical Review Boards: The following expert bodies, envisaged to be established by the Assembly of Members of BBMRI-ERIC on the proposal of the Director General and the Management Committee, shall function in an advisory capacity to the Director General, the Management Committee and the BBMRI-ERIC National Nodes:

- The Scientific Review Board, responsible for scientific evaluation of access requests received by BBMRI-ERIC, and
- The Ethical Review Board, responsible for ethical evaluation of requests received by BBMRI-ERIC. Although members of the Scientific Review Board and the Ethical Review Board give advice to BBMRI-ERIC, they are not part of BBMRI-ERIC legal entity.

Data protection and management policy: BBMRI-ERIC and Partners will not make public any information of research projects performed through BBMRI-ERIC that can be directly related to an individual. Information on individuals will only be made accessible to authenticated scientific users in a coded or anonymised fashion in the context of specific research projects and upon approval by a competent **Research Ethics Committee (REC)** in compliance with national and EU legislation, and subject to the BBMRI data access conditions. Partners will support integration of their data management system with that of BBMRI-ERIC by complying with the BBMRI-ERIC information requirements. The initial information requirements are realised as the expected minimal common

data content and data structure in relevant databases. No access will be provided for non-research purposes (such as forensic, insurance or employment purposes), except pursuant to a court order.

4.4 EATRIS

The ethical issue policy was not addressed during the preparatory phase. This policy will be developed for EATRIS within the project BioMedBridges. It is planned to appoint an external independent ethics advisor, who will provide a report that must be submitted to the European commission.

4.5 ECRIN

ECRIN will be running a website, called Campus, giving general information on:

- national competent/regulatory authorities and ethics committees
- requirements for submission of a clinical trial application including definition of, and information about, different types of studies and different types of populations.

More information is not available via internet.

4.6 ELIXIR

The ethical issue policy was not addressed during the preparatory phase. This policy will be developed for ELIXIR within the project BioMedBridges.

4.7 ERINHA:

According to their website this ESFRI project has installed both a scientific advisory board and an ethics advisory board.

4.8 Infrafrontier

There is no overarching ethical issue policy. All scientific platforms and services offered by Infrafrontier are operated through the national infrastructure components and have therefore to comply with national ethical and animal welfare regulations. No further information on the ethical issue policy could be obtained.

4.9 INSTRUCT

No information on the ethical issue policy could be obtained from the internet.

4.10 BioMedBridges

BioMedBridges is a joint effort of ten biomedical sciences research infrastructures on the ESFRI roadmap. This project also includes Euro-BioImaging. Together, the project partners will develop the shared e-infrastructure - the technical bridges - to allow interoperability between data and services in the biological, medical, translational and clinical domains and thus strengthen biomedical resources in Europe. To achieve this in a way that covers all applicable ethical considerations, the project will develop and follow an ethical framework which includes monitoring by an ethics committee comprising external experts and an ethics management report to the European Commission.

4.11 Other activities

With respect to IMI proposals have to comply with information from the EC on ethical issues, which is available on http://cordis.europa.eu/fp7/ethics_en.html. No further information on the ethical issue policy could be obtained. It is also of note that in **Social Sciences and Humanities** respective activities were launched (http://dasish.eu/about_dasish/executive_summary/DasishA3_3.pdf/) and have to be taken into account. The same is true for **Information and Communication Technologies** (ICT) (http://cordis.europa.eu/fp7/ethics-ict_en.html).

4.12 Applicability for Euro-BioImaging

The yet available solutions to solve ethical issue in the different BMS ESFRI RI projects, as described above, are not directly applicable within Euro-BioImaging. Furthermore we feel that due to the wide range of activities in Euro-BioImaging, it is difficult to provide an immediate solution. Thus the approach of BioMedBridges to more general guidelines is highly supported. This approach is especially suitable, as the ethical issues can be looked upon from different angles.

Furthermore it seems that ethical issue policies within the different BMS ESFRI RI projects are not yet harmonised across Europe. Admittedly this cannot be expected, as some of the projects are still in the preparatory phase. Again, therefore the BioMedBridges project is an important first attempt to develop a harmonised concept for ethical issues relevant for ESFRI BMS RIs.

5 Proposal for addressing ethical issues within Euro-BioImaging

Euro-BioImaging does not aim to replace or double local or national ethics committees, which in turn have to comply with the European existing ethical rules and guidelines for biomedical research. The FP7 ethics checklist (http://cordis.europa.eu/fp7/ethics_en.html#ethics_cl) can serve as a basis.

A first step will be to seek ethical advice from local and national boards as these institutions are responsible for respective permissions.

In a second step it is proposed that Euro-BioImaging installs an ethics advisory committee. The scope of its activities will comprise:

- a continuous evaluation of the activities of Euro-BioImaging relevant to ethical issue policy
- Providing regular reports on ethics issues to the Euro-BioImaging Board
- coordination of ethical issues
- analysis of the requirements from the ethics review report
- overseeing the delivery of the progress of compliance with ethics requirements reports
- providing advice on ethical issues and related matters to the Euro-BioImaging Board ensuring that Euro-BioImaging operates to appropriate ethical standards and complies with relevant aspects of the ethical governance framework.
- confirming legitimacy of data samples, i.e. collect documentation showing that data used in this project are either legitimately available commercially or have been obtained following appropriate ethical approval.

In parallel Euro-BioImaging will cooperate with other ESFRI programmes in the BioMedBridges project to harmonise ethical, legal and quality standards across Europe. Changes to the structure and composition of the ethics advisory committee can be performed, as changes are emerging and seem to be appropriate for incorporation.

More details on overall governance structure including also the ethic advisory committee will be provided in the final business plan.

During our analysis of the ESFRI activities it became clear, that besides establishing an ethics advisory committee there is also a considerable need for providing teaching and training on ethical issues. This will be especially addressed by WP13 of the Euro-BioImaging project.

6 ANNEX

Taken from BBMRI: Annex IV: Examples of Relevant EU Legislation and International Conventions and Regulations

Relevant EU legislation such as:

- The Charter of Fundamental Rights of the EU.
- Directive 95/46/EC of 24 October 1995 on the protection of individuals with regards to processing of personal data and the movement of such data.
- Directive 2001/20/EC of 4 April 2001 on clinical good practice.
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
- Directive 2004/33/EC as regards information to be provided to prospective donors, information required from donors, eligibility of donors; storage, transport and distribution conditions for blood and blood components; quality and safety requirements for blood and blood components.
- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.
- Directive 86/609/EEC of 24 Nov. 1986 on the protection of animals.
- Directive 86/609/EEC of 24 Nov. 1986 on the protection of animals used for experimental and other scientific purposes.
- Protocol on Protection and welfare of animals (protocol to the Amsterdam Treaty).
- Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from the risks related to exposure to biological agents at work (7th individual directive within the meaning of Article 16(1) of Directive 89/391/EC).
- Directive 2004/23/EC of the European Parliament and of the Council on Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells", code number 2002/0128 (COD), Strasbourg, 31 March 2004.
- Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.
- Directive 98/44/EC on the legal protection of biotechnological inventions.

International conventions, declarations, and guidelines:

- Helsinki Declaration in its latest version.
- Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on April 4, 1997, and the Additional Protocol on the Prohibition of Cloning Human Beings signed in Paris on 12 January 1998.
- Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological material of human origin.
- UN Convention on the Rights of the Child.
- Universal Declaration on the human genome and human rights adopted by UNESCO.
- OECD Best Practice Guidelines for Biological Resource Centres, OECD 2007.
- OECD Guidelines on Human Biobanks and Genetic Research Databases. OECD 2009.