EXCELERATE Deliverable 14.2

Project Title:	ELIXIR-EXCELERATE: Fast-track ELIXIR implementation and drive early user exploitation across the life sciences	
Project Acronym:	ELIXIR-EXCELERATE	
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Deliverable title:	POPD - Requirement No. 4	
WP No.	WP14	
Lead Beneficiary:	1 - EMBL (ELIXIR Hub)	
WP Title	Ethics requirements	
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WP leader:	Niklas Blomberg	1 - EMBL (ELIXIR Hub)
Partner(s) contributing to this deliverable:	ELIXIR-Hub	

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Table of content

1. Executive Summary

This deliverable describes the ELIXIR risk management strategy with respect to the General Data Protection Regulation (GDPR)[1], which came into force on 25 May 2018.
The strategy describes the essential procedures and practices within ELIXIR concerning GDPR compliance, performing risk assessment and mitigation.

2. Project objectives

With this deliverable, the project has reached or the deliverable has contributed to the following objectives:

No.	Objective	Yes	No
1	Deliver the long-term strategy for sustaining Europe's core data resources, data standards, data legislation.	x	

3. Delivery and schedule

The delivery is delayed: • Yes ☑ No

4. Adjustments made

Not applicable

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG

Horizon 2020 grant n. 676559

5. Background information

Background information on this WP as originally indicated in the description of action (DoA) is included here for reference.

Work package number	14	Start date or starting event:	month 1
Work package title	**Ethics requirements**		
Lead	Niklas Blomberg (EMBL)		
Participant number and person months per participant 1 – EMBL			
This work package sets out the 'ethics requirements' that the project must comply with.			
Objectives The objective is to ensure compliance with the 'ethics requirements' set out in this work package.			

The deliverable D14.2 refers to the requirement No.4 described in Section 5 "Ethics and Security" of the DoA, as copied below.

Section 5: Ethics and Security

5.1 Ethics

5.1.1 Ethical Governance in ELIXIR

Formal requirements and provisions

Personal genomics and multi-omics data archives are key resources for translational research, personalised medicine and to study the mechanisms underlying complex diseases. ELIXIR will provide open access to bioinformatics resources by providing a data, compute, tools, standards and training infrastructure. However, long-term archiving and re-use of personal -omics data pose significant challenges in the management of ethics, consent for reuse, review of access, data security and governance.

The need to establish a common framework of high ethical standards applicable in the provision of ELIXIR services was therefore recognised already in the **ELIXIR Consortium Agreement** (ECA), the founding document underlying all of ELIXIR's activities.

Horizon 2020 grant n. 676559

Article 11 of the ECA stipulates:

> *The ELIXIR Board shall establish an ethics policy that is in line with relevant laws and regulations and that considers best practices. It shall put in place measures to ensure that activities required as part of the ELIXIR Hub's mission shall be in line with this ethics policy. The ELIXIR Board shall implement mechanisms to ensure that ELIXIR Nodes as well as all other collaboration partners in the context of ELIXIR are made aware of their obligation to ensure compliance of all relevant laws and regulations (and, where applicable, local ethical guidelines) when handling, storing, or processing personally identifiable data resulting from biomedical research.*

The legal implementation of ELIXIR as a distributed infrastructure across Europe - in which the ELIXIR Nodes remain independent legal entities - is based on **Collaboration Agreements** between separate legal entities operating in different jurisdictions. In light of the size and reach of ELIXIR's operation and based on the stipulations of the ECA, the Collaboration Agreements clearly outline the responsibilities of the Nodes as individual service providers and service users for the following, related issues:

- good ethical conduct, ethics governance and oversight
- quality control
- provision of necessary training.

These conditions are implemented explicitly in several articles of the Collaboration Agreement:

> *7. User Access to Services provided by the ELIXIR Node(s)*
>
> *7.1 Training*
>
> *The Node will provide the basic training or support to the Users which it deems necessary in the use of Services provided by the Node as described in the Service Delivery Plan and/or the Commissioned Services Contract.*
>
> *7.2 Terms of Use*
>
> *The Node will provide clear Terms of Use for services. The Terms of Use should at least ensure that the User*
>
> *a. is obliged to be aware of the Node's IP and Data policies;*
>
> *b. complies with the provisions of the ELIXIR Ethics Policy as established and approved by the ELIXIR Board,*
>
> *c. complies with any further relevant ELIXIR policies in scientific, technical and administrative matters as determined and adopted by the ELIXIR Board in accordance with ECA, Art. 6.2.1. b); and*
>
> *d. is responsible for any loss, damage or injury as a result of his/her failure to comply with the [Member State] ELIXIR Node's Health & Safety policies and procedures and as a result of wilful behaviour.*

Horizon 2020 grant n. 676559

10. Governance

10.1 Head of Node

[...] The tasks of the Head of Node include, but are not limited to the following:

g. Ensure the compliance of the Node [and all involved national research institutes] with the ELIXIR Ethics Policy, national regulations and international best practices;

h. Ensure compliance with the Terms of Use as adopted by the [Member State] ELIXIR Node.

i. Oversee the internal quality assurance mechanism the Node has adopted;

[...]

k. Provide evidence to the Ethics Advisory Committee in carrying out a review of the ethical measures in place at the [Member State] ELIXIR Node.

10.2 Collaboration Oversight Group

10.2.1 Composition

The Collaboration Oversight Group is established by the Parties and comprises the ELIXIR Director, the Head of Node and other individuals appointed by them.

