Biobanks-legal and ethical issues

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01 Basic knowledge

Ethics Principles

Protocols have both a scientific as well as a social impact.

A researcher should be aware of the research ethics key principles

- Autonomy
- Beneficence
- Non maleficence
- Justice

All have been operationalised in various soft laws that apply to biobank research

Raw principles can serve themselves as means to verify whether the research complies with the basic principles and could serve as a "***check and balance***" tool of the ethics committees which examine the approval of the studies.

International Instruments

- WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks.
- WMA Declaration of Helsinki.
- The International Ethical Guidelines for Biomedical Research Involving Human Subjects, Council for International Organizations of Medical Sciences (CIOMS).
- The Universal Declaration on the Human Genome and Human Rights, UNESCO.
- The International Declaration on Human Genetic Data, the Universal Declaration on Bioethics and Human Rights, UNESCO.
- OECD Guidelines for Human Biobanks and Genetic Research Databases.

International charter of Principles for sharing data and bio-specimen

ARTICLE 1

"*SHARING DATA AND BIOLOGICAL SAMPLES (BIO-RESOURCES) IS ESSENTIAL FOR ACCELERATING BIOMEDICAL RESEARCH PROJECTS THAT WILL PROVIDE BENEFITS TO CURRENT AND FUTURE PATIENTS…*".

1. GENERAL PRINCIPLES

RESPECT FOR PRIVACY AND AUTONOMY
RECIPROCITY : FEEDBACK OF RESULTS CHANENELLED TO INSTITUTIONS AND PATIENTS
FREEDOM OF SCIENTIFIC ENQUIRY
ATTRIBUTION
RESPECT FOR INTELLECTUAL PROPERTY

2. MTA/DTA TEMPLATE

European Journal of Human Genetics : EJHG; Leiden Vol. 24, Issue. 7, (Jul 2016)

REC

STEP 1

Checklist as a tool for highlighting the main issues that need to be addressed by:

- systematizing
- pulling out the essential ELSI aspects

Difference in legal systems regarding RECs.

In some cases (e.g. Sweden) there are RECs set by law while in other countries they are less "*independent*" and even criticized even as **cumbersome and inefficient.**

Recruiting phase

STEP 2

- Social awareness and community engagement as means to build trust between researchers and participants.
- Transparency of the research for the benefit of the participants and the community at large.
- Eligibility of the participants (age, sex, diagnosis, etc).
- The rights and interests of vulnerable groups should be addressed specifically.
- Due care should be given to address risks of group harm or stigma.

Transparency of the research procedures and methods as well as of the scientific goal is essential for the building of trust and the enhance of community engagement.

Studies have shown South African traditional communities believe that:
a. they will linger in this life if their sample remains in a fridge
b. their blood will be used for “muti” or witchcraft
c. donating samples may be offensive to their ancestors in some way

Consent Form

- Risks
- Benefits
- Data collected strictly necessary for research purpose
- Adequate measures in place
- Further processed by authorized consortium partners
- Voluntary participation
- Free withdraw of consent and of so data will be destroyed
- Right to access data, rectification, erasure, restriction of processing, right to lodge a complain to DPA
- DPO contact details
- Incidental findings/Research results/Society benefit

MTA

Donor's Privacy

Promote Security In International Transactions

Settlement Of Disputes

Termination Of Contract

Jurisdiction

Intellectual Property

Rights/Publications

Confidentiality

DAC

In addition to the role of RECs it is also a common practice in certain research infrastructures to seek an additional approval from a Data Access Committee (DAC).

DTA

Minimum guarantee that the data controllers will be provided in first place the legal means in order to protect their interests and rights against breaches.

Privacy concerns

In compliance with the main principles of moral philosophy it is important that throughout the conduct of the research study the person linked to the data will be never treated as a means for research and as "*pool of information*" but with *respect to their own privacy.*

How does GDPR affect Data Transfer?

GDPR Article 4 and 9
Prohibition by principle
Exceptions regarding processing for scientific research
Pseudonymisation
Consent as one of the legitimate grounds for processing sensitive personal data for health research purposes

A main new in the GDPR affecting research :
Consent can be given for one or more purposes and be modulable (e.g. scientific areas, part of research projects)
Broad consent practices allowed (with conditions)

GDPR

A sample even when pseudonymized still remains a personal data.

On a European Union law context, General Data Protection Regulation 679/2016 (GDPR) introduces a new concept in European data protection law - “pseudonymization”.

Not new in research!

Art.89(1) allows Member States to plan for derogations to a number of data subjects’ rights in the processing for archiving in the public interest, historical, scientific or statistical research in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes and such derogations are necessary for the fulfilment of those purposes.

GDPR

Art.89 and Art 17(3) targets the following individual rights:
Right to access
Right to rectification
Right to erasure
Right to restriction of processing
Right to data portability
Right to object

Data Protection Officer - DPO Section 4
Data Protection Impact Assessment - DPIA Article 35

GDPR

DPIA

When the process of data in particular using new technologies is likely to result in a high risk to the rights and freedoms of the individuals.
Process of genetic data is one of the cases.

7 themes have been tackled Biobanking

Consent
Data portability
DPO
Leading supervisory authority
DPIA
Certification
Notification of personal data breach

Example: Biobanking, ELSI and cancer

Biobanks as a tool...

5 P's of Medicine: The Predictive, Preventive, Personalized, Participatory, and Purpose-Driven Approach

Role of Biobanking :

Genetic data, associated lifestyle data, demographic data, epidemiological risk factors…

ELSI ISSUES: Genetic discrimination, privacy breach.

