ADOPT BBMRI-ERIC
GRANT AGREEMENT NO. 676550

DELIVERABLE REPORT

Deliverable no	D5.4
Deliverable Title	Towards a Certification According to Relevant Standards
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Responsible Partner	BBMRI-ERIC (Common Service ELSI)
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Executive Summary

Given that the proper consideration of ethical, legal and social issues (ELSI) is key to any biobanking activity, BBMRI-ERIC provides services and tools specifically for researchers who need assistance with ELSI matters or have specific ELSI questions. Via the ELSI Helpdesk and ELSI Knowledge Base, BBMRI-ERIC supports the biobanking community by providing personalised support to researchers relating to ELSI concerns, such as data protection, informed consent in health research, amongst other topics, which ultimately serve to facilitate compliance with regulatory requirements and best practice standards.

The ADOPT BBMRI-ERIC funding guarantees funding for a dedicated position of ELSI Helpdesk Coordinator, workshops and activities relating to the ELSI Helpdesk. This report highlights key activities relating to processes developed and put into place regarding operation of the service, leading towards certified procedures.

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Document log

Issue	Date (yyyy-mm-dd)	Comment	Author/partner
D5.4	2018-06-08	Report M30	Jasjote Grewal/Michaela Th. Mayrhofer

Background

Identifying and navigating through applicable ethical and legal requirements when conducting biomedical research can be quite a practical challenge for researchers, especially when a research project encompasses participants from more than two countries and jurisdictions. Given that research is largely a transnational endeavor, multiple legal and ethical questions arise in daily practice, therefore requiring sound and practical solutions. Some questions are quite regular matters (e.g., seeking approval by the competent review ethics committee), whereas others are challenging by the nature of the research question and/or due to the transnational dimension and require special ethical and legal guidance. Furthermore, questions may arise during the proposal writing process, consortium agreement negotiations or while addressing a specific research question. Whereas academic expertise in ethical and legal issues is quite comprehensive and publicly available, practical guidance, especially for transnational research, is not.

The ELSI Helpdesk and ELSI Knowledge Base was therefore conceptualised in order to support the Life Sciences' community and biobank users with the provision of expertise relating to ELSI questions.

Approaches (Methods)

Phases leading towards certification of the ELSI Helpdesk & Knowledge Base

Operating the basis of the BBMRI-ERIC federated model, the Common Service ELSI consists of a network of ethical and legal experts from academia and practice across Europe, based in the BBMRI-ERIC Member and Observer Countries. ELSI experts are at the core of the ELSI Helpdesk and ELSI Knowledge Base, organised into dedicated Task Forces which work on particular ELSI subject matters.

Phase I – 2014: Identifying Tools for Ethical and Legal Guidance

In June 2014, different online tools and services intended to aid sample and data providers in navigating legal and ethical requirements were discussed during a one-day workshop in Berlin.

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It brought together and the BioMedBridges *Legal Assessment Tool* (LAT)[1], the BBMRI *legal WIKI*[2], the *human Sample Exchange Regulation Navigator* (hSERN)[3], the P3G *International Policy interoperability and data Access Clearinghouse* (IPAC)[4]. It was concluded "that mature tools to support sharing of sensitive samples and data are still lacking."[5]

Phase II – 2015: Assessing Tools for Ethical and Legal Guidance

Following the 2014 Workshop, developers and contributing experts of the three tools legal WIKI, LAT and hSERN met in November 2015 to assess the main challenges encountered. The following three challenges were identified:

i. Given that each tool was developed in the context of a particular research project, they were difficult to after the project ended;
ii. The tools shared an unspecified user profile and a lack of user-friendliness; and
iii. The tools only provided generic information and could not provide customized advice, which was often needed.

As a result, it was clear has become apparent that a single, more user-friendly, and sustainable tool was needed, and that the provision of customized advice to researchers should not be ignored.

An opportunity for identifying users and user perspectives occurred in the context of the H2020 project CORBEL[6], which brings together eleven biological and medical research infrastructures (BMS RIs) that aim to create a platform for harmonized user access to biological and medical technologies, biological samples and data services. Therefore, the CORBEL project provided the ideal platform for the exploratory user survey, *Where do you get support with ELSI questions around data and biosamples?* The results of the survey reiterated the need for a tool that is easily accessible, with content that is comprehensive to researchers, as well as being helpful to their specific needs, suggesting that need for a resource that allows multi-level, comprehensive user support for investigators for their daily research practice.

Phase III - 2016: Launching the test phase of the ELSI Helpdesk and ELSI Playground

In 2016, first steps were taken to create a single, more user-friendly, and sustainable tool, by combining the aforementioned tools into one via the 'ELSI Playground'. It became apparent

[1] BMB Legal & Ethical Assessment Tool—BioMedBridges [Internet]. Available from: https://www.biomedbridges.eu/supporting-researchers-sharing-sensitive-data-identifying-requirements Accessed February 27, 2015
[2] the BBMRI legal Wiki Available from: http://www.bbmri-wp4.eu/wiki/index.php/Main_Page Accessed August 8, 2017
[3] hSERN·Human Sample Exchange Regulation Navigator [Internet]. Available from: http://www.hsern.eu/ Accessed February27, 2015
[4] IPAC | Public Population Project in Genomics and Society [Internet]. Available from: http://p3g.org/ipac Accessed February 27, 2015
[5] Sariyar, M., et al. (2015). "Sharing and Reuse of Sensitive Data and Samples: Supporting Researchers in Identifying Ethical and Legal Requirements." Biopreserv Biobank **13**(4): 263-270.
[6] www.corbel-project.eu/

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however that an entire reconceptualization towards a single, user-friendly ELSI support was required.

The test phase of the ELSI Helpdesk 1.0 also became available from 2016 in order to provide practical and general information/guidance to researchers on ELSI issues, as well as customized advice on a case-by-case basis via a Request Tracking System, which monitors incoming enquiries.