10.2.2 Role and tasks of the Collaboration Oversight Group

The Collaboration Oversight Group shall:

a. Identify key performance indicators and establish target values which may be used for the assessment of the service delivery of the Nodes in accordance with the Service Delivery Plan and the Commissioned Services Contract;

b. Monitor the implementation of the Service Delivery Plan and the Commissioned Services Contract and measure the progress of the [Member State] ELIXIR Node by applying the established key performance indicators and target values;

c. Review the [Member State] ELIXIR Node's allocation of funds for the purposes of providing Commissioned Services in accordance with the Commissioned Services Contract; and

d. Monitor the compliance of the [Member State] ELIXIR Nodes with the ELIXIR Ethics Policy.

11. Assessment of the [Member State] ELIXIR Node

11.1 Evaluation by the Scientific Advisory Board

The [Member State] ELIXIR Node shall be evaluated by the Scientific Advisory Board [as determined by the ELIXIR Board]. Upon recommendation of the Scientific Advisory Board

Horizon 2020 grant n. 676559

the ELIXIR Board shall decide whether it wishes to renew or terminate the Agreement (in whole or in part) with the [Member State] ELIXIR Node.

11.2 Review by the Ethics Advisory Committee

The [Member State] ELIXIR Node shall also provide the Ethics Advisory Committee with evidence and information concerning the ethical measures in place in order to ensure that they comply with the ELIXIR Ethics Policy as determined by the ELIXIR Board. Upon recommendation of the Ethics Advisory Committee, the ELIXIR Board shall decide whether it wishes to renew or terminate (in whole or in part) the Agreement with the [Member State] ELIXIR Node.

14. Ethics

Services delivered under the Agreement shall be in line with relevant laws and regulations and that consider best practices as well as with the Ethics Policy adopted by the ELIXIR Board. The ELIXIR Hub shall remind the [Member State] ELIXIR Node of its obligation to ensure compliance of all relevant laws and regulations (and, where applicable, local ethical guidelines) when handling, storing, or processing personally identifiable data resulting from biomedical research.

The [Member State] ELIXIR Node is responsible to implement its own Ethics Policy in order to ensure that the services provided within ELIXIR comply with the ELIXIR Ethics Policy and national rules and regulations as well as international standards of best practice.

To illustrate what this approach translates to in practice, the European Genome-phenome Archive (EGA)[1] - a core resource for sensitive data within ELIXIR - has long-established, solid data security and ethics procedures[2]:

> EGA provides the necessary security required to control access, and maintain patient confidentiality, while providing access to those researchers and clinicians authorised to view the data. In all cases, data access decisions will be made by the appropriate data access-granting organisation (DAO) and not by the EGA. The DAO will normally be the same organisation that approved and monitored the initial study protocol or a designate of this approving organisation.

Submitters retain complete ownership over data submitted to EGA and may control access permissions to the data once submitted (and where required).

Scope of the ELIXIR Ethics policy

Given the legal and organisational conditions underlying ELIXIR's operation, the overarching ELIXIR Ethics Policy must be different to, for example, that of a multinational company where policy and procedure can be driven centrally. In contrast, as the legal basis for ELIXIR requires that each service have its own functioning ethics oversight in place, the ELIXIR-wide approach must allow the ELIXIR Nodes to rely on their own ethics policies without imposing additional compliance systems that may interfere with the existing measures. In addition, as stipulated

Horizon 2020 grant n. 676559

by the ECA, the ELIXIR Ethics Policy must make provisions for the development of expertise and capacity at the Nodes in order to facilitate ethical and legal sharing of valuable life-science data resources.

ELIXIR Nodes have, either directly or via umbrella organisations, engaged in and commented on the implications of the stipulations of the proposed new European Data Protection Regulation. ELIXIR as an infrastructure has also commented on the Regulation. Naturally, the ELIXIR Ethics Policy and any processes around sensitive data will be actively revised and adjusted as necessary should the legal and/or ethical framework surrounding the use of sensitive data change.

5.1.2 ELIXIR sensitive data strategy

The role of ELIXIR-EXCELERATE

ELIXIR-EXCELERATE will support the implementation of the ELIXIR Scientific Programme and the delivery of ELIXIR's main mission, "to build a sustainable European infrastructure for biological information, supporting life-science research and its translation to society, the bio-industries, environment and medicine". No new data with ELSI requirements will be generated within ELIXIR-EXCELERATE. Supporting the implementation of the ELIXIR infrastructure, EXCELERATE will develop the necessary infrastructure, tools, capacity, knowledge and coordination across Europe's life science data resources, including sensitive data.

The ELIXIR-EXCELERATE consortium - consisting of the infrastructure Nodes in ELIXIR Member States and organisations from Observer countries who are actively working on joining the infrastructure - provides full coverage of the necessary expertise in data management, security and ethics. Figure 1 illustrates the ELIXIR "platforms" - areas of activity aligned with the ELIXIR Programme - in which all ELIXIR implementation activities are coordinated. "Human research data" is one of a number of cross-cutting platforms, highlighting the importance placed on this topic within ELIXIR. EXCELERATE includes a dedicated work package and tasks around the provision and use of sensitive data.

