



## **Euro-BioImaging**

European Research Infrastructure for Imaging Technologies in  
Biological and Biomedical Sciences

WP2 Legal, Governance & Ethical Issues

### **Task 2.1**

**Compile information on possible legal structures and evaluate  
their applicability to Euro-BioImaging**

### **Deliverable 2.1**

**Evaluation of suitable legal structures**

### **Task leader**

NENCKI / EMBL

**January 2012**

## WP2 Deliverable 2.1: Evaluation of suitable legal structures

### Contents

1. Purpose of this report and background.....	2
2. Evaluation of Legal models.....	3
2.1 Experience from other ESFRI Projects .....	3
2.2 General framework conditions .....	4
2.3 Euro-Biolmaging as an ERIC .....	4
2.4 Mixed model: International Consortium Agreement linked to legal entity for the coordinating hub	6
2.4.1 International Consortium Agreement.....	6
2.4.2 International Consortium Agreement linked to an existing Intergovernmental Organisation such as EMBL.....	6
2.4.3 International Consortium Agreement linked to a company limited by guarantee .....	7
3. Governance Structure.....	8

### 1. Purpose of this report and background

Euro-Biolmaging will be established as a distributed European research infrastructure that will have a legal entity that will allow it to handle money and employ staff, etc. This report describes and evaluates several suitable legal models for Euro-Biolmaging taking into consideration a broad range of information sources.

The main objective of WP2 (Legal, Governance & Ethical Issues) is to determine for Euro-Biolmaging an organisational and governance model, a legal structure and guidelines for ethical issues and intellectual property rights. This report mirrors the outcome and discussions of two WP2 meetings at which different legal models were presented and discussed.

The following issues linked to setting up suitable legal structures were identified:

- The legal and governance model should be designed for a distributed infrastructure (“Hub and nodes” structure)
- The diverse requirements of biological and medical imaging communities
- The challenging funding situation in which RI operate

- What the scope of ethics and IPR policy is – for example, examine existing policies and use experience from other RI

During the second WP2 meeting on 20 September 2011 the discussions concentrated on recent developments of ERIC (European Research Infrastructure Committee), which is a relatively new European legal framework based on a Council regulation (see also below).

## 2. Evaluation of Legal models

### 2.1 Experience from other ESFRI Projects

Among other sources, WP2 relied on information that has been gathered for other ESFRI projects in the life sciences, in particular of three projects namely ELIXIR<sup>1</sup> and INSTRUCT<sup>2</sup> and one project in the field of environmental sciences, namely LifeWatch<sup>3</sup>. EMBL coordinates ELIXIR and participated in the INSTRUCT preparatory phase project. EMBL chaired or participated in the respective legal and governance work packages. These three ESFRI projects were chosen as main examples because they will also become distributed research infrastructures, they are at an advanced stage of implementation, and they use three different legal models that provide excellent examples for Euro-BioImaging.

**ELIXIR** will be set up as an international consortium of member states using an existing intergovernmental organisation (EMBL) as a legal entity. EMBL will become a Consortium Partner and provide facilities and services to the new infrastructure and employ ELIXIR staff.

**INSTRUCT** has been established based on an International Consortium Agreement. The partners agreed to establish a company limited by guarantee which is a fully-owned subsidiary of the University of Oxford in the UK as legal entity for the Instruct Academic Services.

**LifeWatch** provides an excellent example for a distributed infrastructure that will become an ERIC.

Both legal work packages within ELIXIR and INSTRUCT consulted international law firms to evaluate different legal models at national, European and international level.

The ELIXIR report on possible legal models by these lawyers took into consideration structures based on EU regulations (e.g. the European Economic Interest Grouping (EEIG)), national models such as companies and also models based on an International Consortium Agreement using an existing intergovernmental research organisation (EMBL) as host of the ELIXIR hub (see for details below under 4.3). The ERIC model, as well as the ICA-model, were deemed the most suitable legal models for ELIXIR. EMBL Council in the meantime agreed EMBL's role as a facilitator for ELIXIR. The first Interim ELIXIR Board meeting took place in November 2011 and will continue to elaborate the chosen model during the negotiations of an International Consortium Agreement.