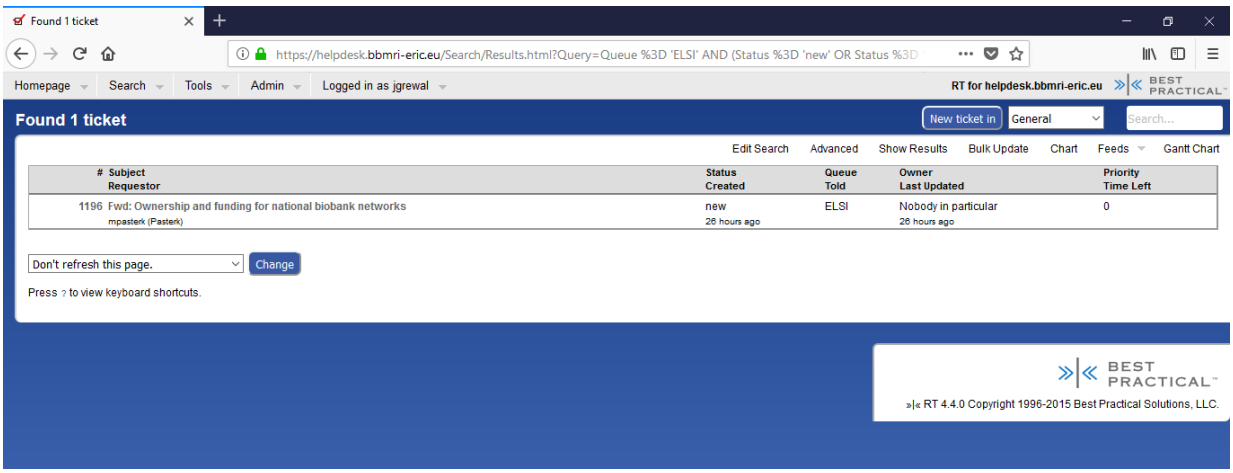

Image 1: Screen shot of incoming requests on Request Tracking System

Additionally, a vacancy was opened for a dedicated ELSI Helpdesk Coordinator, a part-time position, to coordinate the federated BBMRI-ERIC Common Service ELSI Helpdesk (see Appendix). The position is entirely funded by the BBMRI-ERIC core budget.

Phase IV – 2017: The ELSI Helpdesk & ELSI Knowledge Base

The previous meetings and workshops' results lead to the concept paper "Mind the Gap: From Tool to Knowledge Base".

Abstract: With the ELSI Knowledge Base, we introduce a key element of the BBMRI-ERIC Common Service ELSI, which provides ethical, legal and societal support for researchers and biobankers involved in transnational research. In contrast to the customized support provided by the ELSI Helpdesk, the ELSI Knowledge Base will be available to the user on a self-serve basis. The information that is made available through a knowledge base comes from multiple sources, usually from several expert contributors who are well versed on the subject matter. The knowledge base shall provide users with a first orientation on the subject matter, as well as allow them to explore more detailed information if desired in a self-serving manner. It is crucial that the information and knowledge provided is shared in a manner that is user-friendly. Long lists of links, legalistic language and multiple clicks have to be avoided wherever possible. The long-term sustainability and accuracy of a knowledge base needs to be ensured by placing its expert curation and technical maintenance under the responsibility of an organization rather than a research consortium. In its core, it builds on a scenario-based approach using a non-legalistic language. Additionally, the knowledge base connects to FAQs, promotes contract and informed consent templates, how-to-guides, best-practice models and scripts. The ELSI Knowledge Base is a key element of the BBMRI-ERIC Common Service ELSI, which currently serves biobanks but shall be enlarged to serve the BMS community. In contrast to the ELSI Helpdesk, which provides customized support, the ELSI Knowledge Base is available to the user on a self-serve basis. The conceptualization of the ELSI Knowledge Base builds on assessments of several ethical, legal and societal guidance tools that favor a single sustainable knowledge base for closing the knowledge gap by providing

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practical, hands-on guidance for researchers. Ultimately, the ELSI Knowledge Base aims at promoting practical know-how and skills for conducting responsible research.

The manuscript was accepted by Biobanking and Biopreservation and will expectantly be published in August 2018.[7]

In August 2017, the ELSI Helpdesk Coordinator commenced employment to coordinate incoming enquiries from the ELSI Helpdesk, as well as assess ongoing activities with a view to develop and streamlines internal processes. At the end of 2017, the ELSI Helpdesk Review Board was established, consisting of ELSI experts who would meet on a monthly basis to discuss incoming Helpdesk enquiries and offer their expertise in order to effectively respond to questions.

Shortly following the hiring of the ELSI Helpdesk Coordinator, the ELSI Helpdesk and Tools Task Forces were also combined in a single Task Force in September 2017, called the **ELSI Helpdesk & Knowledge Base**, with the Helpdesk providing custom-based support to researchers, and the Knowledge Base promoting outcomes from activities conducted by other Task Forces. The conceptualization of the ELSI Helpdesk and Knowledge Base on the website was commenced.

Phase V 2018 – Developing Internal Processes.

In January 2018, an ELSI Helpdesk meeting took place to discuss the status of the ELSI Helpdesk and Knowledge Base, as well to agree upon next steps. An internal working report was prepared to give an overview of activities undertaken, identify challenges as well as ways forward.The number and type of incoming requests was outlined in order to assess the nature of enquiries (see Annex for ELSI Helpdesk Figures as of June 2018). Having identified key ELSI areas based from incoming requests, an outcome of the meeting was to focus on ELSI education and training in the form of webinars, with particular focus on the GDPR. Indeed, the first webinar took place in April 2018 on the GDPR, with the second taking place in June 2018 on the topic of anonymization and pseudonymization[8].