Screening as a tool...

1. A large majority of cancer deaths are premature and can be prevented through appropriate primary and secondary prevention measures.
2. Early diagnosis ⇨ Cancer screening programs
3. https://ec.europa.eu/health/sites/health/files/major_chronic_diseases/docs/2017_cancerscreening_2ndreportimplementation_en.pdf

COUNCIL RECOMMENDATION on cancer screening (2003/878/EC)
(preamble 10) "***Ethical, legal, social, medical, organizational and economic aspects have to be considered before decisions can be made on the implementation of cancer screening programs.***" (preamble 23) Fully informed participants.

Encourages cooperation between MSs in research and exchange of best practices developing new screening methods or improving existing ones.

Vaccinations as a tool...

Mandating the use of certain vaccines has raised ELSI dilemmas in healthcare systems.

a. In some culturally restricted societies, pre-marital sex is socially unacceptable and parents do not perceive their children as vulnerable to the infection. HPV vaccine is a no.

b. Lack of resources to cover vaccination opens gap of inequalities.

Ways forward...

Avoiding certain practices:

- ✓ Not parachuting research.(e.g. LMICs)
- ✓ Benefit sharing agreements.
- ✓ Respect of autonomy.
- ✓ Transparent IC procedures.

Research can be used to decrease social inequalities in cancer WHEN done in respect to autonomy and dignity of individuals.

WHO Report:

https://www.who.int/social_determinants/thecommission/en/

02

Practical issues

Material & data transfer agreements

What are MTA's & DTA's

- MTAs & DTA's (collectively called "Transfer Agreements") are bilateral agreements, between two organizations, legally binding for the signing Parties, the "Provider" and the "Recipient".
- Material can be bio-specimens but also other types of materials, such as chemical compounds.
- The aim is to set the frame for collaboration among research entities and PIs when data and material are being transferred and define the rights of the Provider and the Recipient.
- They are entered into force for countries within EU as well as with third countries. National legislation applies.
- Public and private entities.

Who needs MTA's & DTA's and why?

- Transfer Agreements provide a mechanism to the data and material owners, (Research Institutions- Universities-Companies-Researchers) in order to protect their interests and rights when transferring their data.
- These agreements promote, inter alia, secure data and material sharing within the research community and promote transparent research especially for materials that will be used in clinical or commercial development.
- BUT an agreement itself, could never protect or guarantee by itself that contractual parties act bona fides and respect the signed terms.
- National legislation will apply for enforcement.
- EU countries GDPR applies.

Negotiation & Execution of the Agreements

- All the terms for each transfer are agreed upon between the parties before actual transfer takes place.
- These agreements should NOT be negotiated by the researchers themselves.
- Responsible for negotiating the terms is the legal or technology transfer offices.
- Cooperation with Principal Investigator (PI) for describing data and material is essential.
- Both Parties and PIs must be fully aware of their contractual obligations.
- In case of breach contractual terms apply.(if transfer between countries international private law is applicable).

Important information included in Transfer Agreements

- Name and full address of the providing and recipient institution.
- Name, title, date of signature of the legal representative and of the P.I, who are signing the agreement.
- Practicalities regarding the purpose for which the data/material are being transferred.

- Detailed description of the data/material that are transferred and the transfer process.(dedicated Annex should be included in the Transfer Agreement.)
- Whereas all Annexes and Appendices form an integral part of the Agreements and are legally binding between the Parties!
- Costs related to the data/material transfer and the party that bears these costs and payment conditions need to be specified

Important information included in Transfer Agreements

- Description of how and by whom data/material will be used.
- Recipient's acknowledges that the material/data shall at all times belong to the Provider.
- Confidentiality term, binding involved in research persons who will make use of data/material.
- If the DTA involves transfer of personal data from the EU to the third countries, compliance with the GDPR rules, is essential.
- Warranties and liability for each of the parties, waivers of responsibility, and further use of data/material.
- Effective date of Transfer Agreement (usually date of last signature).

Important information included in Transfer Agreements

- Intellectual Property issues e.g. copyright issues, acknowledgments based on contribution, industrial property-patents etc.
- The publishing Party shall transmit any material intended for publication to the other Party for review prior to its submission for publication (usually 20-30 days). In case of objection, Parties must resolve disagreement before publishing.
- The New IP deriving from material, can be owned by both the Provider and the Recipient in shares proportionate to their contributions to the creation (Record keeping!).
- In the case new knowledge which is patentable is produced, then the details of shares of the patent among inventors are to be finalized at a separate intellectual property agreement AFTER the new knowledge is produced and BEFORE patent application.
- Negotiation phase NOT only by researchers.

Important information included in Transfer Agreements

- Termination of the Agreement.
- Dispute resolution use of mediation and/or arbitration.
- Jurisdiction - choose the country whose jurisdiction shall apply or choose “silence of law” (Remain silent on jurisdiction. In this case international private law applies).
- Term that the Agreement supersedes any prior agreements, written or verbal.
- Term that the Agreement may be executed in counterparts and may be exchanged by electronic mail but that All properly executed counterparts will constitute one document.

Importance of transfer agreements

- Criticized for being “too complex” and bureaucratic burden to research.
- In March 1995, NIH put in place a simplified MTA systems for sharing non proprietary materials: Uniform Biological Materials Transfer Agreement (UBMTA).
- Addgene (nonprofit plasmid repository) uses implementing letter & an MTA for research conducted by nonprofit or academic institutions (https://www.addgene.org/techtransfer/)
- Litigation on a European level just 23 cases, Bubela et al. Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories, and Litigation, PLOS Biology, DOI:10.1371, February 3, 2015 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315468/)

TEMPLATES

- These Templates where drafted within the framework of the EU funded Project “B3Africa, Bridging Biobanking and Biomedical Research Across Europe and Africa” , by Prof. Jane Reichell, Dr. Santa Slokenberga and Dr. Olga Tzortzatou. Any use of these templates is exclusive responsibility of the respective users.

