



BBMRI-ERIC

Biobanking and
BioMolecular resources
Research Infrastructure

BBMRI-ERIC Common service ELSI What for?

Anne Cambon-Thomsen, Coordinator, Co-director
BERLIN, 9-10/12/2015
Nationales Biobanken-Symposium

Map BMRI-ERIC 2015



 MEMBERS
 OBSERVERS

THE VALUES of BBMRI-ERIC

Pan-European in scope,
combining scientific excellence, transparency,
openness, responsiveness, ethical awareness, legal
compliance and human values.

INTRODUCING BBMRI-ERIC COMMON SERVICES

A Common Service is a key facility providing expertise, services and tools relevant for the pursuance of the tasks and activities of BBMRI-ERIC.

The Common Service ELSI aims to facilitate and support cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices. Among other things, it will provide an ethics check and help-desk format.

Steps in establishing CS ELSI

- BBMRI-Preparatory phase (FP7) – WP ELSI-2008-2011
- Preparatory meeting: 4 March 2014
- Call published: 30 April 2014
- Call closed: 29 July 2014
- Reviewers proposed: 18 August 2014
- Reviewers confirmed: 17 September 2014
- Review received by applicants: 20 October 2014
- Review commented: 28 October 2014
- Assembly of Members: 11 November 2014
- Management Committee: 15 December 2014
- **Common Service ELSI start: 1 February 2015**

CS ELSI

□ **Common Service ELSI start: 1 February 2015**

Resources

Website

Workplan

Report (planned Jan 2016)

See poster BBMRI-ERIC CS

See Newsletters « Biobanks Europe »

<http://bbmri-eric.eu/news-letter>

<http://bbmri-eric.eu/common-services>

Responsibilities – Missions (1)

- **Provide an ethics check** for research proposals submitted to BBMRI-- ERIC for compliance with the BBMRI Business Plan & Statutes and with the European Commission research ethics framework
- **Advise** on a sound scientific/academic basis and experience in ethical reviews of European/international projects
- **Provide solid monitoring of ELSI** issues related to biobanks and biobanking (based on state of the art and deep knowledge of relevant ethical and legal frameworks in application)
- **Follow up relevant evolution in legislations/regulations** at European level ; coordinate answers to relevant public consultations and other possible actions to address joint matters for the biobanking community on the European level

Responsibilities – Missions (2)

- **Provide updated background information and practical guidance to biobankers** to respond to ELSI issues, especially in relation to the exchange of human samples and data for research use in Europe ("**Help-Desk**")
- Ensure the **dissemination of results** of relevant surveys and studies toward various audiences
- **Organise tools and services to address ELSI** issues related to biobanks and biobanking by building on already available tools and generating new ones if necessary
- **Organise experience sharing** and exchanges regarding ELSI aspects between BBMRI-ERIC members
- Set up **training and education** on ELSI issues related to biobanks and biobanking.

Goals - Support

- *vertical support*: **facilitating** the activities of National Nodes by providing an easy access to European and international expertise/ tools/educational opportunities on cross-border ELSI related to biobank-based research
- *horizontal support*: **coordinating** initiatives on ELSI topics, by supporting information exchange, development/ implementation of practical tools
- *transversal support*: **providing ethical guidance** through an Ethics Check and help desk service for projects using the BBMRI-ERIC infrastructure

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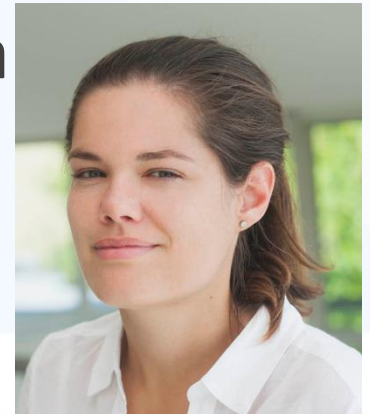
WHERE ARE WE WITH THE BBMRI-ERIC CS ELSI TODAY?

CS ELSI LEADERSHIP

- Lead by a Board of Co-Directors consisting of Anne Cambon-Thomsen (FR), Mats Hansson (SE), Marialuisa Lavitrano (IT) & Jasper Bovenberg (NL)



- Supported by a senior officer (Michaela Mayrhofer) from the Central Executive management office.



