Ethical, Legal, and Societal Implications (ELSI) in the research infrastructure context

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Stephanie Suhr

www.elixir-europe.org

Research infrastructures make resources available to the scientific community.
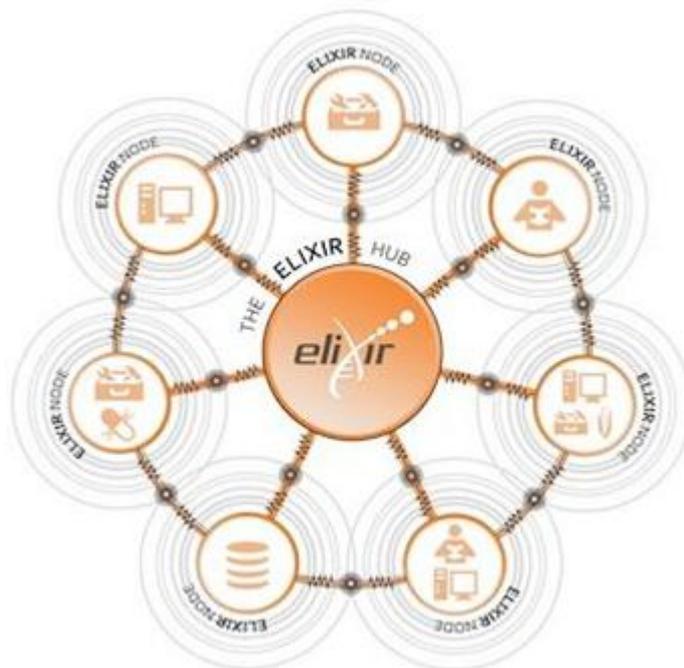
How do you implement regulatory requirements...

- for data and/or samples that were produced in a specific context and are now used for research in many different contexts, and

- across a research infrastructure?

Background: ELIXIR

- ELIXIR is a **distributed infrastructure** with **organisationally independent Nodes**
- ELIXIR **Nodes make key data resources available** to the research community
- The legal basis for ELIXIR requires that **each Service has its own functioning ethics and regulatory oversight** in place

An overarching framework

ELIXIR has developed an Ethics Policy which will:

- **Identify potential risks**
- **Clarify roles and responsibilities**
- **Provide first guidance on high level principles**

From ELIXIR Ethics policy:

4.4 Public benefit

Biomedical research serves the greater well-being of all humankind. Its benefit to society consists in 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.