(For more information on the project and guidance on tools for material and data sharing within and across continents please see also: http://biobanklearning.iarc.fr/ethical-and-legal-guidange-and-tools-for-sample-and-data-sharing-within-and-across-continents/)

MATERIAL TRANSFER AGREEMENT - MTA

MTA Reference Number:

THIS Material Transfer Agreement ("MTA") is made with an effective date of [INSERT DAY, MONTH, YEAR] ("Effective Date")

BETWEEN:

[INSERT NAME AND ADDRESS OF Providing INSTITUTION] ("Provider" with [Dr NAME OF THE INSTITUTION's PI] as INSTITUTION's Principal Investigator hereunder; and

[INSERT NAME AND ADDRESS OF RECEIVING INSTITUTION] (the "Recipient"), with [Dr NAME OF RECEIVING INSTITUTE PI] as Receiving Institute's Principal Investigator hereunder;

(each a "Party" and collectively the "Parties").

Both Parties Agree that:
Subject to the terms and conditions of this Agreement, the Provider hereby agrees to provide, and the Recipient hereby agrees to accept, the Materials and Information specified below for such Purposes of Use and subject to such Restrictions on Use as specified below.
This Agreement is not a contract for sale of goods and nothing in this Agreement shall be considered as granting any license or right under any intellectual property rights or as representing any commitment by either Party to enter into any further agreement, by implication or otherwise.
This Agreement constitutes the entire understanding of the Parties with respect to the matters contained herein; superseding all prior oral or written understandings or communications between the Parties, and it may be modified only by an amendment signed by both Parties.
The Material is not for use in human subjects and will be strictly used either for teaching or for "not – for – profit" research purposes only and is provided free of charge.

1.
•Confidential Information means all information exchanged between both Parties within this Agreement.
• Material means the Material listed in Appendix 1 of this Agreement.
• Purpose means the content of the Appendix 2 of this Agreement.
•Research Group means Dr. .....as the Recipient Scientist and the members of his/her research laboratory.
• Providing Scientist means Dr..... who provides the material to the recipient scientist.
•New IP means that the Recipient's use or possession of the Material or Confidential Information under this Agreement indicatively results from the following: inventions, discoveries, facts, data, ideas, manners, methods or processes of manufacture, methods or principles of construction, chemical compositions or formulations, techniques, products,

prototypes, processes, know how, routines, specifications, drawings, trade secrets, technology methods, works in respect to which copyright subsists and other knowledge.

•Third Party means any party, apart from the Recipient and the Provider, either a legal entity or a person.

•Common Knowledge means any novel knowledge, information and/or data generated as a result of the collaboration between both Parties.

2. Ownership of the Material

The Provider will provide a sample of the Material to the Recipient and may also disclose Confidential Information to the Recipient. The Recipient acknowledges that the Material shall at all times belong to the Provider. The Recipient also acknowledges that the Confidential Information, including any copyright that subsists in any part of the Confidential Information, shall at all time remain the absolute property of their holder.

3. Transfer to Third Parties

The Recipient must ensure that only the Research Group has access to the material. Both the Material as well as the Confidential Information cannot be transferred to any Third Party without the prior written approval on behalf of the Provider. The Provider retains the right to deny any such transfer for whatever reason appears to be infringing its rights.

4. Confidentiality

The Recipient must use the Material and the Confidential Information of the Provider only for the Purpose and must not use the Material or Confidential Information of the Provider for any other reason.

5. Publications an Dissemination

The results arising from the use of the Material within the Purpose of this MTA may be published by the Parties either jointly, or separately. In order to avoid prejudice to any proprietary rights, the publishing Party shall transmit any material intended for publication to the other Party for review at least thirty [INSERT NUMBER] days prior to its submission for publication.

In absence of any objection within that period, the publication may proceed. The Parties agree to solve amicably any disagreement regarding the publication. If a solution cannot be reached the Parties agree not to proceed with the intended publication.

In any such publications, or any other written or oral public disclosures concerning the Research Project, the Parties' respective contribution will be duly recognized by acknowledgment or co-authorship, as appropriate and agreed between the Principal Investigators of the Parties. Notwithstanding the foregoing, neither Party will make any communication orally or in writing, public announcements or press releases concerning the terms of this MTA, the Research Project or any related matter without the prior written agreement of the other Party. Further, neither Party may use the other Party's name and logo without the prior written approval of that Party.

6. Intellectual Property

The New IP in the Material shall be owned by the Recipient. The Recipient grants to the Provider a perpetual, non–exclusive, royalty free license to use the New IP in the Material. The

New IP in a Derivative will be owned by both the Provider and the Recipient in shares proportionate to their contributions to the creation of the Derivative and each party must sign all documents required to record such ownership under this clause. The Recipient shall promptly disclose the New IP to the Provider and must provide a written report to the Provider containing the data and conclusions generated within thirty (30) days of the completion of the testing Purposes.