The ELSI Helpdesk Review Board commenced monthly telephone conferences as of January 2018 to discuss any incoming enquiries or any other Helpdesk-related matters. An internal operating procedure was also drafted and refined, with input from the ELSI Helpdesk Review Board to streamline processes (see Annex). A confidentiality agreement has also been developed for any individuals handling ELSI Helpdesk requests (see Annex). Furthermore, given that a minimum level of information is required in order to effectively respond to enquiries, a draft webmask was developed to ensure that the requestor provides the context, as well as relevant information when submitting their enquiry (see Annex). It was decided that a generic webmask would be appropriate for all BBMRI-ERIC enquiries given that users don't

[7] Mayrhofer, MT, Schlünder I: From Tool to Knowledge Base. In: Biobanking and Biopreservation (peer reviewed, accepted for publication, forthcoming).
[8]BBMRI-ERIC ELSI Webinars [Internet]. Available from: http://www.bbmri-eric.eu/elsi-library/ Accessed June 06 2018

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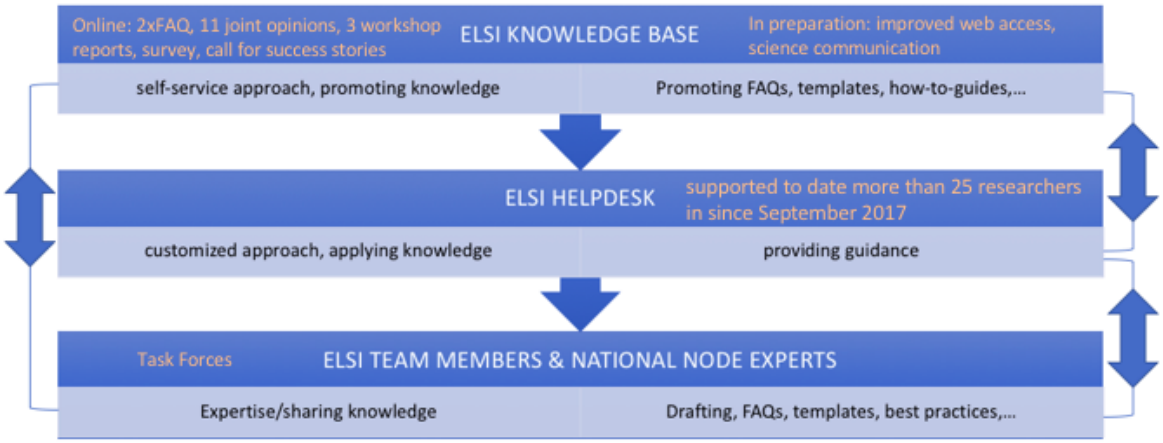
Meetings

Meetings concerning the ELSI Helpdesk Desk & Knowledge Base have taken place consistently at BBMRI activities, seminars and conferences, such as the European Biobank Week 2016 in Vienna, the Global Biobank Week 2017 in Stockholm as well as seminars. Wherever feasible, travel funds from ADOPT BBMRI-ERIC were used to ensure participation.

Results

The relationship between the ELSI Knowledge Base, Helpdesk and Experts has been developed and agreed upon, as below.

Figure 1: Relationship between the ELSI Knowledge Base, Helpdesk and Experts (Task Forces)



The Knowledge Base is a store of information or data that is available to the user on a self-serve basis, with information coming from multiple sources, usually from several expert contributors. The Knowledge Base provides users with a first orientation on the subject matter in a self-serving manner. The Helpdesk takes a customized approach by assisting users on a case-by-case basis, offering more tailored support.

It was agreed that the ELSI Helpdesk Review Board will meet once a month to discuss incoming ELSI enquiries, as well as to offer their expertise related to the ELSI Helpdesk. It was also agreed that internal operating procedures would be developed, setting the base to lead towards certification.

It was agreed that the focus should be on building content for the ELSI Knowledge Base, as well as focus on education and training activities, in the first instance through webinars.

It was agreed that the role for an ELSI Helpdesk Coordinator would be created and advertised. (see Annex).

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It was agreed (and thereafter executed) that the Director General of BBMRI-ERIC and the Chief Policy officer would select the ELSI Helpdesk Coordinator. Ultimately, this was Jasjote Grewal (CV, see Annex).

Discussion and Conclusions

Based on the experiences and assessment of ELSI guidance tools, a reconceptualization put user needs at the centre and promote the establishment of the ELSI Helpdesk and ELSI Knowledge Base. It is crucial that the information and knowledge provided is user-friendly. The long-term sustainability and accuracy of the Helpdesk and Knowledge Base needs to be ensured by placing its expert curation and technical maintenance.

Via the ELSI Helpdesk and Knowledge Base, guidance will be provided on key issues related to biobanking, such as **data protection, informed consent in health research, health research priorities**, and other **ethical legal and societal issues (ELSI)**, with the Knowledge Base comprising of FAQs, promotes contract and informed consent templates, as well as further information.

Setting up appropriate workflows, tracking systems aims a smooth operation and should, in the long run, allow for a certification of the service according to relevant ISO standards.

Next Steps

Short Term:

- Finalise ELSI Helpdesk Operating Procedures

Mid Term:

- Develop ELSI Webinar series for 2018-2019
- Develop BBMRI-ERIC CS ELSI Communication Strategy
- Focus on marketing and promotion of the ELSI Helpdesk and Knowledge Base at European level

Long Term:

- Identify themes coming from ELSI Helpdesk enquiries, and continue to develop content for the ELSI Knowledge Base

References

BBMRI-ERIC ELSI Webinars [Internet]. Available from: http://www.bbmri-eric.eu/elsi-library/ Accessed June 06 2018

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BMB Legal & Ethical Assessment Tool—BioMedBridges [Internet]. Available from: https://www.biomedbridges.eu/supporting-researchers-sharing-sensitive-data-identifying-requirements Accessed February 27, 2015

BBMRI legal Wiki Available from: http://www.bbmri-wp4.eu/wiki/index.php/Main_Page Accessed August 8, 2017

hSERN·Human Sample Exchange Regulation Navigator [Internet]. Available from: http://www.hsern.eu/ Accessed February27, 2015

IPAC | Public Population Project in Genomics and Society [Internet]. Available from: http://p3g.org/ipac Accessed February 27, 2015

Mayrhofer, MT, Schlünder I: From Tool to Knowledge Base. In: Biobanking and Biopreservation (peer reviewed, accepted for publication, forthcoming).