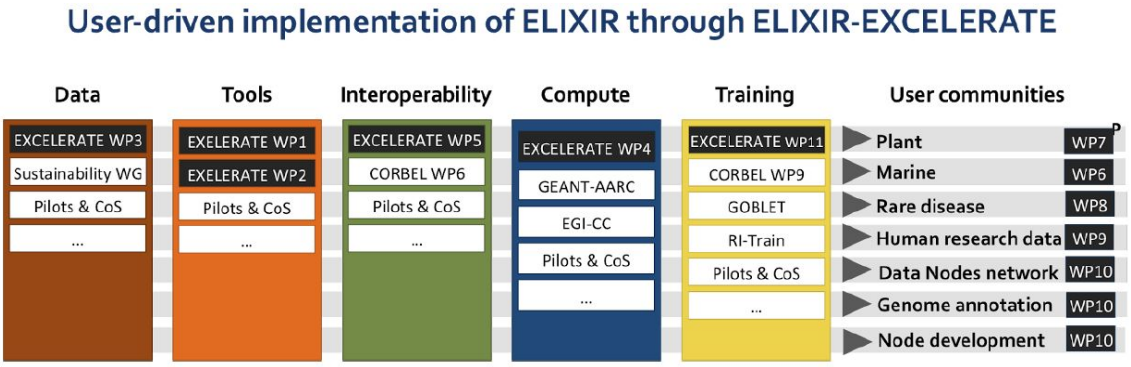

Figure 1: ELIXIR platforms, based on the ELIXIR Scientific and Technical Programme

Sharing and accessing sensitive data within ELIXIR resources securely and ethically

Horizon 2020 grant n. 676559

Keeping sensitive data safe while making it available to authorised users for research has significant technical and technological implications. Since the beginning of 2015, expert staff with relevant experience in the use and safeguarding of sensitive data has been working at the ELIXIR Hub to coordinate a number of ELIXIR core-funded technical activities (pilots) around secure access to sensitive data, which include building up of relevant expertise at the ELIXIR Nodes. The knowledge gained in these pilots is essential and will significantly contribute towards the development of ELIXIR's sensitive data strategy.

EXCELERATE work package 9, "**An ELIXIR framework for secure archiving, dissemination and analysis of human access-controlled data; enabling biobanks, cohorts and local resource services to leverage the EGA**" revolves entirely around enabling secure, legally and ethically compliant access to and sharing of sensitive data. The work package will utilize the scale and experience of the European Genome-phenome Archive (EGA) as the core of an ELIXIR community secure data sharing network for -omics data.

In the context of WP9 and supported by WP4 and WP12, ELIXIR-EXCELERATE will perform a comprehensive review of current practice for archiving and access to sensitive data. The work package has a number of tangible outputs:

- Recommendations on best practice based on a thorough analysis of gaps and major risks
- Tools supporting the collection, submission and interoperability of all types of -omics data from human samples consented for biomedical research
- Extension of secure data access via tried and tested access authorisation management systems and high volume secure data transfer developed in the EGA towards an initially small number or resources, to be scaled up later to match wider European requirements.

The efforts of WP9, and in particular the efforts towards the WP9 deliverable "**Report on implementation of ELSI and policy consideration for controlled access data**" due 31 August 2018, will feed into subtask 12.2.4 in WP12, "**Establish ELIXIR's internal processes for ELSI**". To give this task appropriate visibility, we have added a specific deliverable "**First draft of ELIXIR Ethics Policy"** (deliverable 12.1, reported on 31 August 2016). Once approved by the ELIXIR Board, the Ethics Policy and related processes were included in the **ELIXIR Handbook of Operations** (EXCELERATE deliverable 12.2, reported on 31 August 2016).

On the technical side, Task 10.2 **Capacity Building in Data Nodes Network** in WP10 ELIXIR Node Capacity Building and Communities of Practice includes the development of Good Practices in setting up data Nodes enabling secure storage of sensitive data, such as sequence data related to human research participants. Task 10.2 interfaces with WP4 regarding technical developments on AAI and data transfer. Furthermore, there are connections with WP4 on data interoperability and the Use Case in WP9 on sensitive data.

In addition to the tasks of WP10, **knowledge transfer concerning requirements around the provision and use of sensitive data** will be achieved via WP11 Training and will be closely aligned with the ongoing development of data infrastructure, standards, tools and services in each Node. In WP8 Use Case C: ELIXIR infrastructure for Rare Disease research, supported by

WP11 Training, Task 8.3 will deliver targeted training workshops for the rare disease data user communities.

Timeline for the development of the ELIXIR Ethics Policy

September 2015	Open call for applications to provide independent external expertise on ELSI matters for ELIXIR
February 2016	CORBEL deliverable 7.1 ELSI support needs for BMS RIs identified
August 2016	First draft of ELIXIR Ethics Policy (EXCELERATE deliverable 12.1)
August 2016	ELIXIR Handbook of Operations including ELIXIR's internal processes for ELSI (EXCELERATE deliverable 12.2)
August 2018	Report on implementation of ELSI and policy consideration for controlled access data (EXCELERATE deliverable 9.5)
August 2018	CORBEL deliverable 7.2 ELSI guidance for new scientific, technological and cross-border developments using a "help-desk format"
August 2019	CORBEL deliverable D7.3 Sustainability Plan for extended BMS RI ELSI common services

5.1.3 Key collaborations and international context

Global Alliance for Genomics and Health

The Global Alliance for Genomics and Health (GA4GH)[3] is a community-driven, international initiative with the purpose of carrying out a similar function to that of the World Wide Web consortium in its field; that is, to establish a global framework for the common technical, operational and ethical standards needed to ensure the interoperability of global research platforms dealing with data in a secure and responsible manner. The ELIXIR infrastructure as a whole as well as many ELIXIR Nodes or organisations involved in a Node are Organizational Members of the GA4GH[4], including EMBL-EBI, EMBL, SIB-Swiss Institute of Bioinformatics, the University of Oxford and the Sanger Institute. ELIXIR will continue to collaborate closely with the GA4GH to support the development and implementation of the emerging global code-of-conduct for management and sharing of personal research data and develop training modules for implementation of the GA4GH security framework.