7. Warranties and Liabilities

The Recipient is responsible for the safe handling and storage of the Material in order to ensure that the Material will not cause any harm to any person or property. The Recipient acknowledges that the Material may be toxic, may contain infectious agents or other substances that are hazardous or dangerous or harmful to persons or property. Recipient agrees to waive all claims against the Provider, the Researcher, and their respective employees, agents and trustees, and to defend, indemnify and hold harmless the Provider, the Researcher and the respective employees, agents and trustees from all claims and damages asserted by Recipient or third parties arising from the use, storage, handling or disposal of the Materials, progeny and mutants thereof, or of products or information derived from there.

The Provider makes no representations and extends no warranties of any kind, either expressed or implied. There are no expressed or implied warranties of merchantability or fitness for a particular purpose. Moreover there are no expressed or implied warranties that the use of the material will not infringe any patent, copyright, trademark, or other proprietary rights.

8. Term of the Agreement

The term of this Agreement is …… years starting from the Effective Date. Upon conclusion of the Purpose, or immediate termination of this Agreement by the Provider because of breach by the Recipient, or termination of this MTA for any reason by either Party, the Recipient agrees to discontinue all use of the Provider Material and return all remaining Material to the Provider, or destroy it, as well as provide written notice upon thirty days (30 days).

8. Legislation

The Parties agree that this Agreement shall be governed by and construed in accordance with …….. Legislation. Exclusive place of venue / jurisdiction are the Courts in …….. Each Party shall retain one copy signed by both Parties.

9. Settlement of disputes

All claims, disputes, and controversies arising out of or in relation to the performance, interpretation or enforcement of this agreement, including but not limited to breach thereof, unless amicably settled, shall be referred to mediation before, and as a condition precedent to, the initiation of any proceeding, including arbitration.

10. Miscellaneous

1.This MTA will in no way be construed as creating the relationship of principal and agent, of partnership in law or of joint venture as between the Parties or any other person involved in the Research Project.

2.This MTA may be executed in counterparts and may be exchanged by electronic mail in .pdf format. All properly executed counterparts will constitute one document.

3.This MTA may be amended only by written agreement duly signed by the authorized representatives of the Parties. This MTA is personal to the Parties and neither Party will assign, transfer, or deal in any other manner with its rights and obligations under this MTA without the express prior written consent of the other Party.

This Agreement is duly signed on behalf of the parties as follows:

Signed for and on behalf of the Provider: Signed for and on behalf of the Recipient:

_____ _____

Provider Principal Investigator
Name: Name:
Title: Title:

Recipient Principal Investigator

_____

Legal Representative of Provider
Name: Name:
Title: Title:

Legal Representative of Recipient

Material Transfer Agreement: Finalized 28 September 2018

DATA TRANSFER AGREEMENT
(OUTGOING FOR DATA TRANSFER WITHIN THE EU)

DTA Reference Number: [TO BE INSERTED]

THIS Data Transfer Agreement ("**DTA**") is made **effective in .....as of / / ("Effective Date"),**

BETWEEN:

[INSERT NAME AND ADDRESS OF PROVIDER INSTITUTION] ("ProviderProvider"), with [Dr NAME OF THE INSTITUTION's PI] as INSTITUTION's Principal Investigator hereunder; and

[INSERT NAME AND ADDRESS OF RECEIVING INSTITUTION] (the "**Recipient**"), with [Dr NAME OF RECEIVING INSTITUTE PI] as Receiving Institute's Principal Investigator hereunder;

(each a "**Party**" and collectively the "**Parties**").

The Parties AGREE AS FOLLOWS:

1. This DTA will start on the Effective Date stated above.
2. The following data and all tangible representations thereof (which includes any written information identified to the Receiving Institute as "Confidential" and transferred by the ProviderProvider to the Recipient together with the data):

   [INSERT SHORT DESCRIPTION OF THE DATA TO BE TRANSFERRED],

   held by the Provider ("**Data**") will be made available to the Recipient for the purpose of the collaboration between the Parties in conducting the project entitled:

   [INSERT PROJECT TITLE] (the "**Research Project**");

   The Data and the Research Project are further described in **ANNEX II**.

3. The Provider will transfer the Data to the Recipient upon receipt of the fully-executed copy of this DTA acknowledging and agreeing to its terms.

4. **Annex I** of this DTA describes the obligations of the Recipient regarding the security it will apply to the Data it receives from the Provider under this DTA. ANNEX I and II 1 (*and any other annexes or appendices*) forms an integral part of this DTA and is legally binding between the Parties.

Authorized use of the Data:

5. The Data are made available to the Recipient under this DTA solely for non-profit research, and solely in connection with and for the purpose of the Research Project, free of charge.

Other than for and within the purpose of the Research Project, as described in Appendix 1, the Data will not be further transferred, distributed to third parties or otherwise used without the Provider's prior notice at least one (1) month before the indented transfer. A written approval or justified rejection shall be provided, to the Recipient by the Provider, within twenty (20) days from the request. Receiving Institution hereby agrees to quit from any right opposing against the Provider's final decision, which shall be binding for both Parties from the date it is issued.

6. The Data will be used only and solely by the Recipient and Recipient's authorized and trained personnel, under the responsibility and supervision of the Recipient's Principal Investigator, for the purposes hereof exclusively and under no less stringent obligations than as provided for in this DTA.

7. The Recipient will not seek to reverse engineer or de-anonymize the Data in any way whatsoever and will comply with all relevant and applicable legislation and ethical requirements. The Recipient further represents and warrants that the use of the Data will not violate any acts, laws, by-laws, rules and regulations applicable to the Data.