Executive Board & ELSI team

Executive Board: a representative for Common Service ELSI from each National Node and Observers

- Key role : strategy, orientation, Node input/output**
- 1st meeting : 31/7/15 , Milano**
- ELSI team members (not EB members) who were present: invited**
- Last nomination: UK members (Nov 2015)**
- Still missing Observer countries/institutions representatives**

A distributed operational ELSI team: one or two persons in each national node to participate (part time) to the tasks of the CS ELSI

- Vital role : operational; task accomplishment, Node input/output**
- 1st meeting : 8/9/15 – Paris**

**In addition we rely on number of experts, punctually.
A database of voluntary experts is being constructed.**

CS ELSI Executive Board : role

“A group composed of one ELSI representative for each national node will constitute the **Executive Board** that is essential to bring all the nodes with their cultural and legal differences together for internal decisions and regular consultations (one meeting a year as a rule).

ELSI representatives of observer countries may participate in the exchanges, with no vote for decisions.

The Executive Board is the body setting priorities and validating the annual report, distribution of tasks, and planned budget prior to proposal to the BBMRI-ERIC Directorate.

Final decisions on work programme/budget are in the hands of the assembly of Members.

CS ELSI Team role

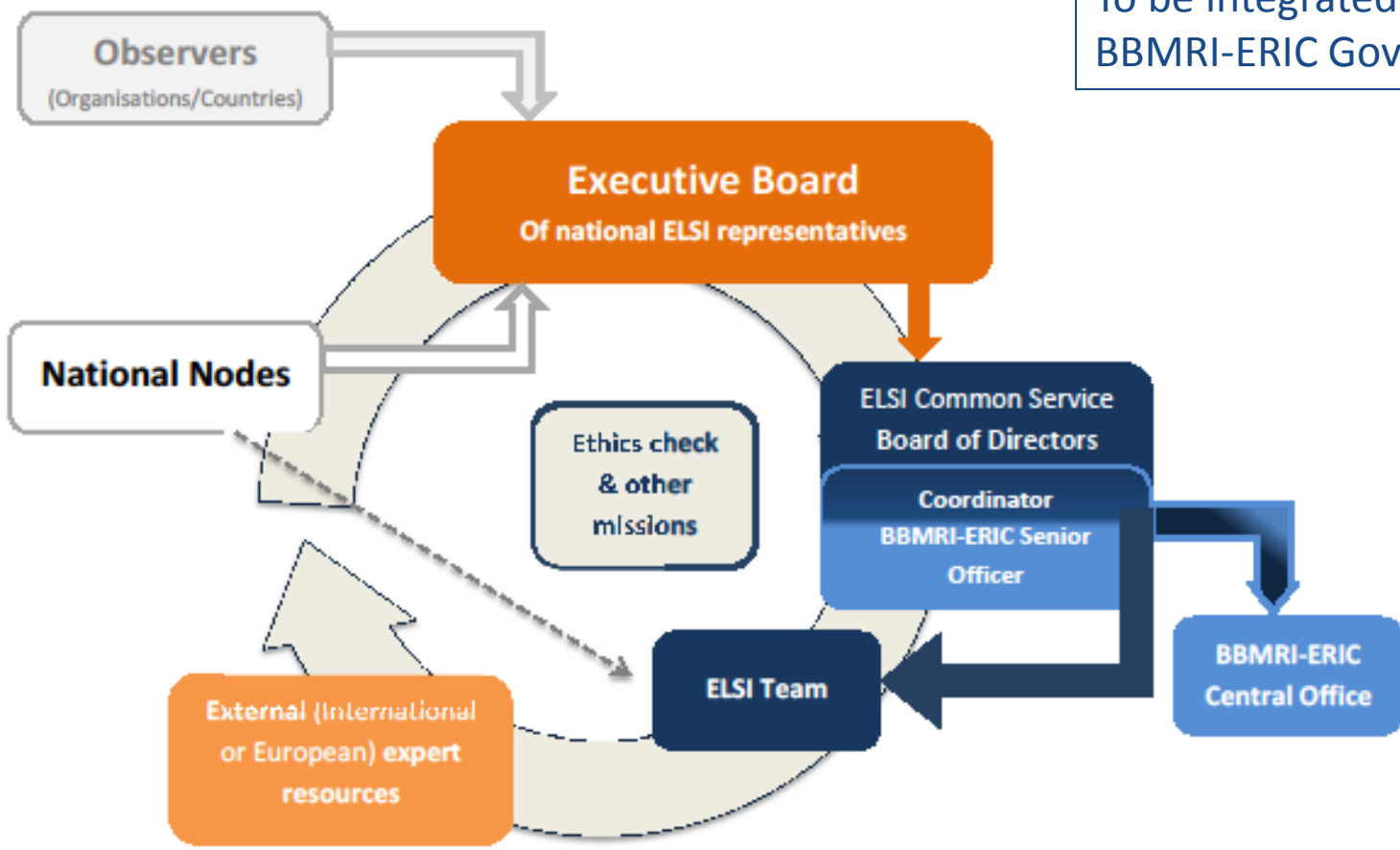
- Distributed team & different contract type, (part time)
- Accomplishes the tasks of the annual work programme
- Operational role
- Proposed by National Nodes but do their work under BBMRI-ERIC CS ELSI direction

