

Conference

## Genetic data in public research databases: Which governance mechanisms should apply?

April 27-28, 2016 / EURAC Bolzano Italy

### Genetic data in public research databases: Which governance mechanisms should apply?

This conference aims to:

- explore ethical and legal challenges that may arise when researchers are required to deposit genetic and genomic research data in public research databases, and
- investigate governance mechanisms that may support ethically and legally compliant data deposit.

Data sharing is necessary to facilitate research on genetic and molecular mechanisms underlying disease. Increasingly, research funders encourage or require that researchers deposit their data (including genotype, phenotype and raw sequence data) in public research databases. The data can then potentially be used for an unlimited number of privately or public-funded research projects, nationally and internationally. Data sharing requests may in some cases be designed as a trade-off. For instance, the funder may agree with a biobank to sequence biological samples at no cost if the data produced are stored in a public research database. Such agreements can be appealing for institutions battling with funding shortages.

Genomic data sharing through public research databases raises ethical and legal questions we aim to explore. Current governance mechanisms and consent procedures primarily rely on the assumption that researchers are able to keep track of how their data is shared and used at any point in time. For instance, researchers have obligations to establish MTAs, DTAs, and inform their research participants about potential uses. However, if the data is deposited in public research databases where the original body loses control over data uses, this may mean that the researchers may not be able to satisfy such obligations and that current governance mechanisms are no longer suitable to protect participants' rights. Current data deposit practices require clarification regarding a number of issues. For instance, indefinite data sharing for a multitude of purposes poses a legal challenge. Also, few guidelines exist to inform researchers on how to inform research participants about data sharing. Furthermore, accountability mechanisms which address potential issues of data privacy breaches are largely missing, despite recent requirements by the OECD to implement such mechanisms.

What are the ethical and legal aspects such databases pose? Are there mechanisms that may support data sharing while promoting better transparency and accountability? How can the ELSI community contribute to develop such mechanisms? National authorities, funding bodies, research database representatives, and legal and ethical researchers will be invited to explore and address these issues during the workshop.

**Scientific Committee:** Deborah Mascalzoni, Isabelle Budin Ljøsne, Heidi Beate Bentzen

## Registration

- CHIP ME members: no registration fee (including social dinner and conference materials/breaks/lunch)
- Non CHIP ME members: 40 € (the registration fee includes the conference material, the participation on the conference as well as coffee breaks and lunch during the conference day)

Participation at the social dinner: 40 €

### Accommodation

Partner hotels: <http://www.eurac.edu/en/services/meeting/partners/Pages/default.aspx>

Accommodations in and around Bolzano: <http://www.bolzano-bozen.it/en/accommodation-bolzano.htm>

### Contacts

For questions concerning the scientific program please contact

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Programme

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## Day 1

### Session 1: Views on genetic data sharing through public research databases

9.00 – 10.50

*What are public research databases?*

- Why do some actors encourage the use of such databases?
- What are the experiences with such databases?
- How are the ethical and legal aspects considered?
- How are the research participants informed?

08.50 – 09.10

*Welcome and introduction*

**Deborah Mascalzoni, Heidi Beate Bentzen and  
Isabelle Budin Ljøsne**

09.10 – 09.20

*CHRIS project*

**Cristian Pattaro**

09.20 – 09.30

*Sardinia Biobank*

**Dr. Cucca, Italy**

09.30 – 09.40

*HUNT study Norway*

**Kristian Hveem**

09.40 – 09.45

*BBMRI Italy welcome*

**Marialuisa Lavitrano**

09.45 – 10.00

*BBMRI-ERIC*

**Michaela Mayrhofer, Austria**

**Irene Schlünder, Germany**

10.00 – 10.10

*Global Alliance*

**Edward Dove, Edinburgh University**

10.10 – 10.20

*EU DG Research & Innovation/health*

**Iiro Eerola**

10.20 – 10.30

*dbGaP*

**Dr. Joanne Nelson, Washington University**

10.30 – 10.45

*Q&A*

10.45 – 10.50

*Coffee break*

## Session 2: Public genetic research databases: What is the legal landscape?

Time: 11.10 – 14.45

*Some key questions:*

- Are there any legal challenges to genomic international public research databases?
- Can the funding bodies make international public research databases a requirement?

11.00 – 11.20

*Italian Data Protection Agency: current legal stand*  
**(Chiara Romano, to be confirmed)**

11.20 – 11.40

*EU data protection perspective*  
**Lee Andrew Bygrave, University of Oslo**

11.40 – 12.00

*US data protection perspective*  
**David O'Brien, Harvard University**

12.00 – 12.20

*Transnational data sharing and jurisdictional issues*  
**Dan Jerker Svantesson, Bond University**

12.20 – 12.40

*Third party access*  
**Heidi Beate Bentzen, University of Oslo**

12:40 – 13:00

*Current legal perspective and how it could adapt to open data*  
**Amedeo Santosuosso, Marta Tomasi, Pavia University**

13.00 – 13.50 *Lunch*

13.50 – 14.45

*Panel discussion on the legal issues* (The speakers from the legal session)

14.45 – 15.15 *Coffee break*

## Session 3: Public genetic research databases: Ethics and policy

Time: 15.20 – 18.00

15.20 – 15.40

*Ethical principles and premises for data sharing*  
**Jan Helge Solbakk and Isabelle Budin Ljøsne, University of Oslo**

15.40 – 16.00

*Concerns and attitudes towards genomic research data sharing and possible governance mechanisms*  
**Mahsa Shabani, KU Leuven**

16.00 – 16.20

*Policy – the Finnish model*  
**Sirpa Soini, Helsinki Biobank**

16.20 – 16.40

*CHRIS' data sharing policy*  
**Deborah Mascalzoni, EURAC research and Uppsala University**

16.40 – 17.00 *Coffee break*

17.00 – 18.00

*Panel discussion on the ethical aspects and governance mechanisms* (The speakers from the ethics and policy session)

## Day 2 – Expert meeting: Developing strategies

09.00 – 12.30

*Round table discussion*

Round table discussion with the speakers from Day 1 and CHIP ME members who wish to stay and participate in the writing of an article on the topic. The aim of day 2 will be to lay the groundwork for an article on ethical and legal aspects of genetic data in public research databases, and possible governance mechanisms.

12.30 – 13.30 *Lunch*

CHIP ME participants may want to have separate meetings in the afternoon after lunch. Rooms will be available for the working groups.