Confidentiality:

8. The Recipient agrees to keep the Data in confidence, except for Data that: (a) are publicly known, or available from other sources which are not under a confidentiality obligation to the source; (b) have been made available by its owners without a confidentiality obligation; (c) are otherwise already known by or available to the Recipient without a confidentiality obligation; or (d) are required to be disclosed by operation of law, provided that the Recipient immediately so notifies the Provider in writing and provides adequate opportunity for the Provider to object to, or restrict, such disclosure or request confidential treatment thereof.

Intellectual property rights and ownership:

9. Except for the rights explicitly granted hereunder, nothing contained in this DTA is construed as conveying any rights under any patents or other intellectual property which either Party may have or may hereafter obtain.

10. The Provider retains ownership and/or custody of the Data as applicable and has the unrestricted right to use, disclose or transfer the Data to any third parties for any other purposes. The Recipient acknowledges and agrees that nothing contained in this DTA is deemed to grant to the Recipient any intellectual property rights in any of the Data provided hereunder. The Recipient furthermore agrees to provide the Provider with a copy of any derived data/variables arising from the use of the Data.

11. The Parties agree that the ownership of any intellectual property rights in the results that may arise out of the Research Project will be owned by the Provider and the Recipient and they shall enter into a separate agreement in order to negotiate in good faith the terms and conditions under which they shall distribute their shares. The Parties will keep all results confidential, and shall only disclose them to third parties under obligations of confidentiality, unless or until the Parties agree that such confidentiality is no longer necessary. In case of disagreement regarding the disclosure or not of the results to third parties, the Parties agree herewith to refrain from disclosing them.

12. Subject to the above provision, the Parties may use the results arising out of the Research Project for their own research/academic purposes only. Any other use (e.g. for commercial use) will be subject to a separate agreement .

Publications:

13. The results arising from the use of the Data within the purpose of the Research Project may be published by the Parties either jointly or separately. In order to avoid prejudice to any proprietary rights, the publishing Party shall transmit any material intended for publication to the other Party for review at least thirty [INSERT NUMBER] days prior to its submission for publication. In absence of any objection within that period, the publication may proceed. In case of disagreement regarding the publication Parties agree to amicably reach a common decision otherwise abstain from publishing. In any such publications, or any other written or oral public disclosures concerning the Research Project, the Parties' respective contribution will be duly recognized by acknowledgment or co-authorship, as appropriate and agreed between the Principal Investigators of the Parties.

14. Notwithstanding the foregoing, neither Party will make any communication orally or in writing, public announcements or press releases concerning the terms of this DTA, the Research Project or any related matter without the prior written agreement of the other Party. Further, neither Party may use the other Party's name and logo without the prior written approval of that Party.

Warranties and liability:

15. The Provider makes no warranty of the fitness of the Data for any particular purpose or any other warranty, either express or implied.

16. The Recipient agrees that, except as may explicitly be provided in this DTA, the Provider has no control over the Receiving Institute's use of the Data hereunder. Consequently, the Recipientagrees that the Provider shall not be liable for such use, or any loss, claim or damages which may arise from or in connection with such use.

17. Each Party represents and warrants that: (a) it has the full corporate right, power and authority to enter into this DTA and to perform its obligations under this DTA; (b) the execution of this DTA and the performance of its obligations do not and will not conflict with or violate any agreement to which it is a party or by which it is bound; and (c) this DTA has been executed by a duly authorized representative.

18. The term of this Agreement is ..... ( ) years starting from the Effective Date. Upon conclusion of the Purpose, or immediate termination of this Agreement by the Provider because of breach by the Receiving Institution, or termination of this DTA for any reason by either Party, the Receiving Institution agrees to discontinue all use of the data, as well as provide written notice upon thirty days (30 days).

Miscellaneous:

19. This DTA is governed by (indicate the applicable law unless Parties agree silence of law).

20. All claims, disputes, and controversies arising out of or in relation to the performance, interpretation or enforcement of this agreement, including but not limited to breach thereof, unless amicably settled, shall be referred to mediation before, and as a condition precedent to, the initiation of any proceeding, including arbitration.

21. This DTA may be amended only by written agreement duly signed by the authorized representatives of the Parties. This DTA is personal to the Parties and neither Party will assign, transfer, or deal in any other manner with its rights and obligations under this DTA without the express prior written consent of the other Party.

22. Either Party may terminate this DTA upon giving the other Party 30 days written notice.

23. Upon expiry or earlier termination of this DTA, the Recipient will securely dispose of the Data or return and delete the Data to the Provider as agreed between the Parties.

24. This DTA will in no way be construed as creating the relationship of principal and agent, of partnership in law or of joint venture as between the Parties or any other person involved in the Research Project.

25. This Agreement sets forth the entire understanding between the parties and supersedes any prior agreements, written or verbal.

26. This DTA may be executed in counterparts and may be exchanged by electronic mail in .pdf format. All properly executed counterparts will constitute one document.

This DTA is duly signed on behalf of the Parties as follows:

Signed for and on behalf of the Receiving Institute:	Signed for and on behalf of the Provider:
The Receiving Institute's Authorized Official Name: Title:	the Provider's Authorized Official Name: Title:

Data Transfer Agreement: Finalized 28 September 2018

Read and acknowledged by the Principal Investigator of the Receiving Institute:	Read and acknowledged by the Principal Investigator of the Provider:
_____	_____
Name:	Name:
Title:	Title:
Email:	Email:
Date:	Date:

DISCLAIMER: This is a Sample Template. This template is based the World Health Organization International Agency for research on cancer publicly available document NO. CIRC 72 (09/2017), as modified by Santa Slokenberga, Jane Reichel, and Olga Tzortzatou for the purposes of B3Africa project. Any use of this Sample Template is exclusive responsibility of the respective users.