Key role in :

- Providing information on ELSI in the National Node
- Tools/ public consultations requiring national inputs
- Data base of experts
- Ethics check

Organogramme of the BBMRI-ERIC ELSI Common Service

To be integrated in the general BBMRI-ERIC Governance flow chart



BBMRI-ERIC ELSI Common Service

Work plan 2015:

Set up, establish procedures, construct network

The key action points for 2015 were:

- Set up the governance and operational management
- Prepare & circulate Ethics-check draft template
- Establish procedure how to screen public circulation documents (limit to CoE and European Union)
- Update BBMRI-ERIC Website section for CS ELSI
- Include ELSI news & relevant meetings in monthly mailchimp news service & website
- Set up Intranet section for CS ELSI
- Dissemination: attract further ELSI experts

Tasks and Deliverables 2015

Task 1 Ethics check - Organisation of the expert network, advice function and help desk

Task 2 Follow up of legal, regulatory, ethics framework evolution at European/international level

Task 3 Implementation of the experience sharing mission : Workshop Paris Sept 2015

Task 4 Implementation of the dissemination action

Task 5 Existing Tools improvement

Other additional activities

Lead or Participate in ELSI activities in projects (h2020) where BBMRI-ERIC is involved

- ADOPT
- CORBEL
- Cyprus BIOBANK

Meetings in 2015

BoD face to face meetings : Feb 3, and Jul 27, Milano;
planned: 12/1/16 (Brussels)

BoD telephone/skype meetings : 27/3, 17/4, 21/5,
18/6, 5/10, 30/11

EB : 31/7 (Milano)

ELSI team : 8/9 (Paris)

Sub group: tools 12/12 (Graz, with BioMed Bridges)

Informal or ad hoc meetings whenever possible/
suitable

Examples of achievements

Working methodology

Coordination by CS ELSI

Works in National Nodes

Experience sharing and communication as a key

Consensus as a virtue: a practice and a result allowing standardized approach



A- Answers to relevant public consultations for biobanks

Council of Europe's Recommendation (2006)4 on research on biological materials of human origin

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

DH-BIO/INF (2014) 3

Strasbourg, 18 March 2014

COMMITTEE ON BIOETHICS (DH-BIO)

Working document on research on biological materials of human origin

This working document is made public under the responsibility of the Committee on Bioethics (DH-BIO). The purpose of this consultation is to elicit comments which will be taken into consideration in finalising the revision process of Recommendation (2006) 4 of the Committee of Ministers of the Council of Europe, on research on biological materials of human origin.

The DH-BIO would be particularly interested in receiving comments on the following issues:

- Storage for future research of residual biological materials (Article 13)
- Removal, storage and use of biological materials from persons not able to consent (Articles 12, 14 and 17, paragraph 4)
- Governance (Articles 20, 21, 22, 23 and 24)

In addition to the priority issues highlighted above, comments are also solicited on the other provisions contained in this document.

Comments should be as precise and concise as possible. They should refer to specific provisions in the document.

Comments should be submitted in English or French, by 15 August 2014 via email to the following address: dgl.consultation@coe.int.

Draft release: 18 March 2014

Aims: safeguard the fundamental rights of individuals whose biological materials could be included in a research project after having been collected and stored:

- for a previous specific research project
- for future unspecified research or
- as residual material originally removed for clinical or forensic purposes.