Sariyar, M., et al. (2015). "Sharing and Reuse of Sensitive Data and Samples: Supporting Researchers in Identifying Ethical and Legal Requirements." Biopreserv Biobank **13**(4): 263-270.

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Appendix

November 2016 – Vacancy Note for ELSI Helpdesk Coordinator

VACANCY NOTE

Job title: BBMRI-ERIC ELSI Helpdesk Coordinator

Job Location: The Central Executive Management Office of BBMRI-ERIC in Graz, Austria

Duration: 2 years (24 months)

Job Purpose: The **BBMRI-ERIC ELSI Helpdesk Coordinator** is coordinating the Common Service ELSI Helpdesk and will be supervised by the Director of the BBMRI-ERIC Common Service ELSI.

Short description of BBMRI-ERIC:

The pan-European Biobanking and BioMolecular resources Research Infrastructure is a distributed bio-medical and life science infrastructure for sustainable storage and dissemination of biobanked samples and associated data in Europe. On 3 December 2013, BBMRI was officially awarded the Community legal framework for a European Research Infrastructure Consortium (ERIC). This specific legal form is designed to facilitate the joint establishment and operation of research infrastructures of European interest. BBMRI-ERIC will provide access to the collections of partner biobanks and biomolecular resources, their expertise and services on a non-economic basis.

BBMRI-ERIC is an ***inclusive, equal-opportunity employer*** *offering attractive conditions and benefits appropriate to an international research organization. Further information on the aims, mission, governance, statutes of BBMRI-ERIC can be found at www.bbmri-eric.eu.*

Key Responsibilities and Accountabilities of the Role

The Common Service ELSI is setting up a federated ELSI Helpdesk for the member states of BBMRI-ERIC. It's going to be a federated model where ELSI experts from the National Nodes and/or Common Service ELSI will provide customized assistance to scientists when setting up and conducting biobank-related research projects. Requests will be forwarded to the ELSI Helpdesk Coordinator through BBMRI-ERIC's request tracking system. Depending on the complexity of the questions, the coordinator will answer directly and/or organize the response with the support of one or several National Node/Common Service ELSI experts. Questions requiring input from national ethical and legal regulatory frameworks will be directed to the National Nodes. The Coordinator of the BBMRI-ERIC ELSI Helpdesk is thus responsible for coordinating the federated BBMRI-ERIC Common Service ELSI Helpdesk. He/she organises an ELSI team with representatives from the National Nodes and/or the Common Service ELSI including different kinds of expertise (e.g., law, ethics, and societal issues). He/she works under supervision of the Director of the Common Service ELSI. He/she manages and edits the information on the BBMRI-ERIC website as regards to the ELSI Helpdesk and its tools.

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Requirements of the Role

The BBMRI-ERIC ELSI Helpdesk Coordinator is expected to have experience regarding the specific ethical, legal and societal issues of European biobanks, especially knowledge about both European and national laws. Hence, a legal background is considered a plus. Interpersonal skills, the ability to liaise with ELSI colleagues and stakeholders in a distributed, international, interdisciplinary environment are essential requirements. As English is the common working language of BBMRI-ERIC applicants must be fluent in English. The jobholder will be asked from time to time to work outside normal working hours and occasionally to undertake national and/or international travel. We are seeking for highly motivated people with a minimum of a master's degree and preferably with a PhD, (especially in law).

Employment Terms and Conditions

The BBMRI-ERIC ELSI Helpdesk Coordinator will be directly employed by BBMRI-ERIC in its Central Executive Management Office in Graz, Austria. For jobholders coming from BBMRI-ERIC member states a secondment against reimbursement is possible. Details are subject to negotiation. The employment follows the Austrian employment law. BBMRI-ERIC offers fringe benefits like complementary health insurance, and a private pension scheme, relocation and travel grant as well as local support for housing. It is a part-time position (50%).

Salary

According to European/international standards for similar role and responsibilities and requirements of this function (2.400.-€ as minimum monthly gross salary; final salary dependent on terms of qualification and experience).

Application Procedure

For applications to be valid, candidates must submit:

- A Curriculum Vitae [CV] with photo;
- A letter of motivation;
- Supporting documents (for example, certified copies of degrees, references, etc.).

In case of any questions, please contact:
Michaela Th. Mayrhofer PhD, Senior Project Manager/Chief Policy Officer Common Service ELSI, michaela.th.mayrhofer@bbmri-eric.eu, +43 664 88 72 18 74 (not available between the 23rd of December – 8th of January 2017)

Please send the required documents via e-mail to the following address:
Markus Pasterk, Administrative Director, admin.dir@bbmri-eric.eu

Deadline for application is the 13st of February 2017; anticipated start of work 1st of March 2017.

