Euro-BioImaging ERIC:

Ethical, Legal and Social Implications (ELSI) Policy

Contents

I. Considerations

1. The Euro-BioImaging ERIC (hereinafter "Euro-BioImaging") Statutes place special emphasis on the development of an Ethical, Legal and Social Implications Policy (hereinafter "the ELSI Policy") in order to support smooth access to imaging technologies, especially in relation to medical imaging technologies.
2. Euro-BioImaging enables access to a broad range of state-of-the-art technologies in biological and biomedical imaging for life scientists. Euro-BioImaging consists of a set of complementary and strongly interlinked, geographically distributed Nodes (specialised imaging facilities) to grant access to scientists from all EU Member States and beyond. In addition the Hub coordinates dedicated data management and training activities tailored to the needs of users of the imaging infrastructure.
3. Access to imaging technologies especially provided by the medical Hub will often bring the users in touch with data from human research participants and which are used in the context of clinical and health research. Gaining and deserving the trust of patients, study participants and donors concerning the proper handling of their data is of utmost importance for research to proceed and generate benefits for society.
4. The purpose of the ELSI Policy is to ensure that all services offered in the context of Euro-BioImaging take place in an ethically and legally sound manner and considering social implications by consolidating requirements that are shared across all Euro-BioImaging Members, the Hub and the Nodes. The ELSI Policy imposes no additional constraints on existing user access modalities than those provided by existing legal and ethical requirements.
5. The Euro-BioImaging Nodes are responsible for the implementation of the requirements of the Policy with respect to the provision of Euro-BioImaging Services.
6. The ELSI Policy intends to provide the required basis to satisfy the ethics requirements of funders, such as for example those of the European Commission.
7. Euro-BioImaging services participate in a multitude of research projects in both national and international settings that are governed by project-specific policies and codes. Such policies may impose additional requirements on Euro-BioImaging services that go beyond the scope of the ELSI Policy.
8. The ELSI Policy acknowledges the following international legislation:

    - Universal Declaration of Human Rights, 10 December 1948
    - Article 8 of the European Convention on Human Rights
    - WMA Declaration of Helsinki about ethical principles for medical research involving human subjects (1964) and related amendments
    - EU Clinical Trials Directive (2001/20/EC)
    - EU General Data Protection Regulation EU 2016/679
    - European regulation on the protection of animals used for scientific purposes:

        I. European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes, Strasbourg, 18.III.1986.
        II. Directive 2010/63/UE, 22 September 2010, on the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes.

III. Commission Implementing Decision of 14/11/2012, n. 2012/707/UE, establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.
IV. Commission Recommendation No 2007/526/EC of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes.

II. Scope

The ELSI Policy applies solely to Euro-BioImaging ERIC services, i.e. the provision of access to imaging technologies through Euro-BioImaging ERIC services as well as coordination of dedicated data management and training activities tailored to the needs of users of the imaging infrastructure. It does not apply to any other services or research activities provided by the institute(s) constituting or affiliated with the Euro-BioImaging Nodes.

Euro-BioImaging ERIC's services will relate to the following fields, which are relevant from an ethical point of view:

- Research involving
  - laboratory animal models (e.g. of human pathologies), including transgenic animals
  - Embryonic Stem Cells (ESCs)
  - derivation of cells from embryos
- Research involving human data collection and images acquisition on humans or human tissues
- Privacy: processing of research related personal data, (e.g. health related data, genome data etc.)

While research related data in the context of Euro-BioImaging ERIC services is covered by the ELSI Policy, all personal data in relation to users of the Euro-BioImaging services and Euro-BioImaging ERIC staff is covered by Euro-BioImaging ERIC's Data Policy.

The ELSI Policy acknowledges that Nodes are hosted by already existing national research institutes, which are bound by national law and by their own regulations. It falls into every Nodes' responsibility to offer services that comply with all relevant (e.g. EU-level, national and local or internal) legal and ethical requirements.

For ethical and legal aspects related to clinical data management, Euro-BioImaging ERIC will support the community to address the challenge of developing technologies that simultaneously respect community standards and patient privacy, and are consistent with national and international data privacy laws in connection with human samples and data.

III. Legal Basis

As set forth in Art. 34 of the Euro-BioImaging ERIC Statutes, the Euro-BioImaging Board shall establish the ELSI Policy that shall be in line with relevant laws and regulations and that considers best practices.