---

<sup>1</sup> <http://www.elixir-europe.org/>.

<sup>2</sup> <http://www.structuralbiology.eu/>.

<sup>3</sup> <http://www.lifewatch.eu/>.

The INSTRUCT report on legal models dealt mainly with a set of pre-selected legal models: ERIC, International Consortium Agreement using the EMBL structure and AISBL based on Belgian law. Again, ERIC as well as the model introducing an International Consortium Agreement and using the EMBL legal structure were considered as the most suitable models. In the meantime it was decided to set up INSTRUCT as a company limited by guarantee in combination with an International Consortium Agreement concluded among the partners.

## 2.2 General framework conditions

There are two framework conditions that would stay the same in all legal models; the membership structure and the distributed “Hub-and-Nodes” structure.

As a European research infrastructure, Euro-BioImaging will be established and operated by a consortium of **member states and intergovernmental organisations**. Even if the underlying rules for a legal model would allow for a more diverse membership (e.g public and private national institutions within a company limited by guarantee) it would be advisable to limit membership to states and IO. States would certainly be able to appoint a national institute as their representative.

Euro-BioImaging will be based on a distributed model in which the “Coordinating Hub” will liaise with research organisations in the Euro-BioImaging member states to ensure provision of bioimaging services at the European level. Euro-BioImaging will need a legal structure that can handle money and employ staff, etc. This could be an existing legal entity or a new one.

Several potential options for a legal structure were analysed by WP2, such as an ERIC or mixed models that would link the instrument of an International Consortium Agreement to a legal entity.

## 2.3 Euro-BioImaging as an ERIC

The Community legal framework for a European Research Infrastructure Consortium (ERIC) is based on a Council Regulation (EC) No 723/2009 that empowers the Commission to set up legal entities called “ERIC”.

This legal instrument is designed to facilitate the joint establishment and operation of research infrastructures of European interest (at least three Member States) and is a new legal instrument and so far one infrastructure was set up as an ERIC (i.e. Share ERIC - Survey of Health, Ageing and Retirement in Europe). Three other ESFRI projects have applied to the European Commission to become an ERIC (Euro-Argo, ECRIN and Clarin) and several other ESFRI projects are preparing for or considering an ERIC (e.g. BBMRI, LifeWatch, EATRIS, European Social Survey).

The process of setting up as an ERIC is two-fold. At national level an application to the European Commission has to be prepared. The EC and a committee of EU member state delegates then decide whether or not the infrastructure’s application complies with the ERIC Regulation. The application must include:

- Draft statutes
- A technical and scientific description of the research infrastructure

- A Declaration by the host Member State recognizing the ERIC as an international body or organization to be able to profit from privileges such as tax exemptions and exemptions from excise duties according to two European Directives<sup>4</sup>.

The process then continues at the European level. The European Commission starts an evaluation process to decide whether or not the infrastructure's application complies with the ERIC Regulation. The correct execution of this task is controlled by the ERIC Committee composed of representatives from all EU Member States.

Whilst the length of the national setting-up process is different in each case, the application process at European level will take between 3 to 9 months according to the European Commissions.

Using this model would allow Euro-BioImaging to have a permanent structure and to profit from having a legal personality recognized by all EU Member States and privileges linked to it. ERICs will not be bound by the procedures of the Public Procurement Directive as implemented in national law and they will be exempted from paying VAT and excise duty. Another advantage is the fact that ERICs normally do not have to undergo the time-consuming process of ratification.