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June 2018 – ELSI Helpdesk Requests: Figures

ELSI HELPDESK REQUESTS: FIGURES

(Updated as of June 2018)

ELSI Helpdesk Requests to date: #18
Spam: +30

	Request	Opened / Re-opened	Requestor	Route	Date of first Action	Date of last Action	Resolved	Comments
1.	Requesting information for a Master thesis	26.01.17	Student	Direct	05.03.17	17.03.17	17.03.17	Concerned single European Coding System for human tissues and cells (following the 2015/565 Directive of the European Commission) This was forwarded again from BBMRI-ERIC HQ on 07.03.17, and resolved on 17.03.17
2.	Ethics Check - the UM Cure 2020	15.02.17	Project Manager	Direct	17.02.17	27.10.17	27.10.17	This was ongoing correspondence and communication also took place privately
3.	Updating the GDPR FAQ	01.03.17	CS ELSI Expert	Direct	03.03.17	03.03.17	05.03.17	Looks like a test. Unable to see the entire correspondence
4.	Translation of GDPR FAQ	10.03.17 19.12.17	CS ELSI Member	FW from BBMRI-ERIC HQ	10.03.17 19.12.17	14.03.17 19.12.17	17.03.17 18.01.17	

5.	Registration of biological samples in a biobank	23.03.17	Researcher	FW from BBMRI-ERIC HQ	24.03.17	24.03.17	24.03.17	SS requested more info. No response
6.	Retrospective data collection	13.04.17	Researcher	Direct	14.04.17	29.04.17	29.04.17	Concerned Greek legislation
7.	Access policy and quality training	02.08.17	Biobanker	Direct	13.10.17	08.01.17	08.01.17	Bulk of this resolved in November 2017. Access policy was sent in January 2018.
8.	Request for BBMRI-ERIC informed consent form for secondary use data	14.08.17	External ELSI Researcher	Direct	02.11.17	02.11.17	04.12.17	Started to enquire about this request internally from 16.10.17.
9.	Evaluation of Swiss consent form	17.10.17	Contributing CS ELSI expert	FW from CS ELSI Member	17.10.17	20.11.17	08.01.17	
10.	Further processing of data	20.10.17	NHS	FW from BBMRI-ERIC HQ	01.12.17	01.12.17	05.02.18	
11.	Data Protection and Directories/Locators	04.12.17	NN Director	Direct	06.12.17	11.01.17	23.01.17	Put expert and requestor in touch in December 2017. Was informed it has been resolved.
12.	ELSI Workshop and Training	22.12.17	Biosampling Director	Direct	18.01.18	29.01.18	05.02.18	

13.	Information specifically for MTM	10.01.17	Project Consultant	Direct	18.01.18	18.01.18	18.01.18	
14.	Project support	31.01.17		Direct	05.02.18		01.06.18	To be closed – there has been no response from the requestor.
15.	Post project governance of a non-EU biobank	02.02.18	External Ethics Advisor	Direct	05.02.18	12.03.18	01.06.18	Request closed on the basis that there was no response from the requestor. Tickets on the same request were merged.
16.	Ethics Check - MICROPRED	05.12.2017	Project Manager	To Chief Policy Officer	07.03.2018	06.04.2018	06.04.2018	The request was linked to a project proposal. BBMRI-ERIC is partner. It was communicated and handled by MTM, who drafted and completed with input by the project manager. Whilst the request was submitted well in advance, responses could only be delivered a 1 week - 2 days prior the submission deadline given that the proposal was not mature enough earlier.
17.	Ethics Check - EUCAN-Connect	14.03.2018	Project manager and coordinator	To Chief Policy Officer	05.04.2018	05.04.2018	05.04.2018	The request was linked to a project proposal. BBMRI-ERIC is partner. It was communicated and handled by MTM, who drafted and completed Section 5.1 and ELSI self-assessment questionnaire along with the project manager and coordinator. Whilst the request was submitted well in advance, responses could only be delivered a 1 week - 2 days prior the submission deadline given that the proposal was not mature enough earlier.
18.	Ethics Check - CINECA	13.04.2018	Project Coordinator	To Chief Policy Officer	13.04.2018	17.04.2018	17.04.2018	The request was linked to a project proposal. BBMRI-ERIC is partner. It was communicated and handled by MTM, who checked Section 5.1 and ELSI self-assessment questionnaire as completed by the coordinator and advised on adaptions. Whilst the

								request was submitted well in advance, responses could only be delivered a 1 week - 2 days prior the submission deadline given that the proposal was not mature enough earlier.

To Note: The ELSI Helpdesk receives many general enquiries that are not related to ELSI issues. As a result, these enquiries have been excluded from the current figures.

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June 2018 – The ELSI Helpdesk: Operating Procedures

THE ELSI HELPDESK – OPERATING PROCEDURES

Aim:
The aim of the current document is to set out the operating procedures relating to the BBMRI-ERIC ELSI Helpdesk. The procedures described below outline the framework within which ELSI Helpdesk operates with regards to receiving, registering, responding to and tracking any incoming requests to the ELSI Helpdesk. This document is intended for internal use within the BBMRI-ERIC.

Activities:
The ELSI Helpdesk is a personalised support service assisting researchers who have ethical, legal and societal (ELSI) questions in the context of a research project. The ELSI Helpdesk provides guidance in order to promote compliance with regulatory requirements and best practice principles.

Operation:

Framework
The ELSI Helpdesk comprises of 3 primary contact points, whose role and function are set out below:

Contact Points	Function
ELSI Helpdesk Coordinator	The ELSI Helpdesk Coordinator is the primary contact point for receiving enquiries, and liaising with the requestor, as well as with the ELSI Helpdesk Review Board and any external experts. The ELSI Helpdesk Coordinator communicates the final response to the requestor.
ELSI Helpdesk Review Board	The ELSI Helpdesk Review Board is comprised of ELSI experts who convene on a monthly basis to review incoming requests. Members offer their expertise to effectively respond to requests.
External Experts	External experts comprise of legal, ethical and societal experts who may be consulted on an ad hoc basis in the event their specific expertise is sought for an incoming request.