Starting in 2015, ELIXIR will implemented an initial data discovery service based on a GA4GH Beacon[5]. This pilot initiative, which is part of the ELIXIR Human Data Community, provided initial secure, consent-based data discovery services on genomic data held in the European Genome-phenome Archive (EGA) or which constitutes part of the resources at certain Nodes. The output of the pilot was be integrated and support technical interfaces within

ELIXIR-EXCELERATE work packages and support the EXCELERATE Data Nodes Network capacity building effort.

In general, ELIXIR Nodes are engaging at various levels and in a number of activities of the GA4GH. Perhaps of most relevance, Paul Flicek, Senior Scientist at EMBL-EBI and leader of the Vertebrate Genomics Team and in charge of the EGA, is co-leading the GA4GH working group[6] on data security providing global best practice guidance. Bartha M. Knoppers, Co-Chair of the GA4GH Regulatory and Ethics Working Group[7], is a member of the Scientific Advisory Board of the BioMedBridges project led by ELIXIR, and will continue sharing her expertise as a member of the next cluster project, CORBEL[8], which is also coordinated by ELIXIR.

BBMRI-ERIC

BBMRI-ERIC[9] is the ESFRI research infrastructure for biobanking and biomolecular resources. It has already established an ELSI (ethical, legal and societal implications) Common Service framework[10], which includes a network of experts across BBMRI participating States, which will provide ELSI guidance to the scientific community. Although BBMRI is focussed on the biobanking community, the ELSI concerns for both BBMRI and ELIXIR are very similar with respect to privacy, consent, protection of personal data and the differences in national legislation. Rather than developing the necessary ethics frameworks and policies required by both infrastructure separately and in an effort to maximise infrastructure synergies, ELIXIR and BBMRI have agreed to explore developing them jointly, with expert input from representatives from both infrastructures. To this end, ELIXIR and BBMRI-ERIC are in the process of developing a Memorandum of Understanding with the intent of establishing a long-term relationship and knowledge exchange concerning legal and ethical requirements surrounding the use of sensitive data for research.

CORBEL cluster project of biomedical sciences research infrastructures

The CORBEL project, coordinated by ELIXIR, also addresses the critical issue of secure access to sensitive human research data by mapping secure access practices and streamlining applications across infrastructures. In CORBEL WP7 the BBMRI ELSI Common Services will - based on a thorough analysis of concrete use cases - be extended towards all BMS research infrastructures in a help desk format, ensuring that they have a coordinated approach to ethics and legal requirements as well as data security while meeting good practice.

GÉANT

GÉANT is the leading European collaboration on network and related infrastructure and services. Among other services, GÉANT develops, operates and supports services relating to authentication and identification, trust, and security and certification. In 2014, ELIXIR was one of the first signatories to the GÉANT code-of-conduct for personal data[11],[12] requiring Node services that manage personal data of registered users (user identities, affiliations, etc.) to comply with European data protection requirements and have specific training and to proportionate use policies in place.

Horizon 2020 grant n. 676559

In ELIXIR-EXCELERATE, WP4 Compute, Data access and exchange services also has the role to effectively interface with GÉANT on Europe-wide assurance processes and data protection mechanisms (Authentication and Authorisation for Research Collaboration project, AARC[13]).

5.1.4 Detailed implementation of Ethics Requirements

PROTECTION OF PERSONAL DATA

Requirement 1: Copies of ethical approvals for the collection of personal data by the competent University Data Protection Officer / National Data Protection authority must be submitted.

Not applicable - access to data held in ELIXIR resources is controlled at the resource, involving the responsible ethics or data access committees as required and on a case-by-case basis. No new sensitive data will be generated within EXCELERATE.

Requirement 2: The applicant must comment on the sources of the secondary / existing data; is this existing data publicly available? In case of data not publicly available, relevant authorisations must be provided.

See point 1.

Requirement 3: Regarding data access policy, data protection issues arise: Requirement for the Consortium: The ELIXIR-EXCELERATE proposal makes reference to the report "Assessing the projects on the ESFRI roadmap, A high level expert group report." This report included a Recommendation that drew attention to data access policy and ethical and data protection issues that should be taken into account in the ELIXIR project; this Recommendation should be applied to ELIXIR-EXCELERATE. It must be detailed to the Commission how the expert group report's Recommendation that an overarching Ethics Board be established has or will be put into place, and confirm its role regarding ELIXIR-EXCELERATE. The ethics governance structure and process for ELIXIR-EXCELERATE must be clearly laid out (and funded).

See detailed response.

Requirement 4: The Ethics Board must review and report to the Commission on all these matters and review all associated data protection risks in ELIXIR-EXCELERATE. It must be outlined and reported to the Commission how any risk is being assessed, avoided or mitigated. This report must consider the forthcoming changes in EU Data Protection law.

See detailed response and WP9 deliverable "Report on implementation of ELSI and policy consideration for controlled access data", due in month 36 of the project.