The ERIC framework is a compromise between the national company model and an Intergovernmental Organisation. Among other reasons the regulation was established to overcome the lengthy setting up process of Intergovernmental Organisations, which often originates in the necessity of a ratification of the membership decision. However, so far the setting up process for those ESFRI projects intending to set up as an ERIC in Germany or France was delayed due to hurdles at national level. Some of these hurdles were due to the fact that this instrument was relatively new at the time and that few Member States were willing to host an ERIC and act as pioneers. The biggest stumbling block seems to be the recognition process as an international body for the purposes of the VAT and excise duty directives. It is up to the Member States to decide within their national laws whether or not they would accept a Research Infrastructure as an institute that profits from certain privileges. In France, the initial hurdles were removed in the middle of 2011. Legal constraints still prevent Germany from hosting an ERIC, but these are scheduled to be solved in the course of 2012. Currently the European Commission is not aware of any other EU Member States blocked in their ability to set up ERICs.

Another downside of ERIC is that staff working in an ERIC would not profit automatically from any privileges since national labour law applies. The ERIC would be bound to national regulations of those countries that host the ERIC seat and other sites. The first ERIC that is in place at the moment – SHARE – decided not to employ staff at all, which will be employed by participating institutes in the Member States, namely separate legal entities.

LifeWatch will become a distributed infrastructure based on the ERIC model. Its statutory seat will be in Spain and according to the ERIC regulation its members will be EU Member states, associated countries

---

<sup>4</sup> The infrastructure must be recognized as international body in the sense of Articles 143(g) and 151(1)(b) of Directive 2006/112/EC and as international organisation in the sense of the second indent of Article 23(1) of Directive 92/12/EEC.

<sup>5</sup> See the ERIC practical guidelines published by the EC, <http://ec.europa.eu/research/infrastructures>, p. 9.

to the EU and International Organisations. LifeWatch will have “Common facilities” being part of the legal entity and independent legal entities connected via bilateral service level agreements. LifeWatch is an excellent example of an infrastructure that would use the full potential of an ERIC. It plans to establish a distributed infrastructure with components legally belonging to the same entity, and further components having strong contractual links to the central legal entity.

- ERIC would be a suitable legal framework for Euro-Biolmaging. Currently Germany would not be able to be the host for the statutory seat.

## **2.4 Mixed model: International Consortium Agreement linked to legal entity for the coordinating hub**

### **2.4.1 International Consortium Agreement**

All mixed models have in common that the members – states and intergovernmental organisations – would conclude an International Consortium Agreement and decide to use an existing legal entity for legal actions or to establish a new legal entity for these purposes.

The International Consortium Agreement would deal with Euro-Biolmaging’s mission and strategy, obligations of the Consortium Partners, governance structure, budget and liability issues etc. The agreement would also endeavor to make sure that Euro-Biolmaging becomes a research infrastructure with its own identity and visibility.

The ICA could be set up as a binding or non-binding instrument. Whether an international agreement is binding or not, depends on its terms and the circumstances in which it was drawn up.

Some of the more advanced ESFRI projects decided to establish a non-binding Memorandum of Understanding (MoU) before they started preparing the International Consortium Agreement.

### **2.4.2 International Consortium Agreement linked to an existing Intergovernmental Organisation such as EMBL**

In this mixed model Euro-Biolmaging, i.e. the coordinating hub, would make use of an existing international organisation, which would at the same time become a Consortium Member. As highlighted above this mixed model was chosen by ELIXIR, which has already entered into the implementation phase. To illustrate how this model might be applied for Euro-Biolmaging we will describe hereinafter how it was set up for ELIXIR.

The ELIXIR Consortium Partners and EMBL will conclude an International Consortium Agreement that deals with the Partner’s obligations. EMBL’s obligations will not be financial contributions to ELIXIR as will be the case for the other partners. In the International Consortium Agreement, EMBL agrees to provide services, offices and facilities to the infrastructure’s management (e.g. Director and Secretariat) and employ staff that will work for ELIXIR. It will take over the financial management and separate

auditing will give the members sufficient control over their financial contributions. For most of these contributions it will ask for compensation from ELIXIR.

Under this model ELIXIR will benefit from EMBL's legal personality. Legal transactions for ELIXIR will be handled using EMBL's legal personality. The ELIXIR Hub will profit from privileges and immunities granted to EMBL. EMBL will be bound to the provisions of the International Consortium Agreement and the decisions of the Consortium partners.