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Tasks

	ELSI Helpdesk Coordinator	ELSI Helpdesk Review Board	External Experts
Receives incoming requests	X		
Provides personalised receipt to the requestor	X		
Ensures all relevant information and documentation to request has been obtained	X		
Liaises with the requestor on an ongoing basis through the duration of the request			
Determines whether requests fall within the scope of the service	X in the first instance	X	
Prioritises requests in the event there are multiple requests	X	X	
Ascertains the time frame needed to respond to requests		X	
Provides expertise to incoming requests		X	X
Formulates the final response	X		
Verifies final responses before they are sent to requestors		X	X
Provides the final response to the requestor	X		
Provides the satisfaction survey to the requestor	X		

Service Request

i. A request to the ELSI Helpdesk is made in writing via the central email address elsi@helpdesk.bbmri-eric.eu, as found on the BBMRI-ERIC website. Registration of requests are centralised on the Request Tracker system.

ii. Any requests received to personal emails or over the telephone are processed in accordance with the present operating procedure and conditions, including with regards to registration and confidentiality. Any such requests received are forwarded by the recipient to the central email address above so that that they can be registered and tracked.

iii. In order to process requests sufficiently, the requestor is required to provide the following information:
    a. First name and surname, institutional and/or biobank affiliation, professional email address and/or telephone number;
    b. The subject and content matter of the request, which must be sufficiently clear as deemed by the ELSI Helpdesk Coordinator and Review Board. Information regarding the context of the request and explicit questions should be provided
    c. Whether the requestor has already consulted internal support services in their own institution. Should this be the case, details of the relevant service and/or contact point should be provided in order to facilitate communication. Should the answer be no, the ELSI Helpdesk Coordinator may invite the requestor to make an internal enquiry in the first instance; and
    d. Any important dates that are relevant when responding to the request, for example a deadline related to the submission of the project;
    e. Any other complementary information deemed relevant to the request.

iv. Any person authorised to handle requests, or who has access to consult or to edit the documents and information transmitted by the requestor, is bound by confidentiality.

<u>Receipt of Requests</u>

i. An automatic confirmation of receipt is delivered to the requestor once an email has been sent to the central ELSI Helpdesk email.

ii. Each request made online to the central email address is systematically communicated to the ELSI Helpdesk Coordinator. Requests sent to the central email benefit from automatic transmission to the ELSI Helpdesk Coordinator, thereby reducing processing time.

iii. In addition to the automatic confirmation of receipt, the ELSI Helpdesk Coordinator sends a personalised acknowledgement of receipt to the requestor, as well as seeking to make further clarifications if necessary.

<u>Follow Up of Requests</u>

i. The ELSI Helpdesk Coordinator may ask for additional information in the event that the requestor has provided incomplete, incorrect or incomprehensible information, as outlined in 'Service Request iii a-e'.

ii. Each request is assessed in the first instance by the ELSI Helpdesk Coordinator and in the second instance by the ELSI Helpdesk Review Board to determine if its content falls within the parameters of the service. In the event that the ELSI Helpdesk Coordinator is unsure whether the request falls within the scope of the service, the ELSI Helpdesk Review Board will be consulted. The criteria for accepting a request are presented on the ELSI Helpdesk webpage on the BBMRI-ERIC website (See: http://www.bbmri-eric.eu/BBMRI-ERIC/elsi-helpdesk/.Should the request be a national matter, the ELSI Helpdesk Coordinator and the Review Board will identify a contact point within the relevant National Node, and transfer the requestor to the identified contact point.

iii. The ELSI Helpdesk Coordinator and Review Board convene on a monthly basis via web conference or teleconference to discuss incoming requests as set out in the present document.

iv. In the event that there are multiple requests, the ELSI Helpdesk Coordinator and Review Board prioritise requests based on a first come, first serve basis, unless a particular request is deemed as especially urgent by the ELSI Helpdesk Review Board.

v. An initial estimate of the time needed to respond will be determined by the ELSI Helpdesk Coordinator and the Review Board once all relevant information regarding the request has been ascertained and provided by the requestor. In the event that the request can be processed directly by the ELSI Helpdesk Coordinator and Review Board, an internal deadline is established for responding to the requestor.

vi. The ELSI Helpdesk Coordinator and Review Board can contact experts inside or outside the BBMRI-ERIC network depending on the content of the request and the specific expertise involved. All parties are subject to an obligation of confidentiality concerning any information processed with regards to the ELSI Helpdesk

vii. When requests require consultation with external experts, the ELSI Helpdesk Coordinator and Review Board will identify the individuals with the requisite skills to process the request. The responsibility to contact the identified experts lies with the ELSI Helpdesk Coordinator, or if agreed, a member of the Review Board. The available expert(s) should agree to a deadline with the ELSI Helpdesk Coordinator or Review Board member to provide a response, which should be communicated to the ELSI Helpdesk Coordinator, or alternatively directly to the requestor with the ELSI Helpdesk Coordinator in cc.

Refusal of Requests

i. The ELSI Helpdesk Coordinator and Review Board also reserve the right to refuse a request. Such refusal may occur when the content matter regarding the request falls outside the area of expertise or when the number of claims exceeds the processing capacity of the Review Board. Refusals are recorded in the RT system.

Documentation

i. Any documents necessary for the analysis work of the request should be sent electronically to the Review Board and any external experts.

ii. Any document sent to the ELSI Helpdesk will be kept and used in a confidential manner and will not be disclosed without the consent of the requestor who provided it.

iii. The information contained in request and documents sent to the ELSI Helpdesk will not be reused for purposes other than those related to the response to the request or the management of the service and for generating further knowledge, which will be made available in the ELSI Knowledge Base.