On the importance of DTA/MTA and essential elements see Mascalzoni D. et al. “International Charter of Principles for Sharing Bio-Specimens and Data”, EJHG (2015) 23, 721-728.

03

Last researches on biobanking

BBMRI ERIC

BBMRI ERIC

- A European research infrastructure for biobanking.
- Bring together all the main players from the biobanking field - researchers, biobankers, industry, and patients - to boost biomedical research.
- Offer quality management services, support with ELSI issues, and a number of online tools and software solutions.
- Make new treatments possible

BBMRI ERIC

BBMRI-ERIC®

FIND SAMPLES AND DATA | ABOUT v | SERVICES & SUPPORT v | EU GRANTS v | NEWS & EVENTS v

- B1MG
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- BY-COVID
- CETOCOEN EXCELLENCE TEAMING PHASE II
- CINECA
- CONCEPTION
- CY-BIOBANK
- DIAMONDS
- EDIREX
- EJP RD
- EOSC FUTURE
- EOSC-LIFE
- EPND
- ERIC FORUM
- EUCAN-CONNECT
- EUCANIMAGE
- EUCANSHARE
- HEALTHYCLOUD
- IC2PERMED
- INTERVENE
- ISIDORE
- RABBIT 2
- RI-VIS
- SPIDIA4P
- COMPLETED PROJECTS

Home - EU Grants

EU GRANTS

To date, BBMRI-ERIC has been awarded more than €7 million in additional funds thanks to its participation in the EU's 7th Framework Programme and Horizon 2020.

As its main goal, BBMRI-ERIC aims to improve the accessibility and interoperability of existing collections of biological samples from different (sub)populations of Europe, including both population-based and clinically-oriented sample collections.

Including 21 Members, BBMRI-ERIC is a globally unmatched, Europe-wide platform for translational medical research with the aim to develop personalised medicine and disease prevention for the benefit of European citizens.

HOW TO PARTNER UP WITH US

We welcome requests from individual researchers as well as research teams seeking project collaborations with BBMRI-ERIC and/or its Nat Nodes. Please send an email to contact@bbmri-eric.eu with the follo information:

- Name of the PI
- Call ID and call text
- Aim of the proposal (short description)
- Desired collaboration/contribution of BBMRI-ERIC
- Adherence to non-exclusivity

DISCOVER ALL THE EU PROJECTS WE PARTICIPATE IN

B1MG - BEYOND 1 MILLION GENOMES

BIGPICTURE

BBMRI ERIC

BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

FIND SAMPLES AND DATA | ABOUT v | SERVICES & SUPPORT v | EU GRANTS v

Home - ELSI

ELSI SERVICES & RESEARCH

RESEARCH

We conduct research relating to ethical, legal and societal issues (ELSI). This is fundamental to staying up to date with and contributing knowledge to our services and training.

- EU Projects
- Publications and Results

SERVICE

We support the biobanking and life science RI communities by facilitating compliance with regulatory requirements and best practice standards.

- ELSI Helpdesk
- ELSI Knowledge Base
- Ethics Check
- ELSI-Related Public Consultations
- Task Force Societal Issues
- Task Force GDPR
- Task Force Research Ethics Committees

TRAINING

We provide training and workshops on ELSI issues such as Data Protection Impact Assessment (DPIA), ethical compliance and social engagement, among others.

- ELSI Webinars
- ELSI Training Courses

BBMRI GR

BBMRI.gr
Biobanking and
BioMolecular resources
Research Infrastructure
Greece

- Coordinating by BRFAA
- Creating a network of Greek Biobanks and connecting them with the BBMRI-ERIC
-
- Expansion and upgrade of existing collections of human biological material in Greece by applying high-quality scientific standards for collection, processing and storage, with harmonization of BBMRI-GR with BBMRI-ERIC
- Representation of the national node in the BBMRI-ERIC ELSI team.
- Optimal harmonization of procedures within BBMRI-GR to integrate existing biobanks into a national research infrastructure

Beyond 1 Million Genomes

B1MG

- Create a network of genetic and clinical data across Europe.
- It provides coordination and support to the 1+ Million Genomes Initiative (1+MG).
- This initiative is a commitment of 23 European countries to give cross-border access to one million sequenced genomes by 2022.
- B1MG will go 'beyond' the 1+MG Initiative by creating long-term means of sharing data beyond 2022 and enabling access to beyond 1 million genomes.

B1MG

Goals

- To work with regional, national and European stakeholders to define the requirements for cross-border access to genomics and personalised medicine data.
- To translate requirements for data quality, standards, technical infrastructure, ELSI into technical specifications and implementation guidelines that capture European best practice.
- To drive adoption and support for long-term operations by providing guidance on phased development and a methodology for economic evaluation.

B1MG

WP1: Stakeholder engagement

This WP will consult project stakeholders, from patient and citizen organisations to policy makers and relevant parties in academia and industry. These stakeholders will help shape the outcomes of the project, to ensure that everyone across society trusts the data sharing process, and benefits from the personalised medicine made available.

→ Work Package 1 page

WP2: Ethical, Legal and Social Issues (ELSI)

This WP will address the legal and ethical issues surrounding accessing and transferring personal health data. It will create a toolkit of ELSI policies and recommendations that will be the basis for sharing genomic and health data across Europe.