IV. Basic Ethical Principles

1. Introduction

Euro-BioImaging is committed to four principles whose canonical status is widely acknowledged in medical ethics:

- Autonomy
- Beneficence
- Non-maleficence
- Justice

Euro-BioImaging will support its users and Nodes to adhere to these basic ethical principles.

2. Autonomy

The principle of Autonomy (as opposed to paternalism) includes the right of an individual to make his or her own choice.

The principle of Autonomy and self-determination is acknowledged by respecting the preferences of the individual by guaranteeing for informed consent. Informed consent is guaranteed through four components:

- Competence: the individual needs to be competent - mentally and physically - to grant consent.
- Disclosure: the individual needs to be provided with all necessary information (e.g. regarding effects of a surgery both probable and possible) and has obviously fully understood the proposed treatment.
- Voluntariness: the individual needs to agree to the procedures voluntarily (without pressure).
- Informed consent: the individual needs to provide informed consent to the treatment in light of the above.

Persons who are not in a position to make decisions freely and independently (people incapable of giving Consent) are covered by provisions of special protection.

3. Beneficence (including public benefit)

The principle of Beneficence means acting with the best interest of the other in mind (support of public benefit).

Biomedical research should strive to serve the greater well-being of all humankind. Its benefit to society should be achieving greater insight into the foundations of biology as well as in integrating its findings into clinical care. For the sake of realising societal benefit, it is necessary to ensure

- the broadest participation, which includes the general public, in sharing the benefits of scientific advancement; and
- the best preparation and design of a study to avoid any harm of third-party's right.

4. Non-Maleficence

The principle of Non-Maleficence translates into "above all, do no harm" and includes the principle of good scientific practice.

Good scientific practice includes scientific honesty and diligence (professionalism, forthrightness, transparency) in the stewardship of data, samples, and research results. It is subverted by scientific dishonesty (deception, fraud, illegitimate use of knowledge from other sources).

5. Justice

The principle of Justice emphasizes fairness and equality among individuals, including non-discrimination.

Protection against discrimination requires equal treatment and respect for all persons whose data are used in research. The interests and needs of every person must be respected without bias; every person must be protected from harm and treated with care impartially.

Stigmatisation of subsets of the population via certain data analyses is to be avoided even if it may be induced unintentionally.

V. Ethical requirements

Euro-BioImaging, either at the governance, coordination, and operational levels, is committed to keep a code of conduct in full compliancy with the EU and national ethical regulations for human and for animal biomedical research.

Service provision at Euro-BioImaging Nodes that have the potential to harm living vertebrates (other than man) and cephalopods must comply with national and international legislation as well as other regulations in place.[1] While countries have equivalent legislation in place covering animal protection in laboratories, and referring to the same principles above, their application may differ from Country to Country. Euro-BioImaging Nodes are bound by their national/local rules when granting access to Euro-BioImaging services involving animal experiments.

[1] In particular European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (1986), amended by the Directive 2010/63/EU.

Ethical standards as defined in the Declaration of Helsinki must be followed whenever human subjects or human organs, tissues or cells are involved in biomedical research. Nodes must obtain ethical approvals by the competent local/national ethical/legal bodies for the procedures to be followed during service provision that involves human participants (physical intervention on human participants, personal data collection and processing, further processing of previously collected personal data). Approval by the territorial competent authorities must be obtained as well when service provision involves human organs or tissues derived from human embryos/foetuses (and tissues/cells derived thereof). Experiments carried out at Nodes shall respect the principles outlined in section IV of this policy at all times.

The Service Level Agreements between the Euro-BioImaging Hub and the Euro-BioImaging Nodes will explicitly mention that the Euro-BioImaging Nodes take the responsibility for compliance with both EU and National regulations in case of provision of Euro-BioImaging Services that involve human or animal research. It is in the responsibility of the Nodes to implement procedures and to obtain specific authorizations from national/local legal bodies and ethics committees prior to the execution of the access.

VI. Entry into force, amendments and monitoring

1. Entry into force and amendments

The Policy is established and may be amended by the Euro-BioImaging Board by a two-thirds Majority pursuant to article 29.8 (j) of the Euro-BioImaging ERIC Statutes, which entered into force on (October 29, 2019).

The Policy shall come into effect on the date of its adoption, on the date of May 5, 2020.

2. Monitoring

The Euro-BioImaging Directorate, together with the Nodes and other individuals appointed by them, shall monitor the compliance of Euro-BioImaging services provided by Nodes.

Based on the monitoring, the Euro-BioImaging Scientific Advisory Board shall assess the Node's compliance with the Policy when providing Euro-BioImaging services.