Response to Requests

i. Following necessary consultation of a request, a single common response is formulated and sent by the ELSI Helpdesk Coordinator through the RT system in written form. Acknowledgement is to be given to the ELSI Helpdesk Review Board and any other external experts.

ii. Responses to requests will be provided in writing.

iii. Internal validation of outgoing responses will be conducted by the ELSI Helpdesk Coordinator, who will consult a member of the Review Board if necessary.

iv. Responses to requests will be sent via e-mail. In the event that the requestor does not respond to the final response, he / she will be contacted again to confirm receipt.

v. The requestor retains the right to disagree or challenge the final response provided by the ELSI Helpdesk Coordinator and Review Board on no more than one occassion. Any such challenge should be communicated to the ELSI Helpdesk Coordinator in writing within 14 working days after the final response, in which case a further consultation will take place with the ELSI Helpdesk Coordinator and the Review Board at the subsequent monthly meeting. In such an event, external opinion may be sought and the response will be validated by the Review Board once again prior to sending it to the requestor. External opinion sought and

verified by the ELSI Helpdesk Review Board will be deemed as the final and concluding response.

Satisfaction questionnaire

i. Following the submission of a response, a satisfaction questionnaire will be sent to the requestor.

ii. Only one questionnaire should be sent per request.

iii. The questionnaire is intended to be used in the system of management and improvement of the quality of the service. Once completed, it must be returned by email to the ELSI Helpdesk Coordinator. The questionnaires may be presented during management reviews.

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June 2018 – Confidentiality Agreement

PERSONAL CONFIDENTIALITY UNDERTAKING AND NON-CONFLICT OF INTEREST DECLARATION

I have been asked and I am willing to provide expertise as part of the BBMRI-ERIC ELSI Helpdesk service on a *pro bono* basis. In this task I will learn details of the incoming request, as well as any other associated information and documentation that are not publicly available. I understand that the incoming request and associated information are provided to me confidentially and only for the purpose of providing my expertise

I understand that the incoming request and associated information is confidential, except to the extent:

(i) It is or becomes generally available to the public other than through my unauthorised action,
(ii) I can show that I already knew the information before I received it in connection with the BBMRI ERIC ELSI Helpdesk and I had no prior obligation to keep it confidential,
(iii) a third party discloses the information to me on a non-confidential basis, and I have no knowledge or reason to expect that the information should be confidential,
(iv) I can show that I have arrived at or developed the same information independently without the use of, reference to or reliance on the incoming request and associated information, or
(v) There is a mandatory legal obligation for me to disclose the information.

I will not use any confidential information about the incoming request and associated information for any other purpose than to provide expertise and I will not discuss or otherwise disclose it to anyone without BBMRI-ERIC's prior written permission. I will destroy the confidential information when I no longer need it for providing expertise and even earlier if BBMRI-ERIC so requests, for example if the request is withdrawn. I may discuss the request with the other persons who have agreed to provide expertise on the request, whose names and contact details BBMRI-ERIC informs me of. I will submit my findings to BBMRI-ERIC and/or my fellow reviewers, as BBMRI-ERIC instructs, and not to any other party.

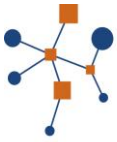
I also understand that the provision of my expertise must be independent and objective, free of conflicts of interest. A conflict of interest arises in cases of competing professional or personal interests, which could risk – or be seen to risk - impartial assessment of the research proposal. It may arise for example through participation in the proposed research or participation in competing research projects, participation of a relative or another close person in the proposed or competing research, financial interests dependent on the review or the performance or outcome of the research, or when my independence and objectivity could be questioned because of other similar reasons.
(Please discuss with BBMRI-ERIC before accepting to perform the review, if you are concerned about potential conflicts.)

I declare that I am not aware of having any conflicting interests in relation to reviewing the incoming request. I will inform BBMRI-ERIC without delay, if during the review my situation changes or I find out about a conflicting interest.

_____
Expert's Signature

_____
Typed Full Name *(first name / family name)*

____.____.20____



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Date *(dd/mm/yyyy)*

Received:

_____ ____.____.20____

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June 2018 – Draft Webmask for Incoming Enquiries

Helpdesk – Webmask for Enquiries

If you have an enquiry, our Helpdesk is on hand to help! Please fill out the below form and provide us with as much relevant information as possible. This will enable us to better respond to your question and get back to you sooner.

Full Name:*

Email Address:*

Tel Number:

Position & Institution:*

Country:*

The Nature of Your Enquiry*:

ELSI Helpdesk: ☐ Ethics Check: ☐ Quality Management: ☐

Rare Diseases: ☐ IT: ☐ Other: ☐

Your Enquiry:*

Will you be collaborating with non-EU partners? If so, please state which countries they are based in:

Any further information that may be relevant:

In the event we need to contact you, please state the best mode/time to reach you. We would be grateful if you could share your telephone number so that we process your request quicker.

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Please check the box if you would like to receive a copy of your enquiry: ☐

*Obligatory information

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CV: Jasjote Grewal

Curriculum Vitae
Name: Ms Jasjote GREWAL
Nationality: British
Home Address: [redacted]
Mobile: [redacted]
Email: [redacted]

EMPLOYMENT

06.2013 – 05.2017 **Research Fellow in Biolaw**
Centre for Ethics and Law in the Life Sciences
Leibniz Universitaet Hannover

- **REBIRTH** (From Regenerative Biology to Reconstructive Therapy), Funded by the German Excellence Initiative by the German Research Foundation (DFG) ○ Providing legal and ethical support to REBIRTH research groups working in the area of regenerative medicine.
- **EBiSC** (European Bank for induced Pluripotent Stem Cells), Funded by the Innovative Medicines Initiative (IMI) ○ Involvement in drafting of project proposal as well as project management ○ Contributed to drafting of consent documentation and development of governance framework
  - ○ Stakeholder engagement with European industrial and academic partners ○ Analysis of European and domestic legislation and policies in relation to induced pluripotent stem cell research and biobanking in Europe
- **EUCEllLEX** (Cell-based regenerative medicine: new challenges for EU legislation and governance), Funded under FP7
  - ○ Conducted research in relation to domestic laws regarding cells banks

04. – 06.2013 **Research Intern**
Department of Ethics and Social Determinants
World Health Organization, Geneva
○ Conducted research in relation to global health ethics, vaccines and biobanking