→ Work Package 2 page

WP3: Standards and quality guidelines

This WP will identify gaps and best practices to facilitate cross-border searching, linking and analysis of genomic and health data. It will produce a set of recommendations and guidelines that cover the minimal requirements for the provenance of the samples, the generation of the whole genome sequencing (WGS) and whole-exome sequencing (WES) data.

→ Work Package 3 page

WP4: Federate secure cross-border infrastructure

This WP will describe the infrastructure needed for secure cross-border data discovery and access in Europe. It will look at the security requirements, interoperability standards and technical components needed to enable cross-border services. WP4 will also increase technical capacity across the European Member States.

→ Work Package 4 page

WP5: Delivering Personalised Medicine cross-borders: Implementation in healthcare systems and societal impact

This WP will work with national healthcare systems to combine the project outcomes into the **B1MG maturity level model**. This will allow the healthcare systems to assess their readiness to integrate into the federated secure cross-border infrastructure (WP4) and adopt the supporting standards and recommendations (WP2, WP3 and WP4). This integration will enable them to access personalised medicine data across borders.

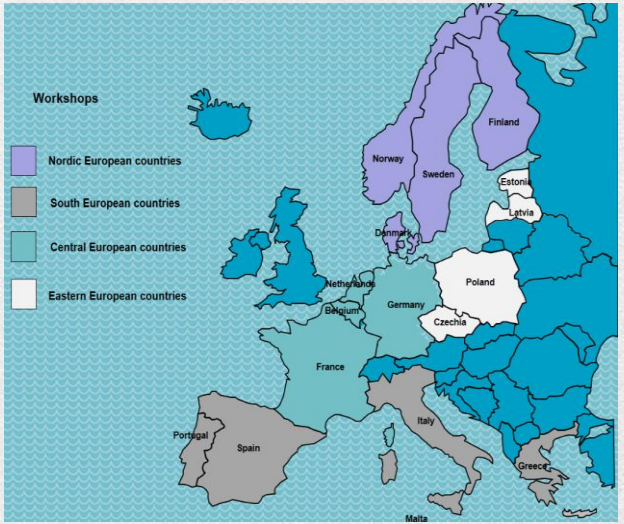
→ Work Package 5 page

WP6: Coordination Office

B1MG

D2.3 - Analysis of legal framework and development of common minimum standard

- **4 workshops** “GDPR implementation across Member States and secondary use of data from healthcare to research and vice versa”.
- **20 experts** in this field in their country.
- The emerging challenges in this processing will in turn inform and contribute to the design of the best possible secondary use of data in order to develop the B1MG ethico-legal framework taxonomy.



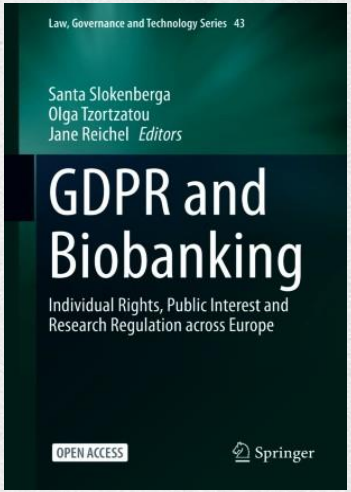
Other resources

- Published in Cancers Biology the openly accessed paper: “Harmonization_after_the_GDPR_Divergences_in_the_rules_for_genetic_and_health_data_sharing_in_four_member_states_and_ways_to_overcome_them_by_EU_measures_Insights_from_Germany,_Greece,_Latvia_and_Sweden”.

- “GDPR and Biobanking” (2021) - chapter on Greece https://doi.org/10.1007/978-3-030-49388-2_16

- Glossary Mapping European Research Ethics Committees & ethics review processes for biobank-based research (2021) DOI: 10.5281/zenodo.4580480

- Biobanking and risk assessment: a comprehensive typology of risks for an adaptive risk governance (2021) DOI: 10.1186/s40504-021-00117-7



EUROPE BIOBANK WEEK 2020

17 – 20 November | Virtual Conference

BIOBANKING FOR GLOBAL CHALLENGES

Mapping European RECs & ethics review processes for biobank-based research

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BBMRI-ERIC

INTRODUCTION

Facilitating the use and exchange of biological samples and associated health data in large cross-border collaborations is essential to promoting biomedical research. However, practices for the ethical review of research projects are not harmonized across European countries and there are no systems for mutual recognition of ethical approval decisions (RECognition). Variations in legal frameworks provide an additional level of complexity to this landscape.

Thus shared information on Research Ethics Committee (REC) requirements in different EU countries is a critical element for a harmonized and collaborative environment. It leads to a need for an updated mapping of ethics review processes for biobank-based research at European level. To promote a framework of mutual RECognition, it is key to understand the common needs and challenges and the national level REC workflows, needs and requirements.

The **Task Force REC**, as a part of the ELSI Services of BBMRI-ERIC dedicated to RECs' needs and issues, has launched a pilot survey targeting nine EEA Countries (Austria, Czech Republic, Germany, Greece, Italy, Latvia, Malta, Norway, United Kingdom) as the first step of an extensive European REC mapping of practices and legal landscapes for ethical approval.