Through statues, an International Consortium Agreement and its public image, the new infrastructure will take care that it is recognized within the scientific community as an independent organization. The experience with ELIXIR so far is very positive and the ICA involving EMBL will be finalized in the course of 2012.

- The mixed model using EMBL's legal structure would be a suitable framework for Euro-Bioluming that would make use of an existing Intergovernmental Organisation. An International Consortium Agreement would define all details to ensure Euro-Bioluming becoming an independent and visible infrastructure within the European research landscape.

### **2.4.3 International Consortium Agreement linked to a company limited by guarantee**

Another alternative of a mixed model would be the establishment of a new legal entity by the Consortium Partners for the Hub activities. This could be for example a company limited by guarantee based on national law such as the German GmbH, the UK Private Company Limited by Guarantee or the French Société Civile.

The limited liability company is the most popular type of business structure. It is the typical form used normally by small and medium-sized companies, but could also be used by bigger entities. A limited liability company can be established for profit but also as a non-profit company. All national company models have in common that the shareholders have a limited liability in proportion to their contribution to the capital: liability is limited to the company's assets. Generally, companies can be built with partners (public or private) coming from the host country and/or from any other member state. Partners can be national institutes or governments representing their country. The company model has been used by for example European XFEL and FAIR and will be used by INSTRUMENT and possibly Infrafrontier depending on whether ERIC would be a feasible model in Germany or not.

The articles of association of the company define its organisation, the relationship of the shareholders to each other as well as to the company itself, liabilities of partners, the budgetary procedures and control, staff policy, procurement policy, intellectual property, decommissioning, etc. In Germany for example the Limited Liability Company Act requires for a minimum share capital of € 25.000; in the UK the members of a Private Company limited by Guarantee don't have to have a share capital (except for one symbolic British pound), since members are guarantors rather than shareholders. The members' liability is limited to the amount they agree to contribute to the company's assets if it is wound up.

The mixed model that involves a company has a number of advantages. Companies are easy to set up because they are part of the legal framework of the country where the research infrastructure is established. As a company limited by guarantee Euro-Biolmaging would have a legal personality. The governance structure is easy to adopt and includes a clear line of authority and responsibility covering scientific, technical and administrative aspects of the facility. This legal form would be suited for research infrastructures involving partners from different countries.

However, national instruments are not perfectly designed for international participation and they would not be linked to privileges or immunities. National law would be applicable which might lead in individual cases to inflexibility as regards for example taxation, procurement rules or labour law and salary scales. If possible, according to national law, flexible conditions would have to be negotiated with host countries.

- The model “International Consortium Agreement linked to a company limited by guarantee” would be suitable for Euro-Biolmaging. However, the restriction to national law has some downsides for an international infrastructure.

### 3. Governance Structure

The governance structure of Euro-Biolmaging would most likely be very similar for each of these legal structures and would only change regarding the nomenclature that is sometimes suggested by the legal basis.

Normally the governance structure will comprise a board that is the strategic and decision-making body including the approval of the budget of the infrastructure. It assembles the members of the infrastructure. For ERIC this body is called “Assembly of Members”. In an international organization or a company this body is normally called the governing board or steering council.

This body is supported by a **management body**, which supports the Board and executes its decision. It is normally headed by a **Director** or a Board of Directors, which also legally represents the infrastructure externally. The Director would rely on the support of a **Secretariat**, which would coordinate the activities of the infrastructure, manage the distribution of resources and produce the necessary financial and scientific reports.

The Board and the executive body would be advised by advisory bodies, for example, an independent **Scientific Advisory Board**, which oversees the quality of the Euro-Biolmaging activities at the coordinating hub and the Euro-Biolmaging Nodes, including the evaluation of new nodes.

Euro-Biolmaging **nodes** would take on defined roles in Euro-Biolmaging that would become part of the project via agreements and therefore have to have a legal entity that can enter into bilateral service agreements with the coordinating hub. Most likely a node could be any national or international research organisation that applies (alone or in collaboration with others) to Euro-Biolmaging for strategic integration subject to approval by the Euro-Biolmaging Board.