07.2012 **Research Intern**
HeLEX, Centre for Health, Law and Emerging Technologies
University of Oxford
○ Conducted research and drafted initial paper with regards to reporting of clinically significant findings to patients occurring within research consortia

09.2008 – 09.2010 **Trainee Solicitor**
Departments: Clinical Negligence; Health care advisory & Mental Health; Employment; and Commercial & Property
Hempsons Solicitors, Health and Social Care Law Firm, London
○ Conducted legal and policy research
○ Drafted legal documentation, reports, and communication ○ Provided legal advice to clients, and represented their needs and interests ○ Engaged with a broad spectrum of medical and legal professionals, as well as experts

EDUCATION & QUALIFICATIONS

10.17 - present **Masters in Art & Science**
Universitaet für angewandte Kunst Wien, Vienna

01.2012 – 07.2013	**Master in Ethics: Life, Norms and Society, Specialisation: Bioethics** Centre Européen d'Enseignement et de Recherche en Éthique, University of Strasbourg Graduated with Mention Très Bien (Equivalent to **Magna Cum Laude**), Awarded Major de la promotion Albert Camus for 1st Place **Master Thesis:** "Prenatal Whole Genome Sequencing – Too Much Information?"
10.2010	Admitted as a **Qualified Solicitor in England & Wales**
09.2007 – 06.2008	**Legal Practice Course** The College of Law, London Graduated with **Commendation** (Equivalent to **Cum Laude**)
09.2004 – 06.2007	**Bachelors in Law** (3 year LLB) University of Warwick, UK Graduated with **2.1 Honours** (Equivalent to **Cum Laude**)

PRESENTATIONS & INVITED WORKSHOPS

05.2016	**"Analysing the Effects of Personalised Medicine on the EU Regulatory Framework for Orphan Drug Research & Development" (Poster)** – Awarded Graduate Academy fixed travel grant of 400€ *European Conference on Orphan Drugs and Rare Diseases* 2016, Edinburgh, Scotland
06.2015	**ExPRESS 2015 Expert Patient & Researcher EURORDIS Summer School,** Barcelona, Spain - Awarded Graduate Academy fixed travel grant of 400€
05.2015	"**Happy Birthday! Re-contacting Young People in Paediatric Research. A Look at Case Studies from the EU"** – Awarded participation funding by P³G *3rd P³G International Paediatric Research Platform Think Tank Meeting*, Montreal, Canada
11.2014	**CHIP ME Early Stage Researchers' Network Workshop,** Oxford, UK - Awarded fixed grant of 1,260€ by COST (European Cooperation in Science and Technology) Action IS 1303
10.2014	**"Ethics and Law in Regenerative Medicine: Regulating Innovative Health Technologies"** *48th German Society for Biomedical Engineering*, Hannover, Germany
05.2014	"**Critical Review of MELD-based Organ Allocation from a Public Health and Human Rights Perspective**" *Law and Society Association Annual Meeting*, Minneapolis, USA
02.2013	**"Informed Consent In Paediatric Biobanking"** *REBIRTH Junior Research Workshop: Issues in Ethics, Law and Policy*, Hannover, Germany

ATTENDED CONFERENCES

09.2016	**Fighting Malaria with CRISPR/Cas9: Ethical Implications**, Vienna, Austria
02.2016	**Symposium of the Vienna Center for Rare and Undiagnosed Diseases**, Vienna, Austria
05.2015	"**A European Case Study on the Issue of Re-contact and Re-Consent in Paediatric Biobanking"** *3rd P³G International Paediatric Research Platform Think Tank Meeting* Montreal, Canada

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10.2014	**"Ethics and Law in Regenerative Medicine: Regulating Innovative Health Technologies"** *48th German Society for Biomedical Engineering* Hannover, Germany
05.2014	"**Critical Review of MELD-based Organ Allocation from a Public Health and Human Rights Perspective**" *Law and Society Association Annual Meeting* Minneapolis, USA
02.2013	**"Informed Consent In Paediatric Biobanking"** *The REBIRTH Junior Research Workshop: Current issues in Ethics, Law and Policy* Hannover, Germany

PUBLICATIONS

- Lohse, S. & **Grewal, J.** (2015): Review of Kaye, J. et al. "Governing Biobanks: Understanding the Interplay Between Law and Practice" *SCRIPTed - Journal of Law, Technology & Society* (in print)
- **Grewal, J**., & Hoppe, N. (2015): Don't Forget the Orphans. *European Journal of Health Law*. 22(2): 107-111.
- Kaye, J., Hurles, M., Griffin, H., **Grewal, J**., Bobrow, et al. (2014): Managing clinically significant findings in research: the UK10K example. *European Journal of Human Genetics*. 22: 1100-1104.

GRANTS AND FELLOWSHIPS

- ExPRESS Expert Patient & Researcher EURODRIS Summer School, Barcelona, June 2015
  - Fixed Grant of €400 awarded by the Graduate Academy, Leibniz Universitaet Hannover
- 3rd P^{3}G International Paediatric Research Platform Think Tank Meeting, Montreal, May 2015
  - Participation fully funded by P^{3}G – Public Population Project in Genomics and Society
- CHIP ME Early Stage Researchers' Network Workshop, Oxford, November 2014
  - Fixed Grant of €1,260 awarded by COST (European Cooperation in Science and Technology) Action IS 1303
- DFG Project – REBIRTH:
  - Research Fellow in Biolaw in Cluster Research Unit 10.7 (Ethical and Legal Dimensions)
- EU IMI Project – EBiSC:
  - Research Fellow in Biolaw in Work Package 4.1 (Ethics and Engagement: Responsible Research and Innovation)

PROFICIENCY IN LANGUAGES

- English: Native
- Punjabi: Fluent (spoken)
- French: Intermediate (B1/B2)
- German: Basic Intermediate (B1)