Main concerns of stakeholders

- The policy should…
  - …not introduce additional administrative or technical burden
  - …not make requirements that could come in conflict with other applicable legislation (e.g. national regulations or implementation of e.g. EU-level legislation)
  - …be very clear on what the ELIXIR Service providers are and what they are NOT responsible for
  - …not create ambiguities with respect to responsibilities
  - …not interfere with processes in place at Nodes
  - …emphasise and support the principle of open sharing of data for research.
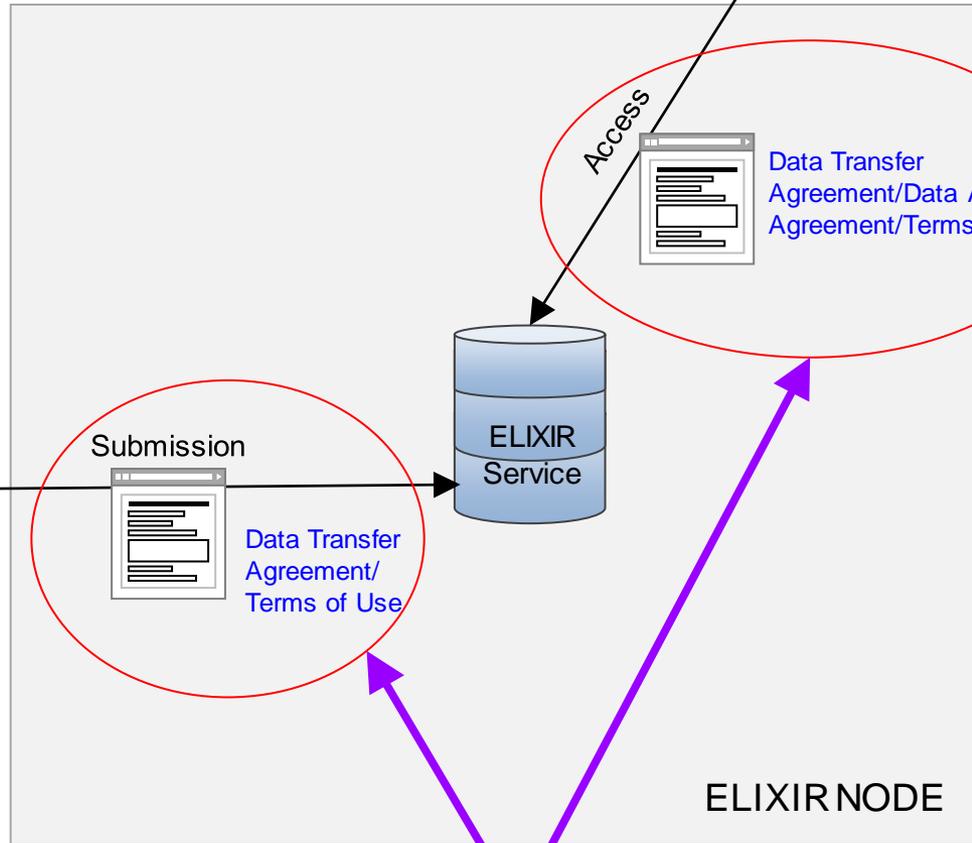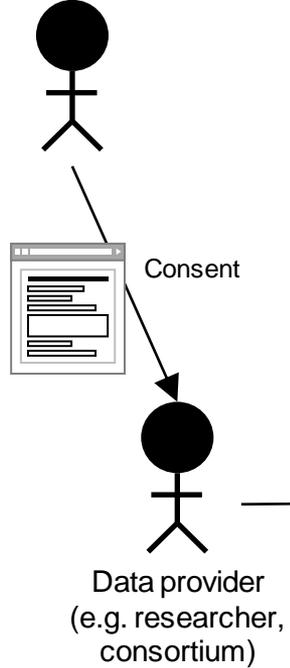
This is key: clarify the respective roles!

- The policy defines the following roles in the context of data provision via ELIXIR Services; each of these has different, clearly defined responsibilities:

  - **Data Provider** means the individual researcher or investigator or body of researchers or investigators that submits data for access and use in the context of an ELIXIR Service
  - **Service Provider** refers to the Node providing an ELIXIR Service (as detailed above)
  - **Data User** means the individual researcher or investigator or group of researchers or investigators that accesses and/or uses data made available as part of an ELIXIR Service

Data subject
(e.g. study participant, patient)

User

Consent

Access

Data Transfer
Agreement/Data Access
Agreement/Terms of Use

Submission

ELIXIR
Service

Data provider
(e.g. researcher,
consortium)

Data Transfer
Agreement/
Terms of Use

ELIXIR NODE

ELIXIR Ethics
Policy

- *The Data Transfer Agreement ensures that data providers and users are aware of their obligations*
- *The responsibility for implementing relevant obligations is cascaded down to the data provider (e.g. ethics review) and/or user.*

COMMON SERVICE ELSI

Facilitates & supports cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices.

Started in February 2015
20+ experts from law, philosophy, social sciences, ethics

- establishment of a sustainable **common service** for all BMS RIs dealing with samples and/or data with ethical, legal and social implications
  - development/improvement of patient information and consent templates
  - integration of the common service into the BBMRI-ERIC tool *Common Service ELSI*

ACCOUNTABILITY

While making the **best use of any entrusted data** (given typically for altruistic reasons), data has to be protected from careless handling, misuse and illegal disclosure.

Hence, the ultimate responsibility is to use data appropriately, so that neither the expectations nor the efforts of the data providers and users go to waste.

CONTACT

CORBEL WP7 ELSI and BBMRI-ERIC

Email: michaela.th.mayrhofer@bbmri-eric.eu
Web: www.bbmri-eric.eu, www.corbel-project.eu

ELIXIR

Email: stephanie.suhr@elixir-europe.org

Web: www.elixir-europe.org