Requirement 5: Data Quality Assurance Governance: Page 9 of the proposal states that a final aim is to safeguard the overall quality and integrity of the data generated and stored. The independent expert Ethics Board must provide the Commission with a report on what quality control assurance processes and standards are being applied in ELIXIR-EXCELERATE to guarantee data quality and integrity (as this is at the centre of whether the ELIXIR infrastructure adds value to the ERA).

See detailed response.

Horizon 2020 grant n. 676559

Requirement 6: The status of the ELIXIR working group drafting ethics policy (that will seemingly be applicable for ELIXIR-EXCELERATE) must be reported to the Commission. It must be confirmed that the independent expert Ethics Board has or is reviewing and monitoring the ethics policy.

See detailed response and timeline.

NON-EU COUNTRIES

Requirement 7: It is stated that all common tools developed for research will be compatible with national and EU legislation and regulation and any ethical issue that may arise within the geographical remit of one Node will be resolved in accordance with the respective local legal entity. However, the applicant must confirm that the ethical standards and guidelines of Horizon2020 will be rigorously applied, regardless of the country in which the research is carried out.

In the review report, the reviewer specifically points out that the Third Countries involved in the project are Israel and Switzerland. Both countries are ELIXIR Member States that are included on the European Commission's list of countries offering adequate protection and having no further requirements ***[14]*** *with respect to the protection of personal data.*

Concerning countries in which research using ELIXIR resources is carried out, i.e. countries in which sensitive data from ELIXIR resources is being used for research: there are safeguards to ensure that all applicable ethical and legal requirements - including those of Horizon 2020 - will be followed. As detailed above, the ELIXIR Collaboration Agreement clearly outlines the responsibility of the Nodes concerning data protection, legal and ethics compliance, provision of training and capacity building. The European Genome-phenome Archive (EGA), having well-established procedures and users from all over the world, is an example for this. Through ELIXIR-EXCELERATE, necessary knowledge transfer and capacity building activities will be carried out to establish best practice in the provision and sharing of sensitive data across the Nodes, and users will be trained.

OTHER ETHICS ISSUES

Requirement 8: It is recommended that the training activities include matters raised in the ELIXIR / ELIXIR-EXCELERATE ethics policy.

See detailed response.

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[1] European Genome-phenome Archive (EGA) https://www.ebi.ac.uk/ega/about

[2] EGA FAQ: data submission https://www.ebi.ac.uk/ega/submission/FAQ#Can_I_submit_my_data_to_the_EGA

[3] Global Alliance for Genomics and Health www.genomicsandhealth.org

[4] http://genomicsandhealth.org/members

[5] http://genomicsandhealth.org/work-products-demonstration-projects/beacon-project-0

[6] https://genomicsandhealth.org/our-work/working-groups/security-working-group

[7] http://genomicsandhealth.org/working-groups/regulatory-and-ethics-working-group

[8] http://genomicsandhealth.org/working-groups/regulatory-and-ethics-working-group

[9] http://bbmri-eric.eu/

[10] http://bbmri-eric.eu/common-services

[11] GÉANT Data protection code of conduct
http://www.geant.net/uri/dataprotection-code-of-conduct/v1/Pages/default.aspx

[12] GÉANT Data protection Code of Conduct endorsement https://wiki.edugain.org/CoCoEndorsement

[13] AARC project https://aarc-project.eu/

[14] See Commission decision on the adequacy of the protection of personal data in third countries:
http://ec.europa.eu/justice/data-protection/document/international-transfers/adequacy/index_en.htm

6. Appendix 1: ELIXIR-EXCELERATE GDPR Risk Management Strategy

1. Background

ELIXIR's purpose is to help Europe's leading laboratories and data centers coordinate the collection, quality control and storage of biological information, and to ensure that these data are integrated and made accessible to all facets of the scientific community. ELIXIR's member states are committed to the provision of open-access data in the interests of advancing research in the life sciences.
The ELIXIR-EXCELERATE project proposal submitted to the call INFRADEV-3-2015 states that a final aim of the project is to safeguard the overall quality and integrity of the data generated and stored within Europe.
During the ethics review, the reviewers of the proposal asked "the independent expert Ethics Board to provide the Commission with a report reviewing the data protection risks in ELIXIR-EXCELERATE (Part B, Section 5.1.4 Detailed implementation of Ethics Requirements - Protection of Personal Data requirement 4).
Based on this comment and in light of the General Data Protection Regulation (GDPR)[2] released by the European Commission, which came into force on 25 May 2018, a specific deliverable D14.2 to review all data protection risks in ELIXIR was added to the project plan. This deliverable reports how data protection risk is being assessed, avoided or mitigated.

2. Scope

The main aim of this deliverable is to describe the risk management within ELIXIR concerning GDPR compliance.

The ELIXIR Nodes are responsible to implement internal GDPR compliance mechanisms and systems in order to ensure that Node-funded and Commissioned Services provided within ELIXIR meet the compliance requirements.

In order to support the institutes within the Nodes ensure that ELIXIR services are all GDPR compliant, ELIXIR will provide information and training to the Nodes regarding GDPR. An iterative assessment of ELIXIR services will be performed. It will include questions around GDPR compliance in the annual Collaboration Oversight Group process that each Node must go

[2] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG

Horizon 2020 grant n. 676559

through.

3. Definition of terms

The definitions below, some of them included in the ELIXIR Consortium Agreement[3], shall be considered for the purpose of this deliverable.