Addressees: States, researchers, relevant bodies or institutions, patient organisations and biobank managers

CS ELSI: Coord. 1st and 2nd round answers

WMA Declaration on ethical considerations regarding health databases and biobanks

Draft release: 18 March 2015

Aims: provide additional guidelines to the Declaration of Helsinki regarding privacy:

- for health databases (systematic system for collecting, organizing, storing health information) and
- for the repositories of human biological material

Addressees: physicians, administrators, researchers, policy-makers

WMA DECLARATION ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS

2015-03-18

A draft from the Work Group intended for open consultation after acceptance of the Executive Committee of the WMA

PREAMBLE

1. The Declaration of Helsinki lays down ethical principles for medical research involving human subjects, including the importance of protecting the privacy and confidentiality of research subjects, and obtaining informed consent for using their health data and biological material.
2. This declaration provides additional principles for the ethical use of data in Health Databases and human biological material in Biobanks, referred to hereafter as biological material, used for research or for other purposes.
3. A Health Database is a system for collecting, organizing and storing health information. It enables the information to subsequently be retrieved in a structured manner. A Biobank is a collection of biological material and associated data from different individuals. Health Databases and Biobanks are both collections of information on individuals, and both give rise to the same concerns about autonomy, privacy and confidentiality
4. In health care provision, health information is gathered by physicians or other members of the medical team to record health care events and to aid physicians in the on going care of their patient. This declaration is intended to cover any use of health information beyond the individual care of patients.
5. Respecting the dignity and autonomy of individuals, physicians have specific obligations, both ethical and legal, as stewards protecting information provided by their patients
6. Ongoing improvements in the understanding of diseases and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions can be significantly accelerated through research using data from Health Databases and Biobanks.
7. Biological material refers to a sample obtained from an individual human being, living or deceased, which can provide biological information, including genetic information, about that individual.

B- Participation to the EU data protection law reform

- Essential role in BBMRI activities on this level
- Workshop in Brussels
- Action day in June
- Drafting a common position/contribution
- Disseminating information about the change regarding safe harbour

C- Presence in various meetings 2015

- UNESCO IBC (unofficial observer) – Paris Oct 2015
- CoE / Ethics committee Serbian Academy of Sciences and Art – Belgrade Nov 2015
- BBMRI-LPC - Budapest, Oct 2015
- BiobankCloud Workshop- Vienna Nov 2015
- **Annual Biobank meeting in Germany 2015– Berlin**
- ERACoNet SysMed ethics procedure discussion - Rome Sept 2015
- 3 Toulouse meetings :
 - Oct 9, BRIF with editors;
 - Dec 3 : Sharing science, sharing values (ATG special issue)
 - Dec 4 : BRIF meeting (identifiers/parameters)

CS ELSI Work plan 2016

Bases :

- The Tender, accepted actions
- Experience 2015
- Follow up actions from 2015
- Actions that were not prioritised in 2015 and are considered pertinent and timely for 2016

Specific Actions Prioritised 2016 (1)

- Organise database ELSI experts – G Chassang
 - Already on track (template circulated)
- **GDPR follow up +++ - Code of conduct, harmonisation**
- Help desk in place and further work on tools –
 - First meeting held to set up the work – Irene Schlunder
- Evaluate the ethics check (ACT) – need experience
- Dialogue workshop with RECs from # countries (DL) (JB)
- ELSI part in MoU with relevant international organisations (ACT) – Discussion with ELSI 2.0 started

Specific Actions Prioritised 2016 (2)

- Booklet on « rules of procedures » and tariffs for external users to be done
- Procedure to enhance public debate and engagement with society (DL) (MLL - Martin Boeckhout)
- Annual workshop (NGS?) (DL) MH
- Education (data protection ?) – Summer school? JB

Under investigation for being organised in 2016



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What can you do?

What are you expecting?

Contact through:

- Website contact address
- The National Node and/or the representatives in
 - Executive board (Roland Jahns)
 - ELSI team German member (Irene Schlunder)

Your expectations

Your projects for ELSI aspects (EU dimension required)

Your questions (beyond German internal aspects)

Your suggestions (experts, topics)

Your news to be disseminated

THANK YOU

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