AIM

To collect and analyse information on the regulatory and procedural framework of the ethical review process of biobank-based research

→ support the scientific community applying for REC review of collaborative biobank-based research

→ induce a harmonization-process among the RECs involved

METHOD

1) Establishment of definitions of the key terms

2) A questionnaire with 7 sections aimed to to gather objective data on national requirements highlighting the following critical issues:

- ✓ the ethical and regulatory framework for biosample/data-based research
- ✓ the ethics committees in charge of evaluating the biobank-based research
- ✓ the rules of operation of RECs for the ethical review of:
  - a. biosample/data-based research projects
  - b. the establishment of a human research biobank
- ✓ the expected process for submitting this type of biomedical research for REC review

ELISurvey Platform as an online survey management system

Preliminary engagement exercise involving National Node Directors & the BBMRI ELSI community

National RECs gatekeepers, the main addressees: people with a key role in the operation of Research Ethics Committees (RECs) on a national level such as for example the chairman of the national ethics commission or of the national REC network. Engaged at least two respondents representing RECs for each of the 9 countries represented in the Task Force REC.

Duration of data collection: from 10th August to 30th September 2020 (This proved too short a timeframe for response from all invited countries, possibly due to work pressure in the ongoing Covid pandemic). The participants will be acknowledged in any publication.

Sect. 1 – REGULATORY FRAMEWORK
Sect. 2 – REC/IEC/OTHER ETHICS COMMITTEES INVOLVED IN THE REVIEW PROCESS OF BIOBANK-BASED RESEARCH
Sect. 3 – ETHICS REVIEW PROCESS FOR BIOBANK-BASED RESEARCH
  3A. PROSPECTIVE COLLECTION OF HUMAN SAMPLES
  3B. RETROSPECTIVE COLLECTION OF HUMAN SAMPLES
  3C. BIOBANK ESTABLISHMENT
  3D. ACCESS AND TRANSFER
Sect. 4 – NATIONAL BODY COORDINATING RECS' ACTIVITIES
Sect. 5 – NATIONAL BODY AND BIOBANK-BASED RESEARCH
Sect. 6 – RECs' NETWORK
Sect. 7– CHALLENGES IN EMERGENCY TIME

FIRST RESULTS

EEA countries involved in the pilot phase

9 countries invited but only 6 responded (green), due to Covid work pressure.

SHARING Definitions

Research Ethics Committees - "RECs": (independent) accredited Research Ethics Committees that review research proposals and/or clinical studies with human participants to ensure that they conform to internationally and locally accepted ethical guidelines. Depending on the Member State legal framework, their review may also include projects aiming at a "secondary use" of human data/human biological samples.

Institutional Ethics Committees- "IECs" (IRB): institutional Ethics Committees/Institutional Review Boards that review research proposals using human biological samples and associated personal data. Usually they are affiliated to research institutions and evaluated by the same research institutions to comply with ELSI international requirements.

Biobank-based research: research using human biological samples and related data, collected, stored and provided by (or mediated through) a biobank, operating in accordance with standard procedures, that ensure sample integrity, quality control, quality assurance and to the respect of ELSI requirements.

MORE IN COMMON

- ☐ all (responding) countries have RECs and institutional RECs
- ☐ all countries have legislation to set up independent RECs but not for institutional ECs
- ☐ RECs set their own procedures on which supporting documents to collect
- ☐ accredited RECs can review prospective and retrospective research in all countries

Biobank-based research is evaluated
- ✓ by both RECs and IECs, depending on the EEA countries
- ✓ without a specific regulatory framework for biobank-based research (except for Norway)
- ✓ with different processes for submitting, depending on the country and the ethics committee

Biobank establishment
- ✓ not all the EEA involved countries require the ethical evaluation of a new biobank

Access to biobank samples
- ✓ only Germany has dedicated access committees. Italian biobanks may have access committees

PRELIMINARY CONCLUSIONS

- **Confusion as to what independence and accreditation are.**
  - Our definition of REC mentions independent and accredited. This created problems for those countries that do not have formal accreditation processes in place.
- **Fragmented situation, within the same country and between European countries.** RECs and IECs review biobank-based research without a common regulatory framework, without sharing common rules as well as not asking for specific ELSI competencies for biobank-based research reviewing.
- **Few countries have a National Commission aimed at standardizing RECs activities** (Italy, Norway, Latvia) or a National REC Network (Germany, Italy, Norway), and these seem not to operate within a common pan-European harmonized framework.
- **Need of**
  - harmonisation of both legislation (often biobank-based research is evaluated by analogy, adopting principles and criteria from regulatory frameworks designed for other specific areas, for example for data processing or clinical trials) **and procedures**
  - **sharing of best practices and common rules** (i.e. for submitting/establishment/access processes)
  - **dedicated training**
- **Expressed need for support by**
  - **ELSI help desk**
  - **Website with the live updated regulatory framework**
  - **Webinar to tackle critical issues**

Between November and December 2020, the survey will be extended to the other BBMRI-ERIC partner states.

ACKNOWLEDGEMENTS

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DE - METHNER ULRIKE BARA, President of the National Ethics Committee
IT - PATRINI CARLO, Vice Chair of the of the Centre di coordinamento nazionale dei comitati etici territoriali per la sperimentazione clinica sui medicinali per uso umano e sui dispositivi medici
IT - RIELLA LUIGI, Coordinator "Grande ospedale metropolitano", Healthcare Advisory
MT - AMULIS PARISI, Chair, Health Ethics Committee, Advisory of Health
MT - SCHEMBRI PATRICK, Chair University of Malta Research Ethics Committee
LV - MEŽINSKA SANDE, Central Medical Ethics Committee
LV - VITA ADUTE, Central Medical Ethics Committee
NO - ALE ARSVEN CAMILLA, The Norwegian Committees for Medical and Health Research Ethics (NEM)
NO - ASTRI ARE, Norwegian National Research Ethics Committees

CONTACT INFORMATION

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- Data Portability in Health Research and Biobanking: Legal Benchmarks for Appropriate Implementation
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Thanks

Do you have any questions?

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