Agreement	The ELIXIR Collaboration Agreement including its annexes.
Commissioned Services	Technical and administrative services that generally fall under the responsibility of the ELIXIR Hub which are carried out by the ELIXIR Nodes and are funded through the ELIXIR Budget as outlined in ECA, Art. 8.6.
Commissioned Services Contract	The Commissioned Services Contract outlines the Commissioned Services for the duration of the Agreement as defined in ECA, Art. 8.6.
ECA	The ELIXIR Consortium Agreement.
ELIXIR Hub	The central organisation coordinating ELIXIR, acting through and under the supervision of the ELIXIR Board and the leadership of the ELIXIR Director. It shall provide administrative and technical services for ELIXIR as established under the ECA. It shall use EMBL's legal personality as mandated by the ELIXIR Consortium.
ELIXIR Programme	The five-year scientific programme adopted by the ELIXIR Board defining the scientific goals of ELIXIR and establishing the steps to achieve them, in accordance with the ECA, hereinafter referred to as "Programme".
EMBL	The European Molecular Biology Laboratory.
EMBL-EBI	The European Bioinformatics Institute, an outstation of the EMBL.
GDPR	The **General Data Protection Regulation** (**GDPR**) (EU) 2016/679 is a regulation in EU law on data protection and privacy for all individuals within the European Union.
Node	An ELIXIR Node is a collection of research institutes within a member country. ELIXIR Nodes run the resources and services that are part of ELIXIR.
Node-funded Services	Technical and administrative Services that fall under the administrative and financial responsibility of the Node and that become part of the Service Delivery Plan, which is part of Annex 1 of the Agreement; the term Node-funded Services has the same meaning as Additional Services as defined in ECA, Art. 8.5.2.
Scientific Advisory Board	A body established according to ECA, Art. 6.4, which is composed of independent scientists that oversee the quality of the ELIXIR activities as supervised by the ELIXIR Board and ELIXIR Director, and carried out by the ELIXIR Nodes and the ELIXIR Hub.
Services	All services labelled ELIXIR Services or ELIXIR Resources, Node-funded and Commissioned, provided by the ELIXIR Nodes and the ELIXIR Hub including associated activities and investment necessary to properly deliver the services, such as the provision of equipment, personnel and/or training.
Service Delivery Plan	The Service Delivery Plan (SDP) outlines the Node-funded Services for the duration of the Agreement.
Terms of Use	Terms of service, which the ELIXIR Node is responsible to establish, and which all Users have to abide by when using ELIXIR Services.
User	Any individual or group of individuals, in academia and industry, that has access to and uses ELIXIR Services.

[3] ELIXIR Consortium Agreement, https://www.elixir-europe.org/documents/elixir_consortium_agreement.

Horizon 2020 grant n. 676559

4. Considerations

4.1 ELIXIR Consortium Agreement:
The legal framework of ELIXIR is based on the ELIXIR Consortium Agreement (ECA), which has been concluded among the Member States and EMBL and officially entered into force on 12 January 2014. The ECA covers ELIXIR's mission, membership, obligations of the Members and the ELIXIR Hub, the governance structure of the ELIXIR Hub and relationship to the ELIXIR Nodes.

4.2 The General Data Protection Regulation (GDPR)[4].
After four years of preparation and debate the GDPR was **approved** by the EU Parliament on **14 April 2016**. The regulation came into effect on **25 May 2018.** Since then there is a risk that non compliant organisations face heavy fines. The EU General Data Protection Regulation (GDPR) replaces the Data Protection Directive 95/46/EC and was designed to harmonise data privacy laws across Europe, to protect and empower all EU citizens data privacy and to reshape the way organisations across the EU approach data privacy.

4.3 Data protection is related to the activities of EXCELERATE WP9:
WP9 concerns the long term archiving and deposition of sensitive human data consented for research use. The activities are centered on the EGA[5], a secure archive jointly developed by the EMBL-EBI and CRG (ELIXIR-ES). As of April 2018, the EGA manages data from over 1680 studies and have established processes for ethical review and data security with the owners of the respective cohorts. Importantly the use and re-use of data is not governed by the EGA and ELIXIR, it remains the full responsibility of the established study Data Access Committees. As part of the agreements governing data deposition and access no additional ethical governance is performed in this project, or the EGA, this sits exclusively with the owner of the cohorts who have established the participant consent. In conclusion, the hosts of the EGA act only as processor following data protection law where the focus of responsibility is on the secure data environment.
The EMBL, through Dr. Paul Flicek (Head of unit Variation at the EMBL-EBI, where EGA is a part), co-leads the global working group on Data Security within Global Alliance for Genomics and Health (GA4GH)[6] that have developed global recommendations for secure management and sharing of human genetic data. These principles are applied throughout ELIXIR-EXCELERATE where appropriate[7].
WP9 reports at month 36 the deliverables D9.4 "Report on the implementation of cloud access and secure user and data management" and D9.5 "Report on implementation of ELSI and policy consideration for controlled access data". Both deliverables can be considered as mitigation measures to prevent any risks on data protection.

4.4 ELIXIR-EXCELERATE WP4 and WP9 have collectively showcased how ELIXIR supports transfer of large volumes of confidential, electronic, human data, while maintaining appropriate access rights. It gives an overview of an improved support to researchers in accessing and processing sensitive data from European Genome-Phenome Archive (EGA). (Milestone M4.2 -

[4] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG
[5] https://ega-archive.org/
[6] http://genomicsandhealth.org/ourwork/working-groups/security-working-group
[7] https://www.ga4gh.org/docs/ga4ghtoolkit/data-security/Privacy-and-Security-Policy.pdf

Horizon 2020 grant n. 676559

ELIXIR Webinar: The transfer of large volumes of electronic, confidential, human data[8]).

4.5 Codes of Conduct

In 2014 ELIXIR endorsed the GÉANT Data Protection Code of Conduct[9], drawn up to meet the requirements of the EU Data Protection Directive in federated identity management, setting out behavioural rules for Service Providers.

In addition, the BBMRI is chairing an initiative to develop a GDPR Code of Conduct for Health Research[10]. The aim of this initiative is to make use of the instrument "Code of Conduct" offered in the GDPR to regulate a sector with sector specific rules. The aim is to harmonise and give guidance in a data protection compliant processing of personal, health-related data for research in the EU. This effort is co-funded by the ELIXIR coordinated project CORBEL (H2020 grant n. 654248).

5. ELIXIR GDPR risk assessment, mitigation and contingency plans

5.1 GDPR risk assessment within the ELIXIR landscape

The assessment of the risk on non-compliance to the GDPR within the ELIXIR landscape was performed in four steps.

5.1.1. Step 1: Set up of an action plan

A meeting was organised on Dec 11, 2017 at the ELIXIR Hub with members of the ELIXIR Human Genomics and Translational Data group, the ELIXIR Director, and the data protection experts of the University of Luxembourg representing the ELIXIR Luxembourg node (ELIXIR-LU). Meeting minutes are available[11].

The participants analysed and stratified the potential issues related to the implementation of the GDPR. For example, most countries are using consent as legal basis but UK prefers to avoid this; EMBL, ELIXIR-LU are actively preparing the implementation of GDPR, but the level of preparation of most ELIXIR Nodes was not clear.
The responsibility on GDPR compliance lies with the Institutes, the Nodes and the member states. The participants proposed the possible roles of ELIXIR regarding GDPR, as provider of guidance for local implementation of GDPR, raising awareness across the Nodes, and identify issues between countries and work with the various Data Protection Authorities.

Finally, the participants defined a plan of action in the short term to address the implementation of GDPR within the ELIXIR community. This plan included:

1- Provision of a Webinar on GDPR
2- Provision of a GDPR readiness survey (high-level) to assess the level of preparation across the ELIXIR nodes.
3- Provision of a workshop with the ELIXIR Nodes representatives

[8] https://www.elixir-europe.org/events/elixir-webinar-transfer-large-volume-data
[9] https://wiki.geant.org/display/eduGAIN/Data+Protection+Code+of+Conduct+Cookbook
[10] http://code-of-conduct-for-health-research.eu/
[11] https://docs.google.com/document/d/1WsmAgH_A_MZLXxCAWOOB9mKAeCJz7so3thHtGdY499o/edit

4- To use ongoing ELIXIR meetings, such as the 2018 All Hands meeting in Berlin, to facilitate further training.
5- To consider further meetings or workshops to address questions related to GDPR in the future.

5.1.2. Step 2: Webinar on GDPR considerations

An ELIXIR webinar, focussed on GDPR and its potential implications for the Nodes was given on Feb 7th 2018 by Regina Becker, a recognised expert in the field, who is affiliated to the Luxembourg Node. A video recording of the webinar is available via the ELIXIR website - link[12]. The webinar was well attended, with well over 153 attendees on the day and an additional 284 views of the recording (up to May 9th 2018). In addition, there were a number of questions arising all of which indicated that there was a requirement within ELIXIR to continue with the rest if the planned GDPR activities (survey and workshop).

5.1.3. Step 3: Survey to ELIXIR nodes

A GDPR survey, anticipated to provide insights into the degree of readiness for GDPR within the Nodes, and to gather information about GDPR related resources developed by the Nodes was designed by Regina Becker and the ELIXIR Hub. The survey[13] was sent via various communication channels to senior representatives of the Nodes on February 21 2018 and remained open for five weeks. The Node response rate was 100% (i.e. all Nodes submitted a response).

The result of the survey indicated that almost all Nodes have realised that the GDPR will have an impact on their data processing and measures to achieve compliance are underway. However, in March 2018, most Nodes were still in the process of analysing the situation and necessary requirements. A reason for this late implementation may be the fact that the national provisions are still not fully clear as the legislative process is still ongoing in most countries.

There is a clear interest in discussing concrete use cases at the ELIXIR level, in most cases on the implementation of a local EGA, but also on Beacon or on the processing activities around compute services and the administrative data and consequences. The ELIXIR Authorisation and Authentication Infrastructure (AAI) will play a central role in the compliance activities of the Nodes and would probably be welcomed also by a broader user community spanning beyond ELIXIR. More than 80% of the Nodes plan to use AAI and more than 75% of the Nodes would also be interested if more services to support GDPR compliance were offered by ELIXIR. Leading themes of interest are: help with proper registries, template documents, and tools for compliance assessment and risk assessment as well as training.

5.1.4. Step 4: Workshop

An ELIXIR-run GDPR Workshop was held on April 16th 2018, at the Fondation Universitaire in Brussels (Belgium). The Agenda/minutes[14] and a Summary[15] are available via these links. The workshop was led by Regina Becker, and included presentations and discussions from a variety of

[12] https://www.elixir-europe.org/events/webinar-gdpr
[13] https://www.surveymonkey.co.uk/r/GDPR-ELIXIR
[14] https://docs.google.com/document/d/1H5b17Bm9taCU1GgD791gc-ilLHGrO9Qc3k1656oSnbs/edit
[15] https://docs.google.com/document/d/1DLKSfNIoDlpTg6rnW2JWCnDEA2crztHciBCLSOSUUKU/edit

Horizon 2020 grant n. 676559

subject matter experts both from within ELIXIR and from partner organisations such as BBMRI. Topics discussed included: An overview of the GDPR, various tools available from the Nodes that may assist in ensuring GDPR compliance and the detailed review of a number of key use cases (Local EGA, Beacons and Compute Services). The Workshop was well attended (34 attendees, representing 16 of the Nodes plus representatives from the Hub and from BBMRI.

5.1.5 Step 5: Further Training

In order to maximise the opportunity for further training afforded by ELIXIR's other ongoing meetings, Regina Becker presented the GDPR aspects in various workshops at the 2018 ELIXIR All hands meeting in Berlin (Germany), June 4th to June 7th 2018. The slides can be found here[16].

Initial output and conclusions from Steps 1-5

The interest in all offered measures (webinar, survey, workshop) demonstrated the need and interest of the Nodes to have information and discussion on the ELIXIR level and the status of readiness as given in the survey suggests that an offer of guidance and tools will be appreciated while the ultimate choice of measure and implementation will still be with the Nodes.

An exchange between Nodes was also seen as useful to be able to learn more about the different national implementations of the GDPR. The many opening clauses for national provisions in particular on the derogations of data subjects' rights for scientific research and the possibility of the countries to have their own provisions for the processing of genetic and health data means knowledge about the legislation and its interpretation on the national level can become important for ELIXIR's transnational services.

The GDPR offers quite some flexibility or scope for interpretation. An aim for 100% exactness and the narrow interpretation of stakeholders like DG Justice of the European Commission, the Working Party 29 or also some legal consultancy can bring the research operations to a halt. To make use of the scope of interpretation, however, a discussion between the Nodes as well as other stakeholders like BBMRI and exchange on best practices can be helpful to find practical solutions and the relevant argumentation to comply with the accountability obligation. Therefore, the possibility to discuss use cases and potential solutions was welcomed as a good idea.

In the future, the initiative of BBMRI to develop an EU-wide Code of Conduct for Health Research in accordance with Art. 40 of the GDPR will help to provide guidance for the processing activities of ELIXIR. However, such a consensus process will take a long time and a working group or task forces for joint solution and tool development will be able to provide more short- and midterm help to the Nodes.

5.1.6. List of identified risks on data protection in ELIXIR

Subsequent to the Workshop, using the feedback obtained during that event and using the information received from the survey, Regina Becker and the Hub team established the primary risks (R1, R2, etc) for ELIXIR Nodes associated with GDPR:

[16] https://elixir-luxembourg.org/gdpr-activities

Horizon 2020 grant n. 676559

R1 - Nodes (and participating institutes) are not sufficiently or adequately prepared.

R2 - Nodes (and participating institutes) do not have the resources to implement the necessary steps to ensure GDPR compliance.

R3 - Nodes (and participating institutes) do not have the tools to implement the necessary steps to ensure GDPR compliance.

R4 - Individual Node Services, included within the overall set of "ELIXIR Services" are not GDPR compliant.

R5 - Transnational services (outside the EU and within the EU with different implementation of GDPR) may not be GDPR compliant or compliant with the respective national GDPR implementation.

5.2 GDPR risks mitigation

With the primary GDPR risks identified, Regina Becker and the Hub team, have established the mechanisms by which those risks can be best mitigated:
To address R1, R2, R3 and R5, it is proposed to run a second ELIXIR GDPR Workshop, with representation from the Nodes, to share best practices (M1), discuss key use cases (M2), establish training as required (M3), share tools that will help more efficiently ensure compliance (M4) and collect transnational requirements (M5).

To address R4, the annual Collaboration Oversight Group review process, established by ELIXIR as required by each Node Collaboration agreement, will be modified to specifically enquire as to whether all the Node Services, as defined in the Service Delivery Plan, are GDPR compliant (M6). In addition, regard will be given during this review process to the state of the Node GDPR roadmap (M7).

5.3. GDPR risk contingency

In the event that a Node service is reported to be not GDPR compliant, even after the activities described herein, the Hub will retain the option to de-register the Service(s) from ELIXIR by removal from the Node Service Delivery Plan at the time of the next COG. The determination of the Service's GDPR compliance will be based on the Node's own assessment (i.e. not by the ELIXIR-Hub) as part of the annual Node COG review process as described above.

6. GDPR risk management processes and implementation plan

Iterative assessment of ELIXIR services for GDPR compliance.

Initial Plan:

- June 6, 2018: HoNs agree plan for further ELIXIR work on GDPR
- June 11, 2018: Deliverable to be sent to the SAB for endorsement
- July 31, 2018: Deliverable deadline for submission to the EC
- November 2018: second ELIXIR GDPR Workshop

Horizon 2020 grant n. 676559

- Post November 2018: HoNs will consider again the need for ongoing collaboration and knowledge sharing in the domain of GDPR

The coordination of this plan will be led by the ELIXIR Hub, with input and implementation by the Nodes, concluded, if appropriate, by review at the ELIXIR SAB.

This implementation plan is integrated within the risk management process already in place at the ELIXIR Hub to track all risks in ELIXIR. The risks identified in this deliverable have been reviewed by the ELIXIR SAB and will be incorporated into the ELIXIR Risk Registry[17].

These are also considered while preparing the ELIXIR Work Programme 2019-23.

[17] https://tinyurl.com/ELIXIR-RR

Horizon 2020 grant n. 676559