



## Data governance and informed consent in the Human Brain Project

December 11<sup>th</sup> and 12<sup>th</sup> 2017

European Institute for Theoretical Neuroscience (EITN), Paris, France

Data on patients and research participants, stored in hospitals around the world, provide a valuable resource for research. The Human Brain Project (HBP) hopes to use these valuable health databases for its research on providing more accurate diagnoses and personalized medicine for brain diseases. The data could for example be brain images, previously received therapies, mental evaluation, genetic information, etc. However, such research raises issues of data governance, informed consent, trust and societal values.

In this seminar, leading neurologists, personal data managers, experts in bioethics and patient representatives come together to discuss the challenges setting up and participating in 'big data' research as suggested by the HBP. In particular the seminar is focused on a discussion of the following questions:

- *Which options exists for obtaining informed consent in big data research?*
- *What can we learn from biobanks and brain image databases about data governance?*
- *How do we empower of data subjects in 'big data research'?*
- *Which options lies in privacy by design?*
- *How can informed consent procedures be improved for unconscious people?*
- *How do we balance data protection and informed consent against other societal values?*
- *How can we develop standard procedures for collecting and researching on clinical data in big data projects?*

The aim of the seminar is to initiate a dialogue between HBP scientists, HBP data managers and external experts and stakeholders, on how to improve data governance and informed consent in big data research projects like HBP. The outcome of the seminar will include recommendations for the research community and concrete input to the HBP Standard Operating Procedures (SOPs) and data policy manuals.

The seminar will take place on **December 11<sup>t</sup> and December 12<sup>th</sup> at the European Institute for Theoretical Neuroscience (EITN), 74 Rue du Faubourg Saint-Antoine, 75012 Paris, France: [www.eitn.eu](http://www.eitn.eu)**. A detailed program is enclosed in this document.

**To sign up** please send an email to Project Manager Karen Riisgaard: [kr@tekno.dk](mailto:kr@tekno.dk). Deadline for signing up is **November 11<sup>th</sup>, 2017**. Please indicate if you would like to take part in the dinner Monday evening.

### Organizers:

The Danish Board of Technology Foundation, led by director Lars Klüver; HBP Ethics Management Group at De Montfort University, led by Prof. Bernd Stahl, both being part of the Subproject 12 (SP12) [Ethics and Society](#) of the HBP; European Institute for Theoretical Neuroscience (EITN).

## Speakers and seminar chairs



**Dr. Simisola Akintoye**  
De Montfort Law School, De Montfort University; HBP Ethics and Society (SP12)



**Dr. Cindy Birck**  
Project Officer at Alzheimer Europe; Developer of Alzheimer Europe database on clinical trials



**Dr. Karin Blümer**  
Ph.D., Veterinarian & Philosopher, Novartis International, Basel, Switzerland; Co-Chair HBP Ethics Advisory Board



**Prof. Dr. Josep Domingo-Ferrer**  
Universitat Rovira i Virgili, UNESCO Chair in Data Privacy; member of HBP Ethic Advisory Board.



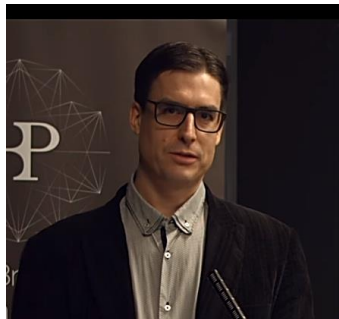
**Prof. Bogdan Draganski, MD**  
Director of LREN (Laboratoire de recherche en Neuroimagerie), Department of Clinical Neurosciences, CHUV; HBP SP8 member and Ethics Rapporteur.



**Dr. Athena Demertzi**  
Researcher in cognitive and clinical neuroscience. Coma Science Group, Université de Liège



**Dr. Michele Loi**  
University of Zürich, Institute of Biomedical Ethics and History of Medicine; Involved in Chip Me and the COST project



**Jeffrey C. Müller**  
École Polytechnique Fédérale de Lausanne (EPFL); HBP Technical Coordinator



**Katrine Ore**  
Faculty of Medicine, Oslo University; HBP Data Protection Officer



**Prof. Wim Pinxten**  
Researcher in medical ethics, scientific integrity, and healthcare for vulnerable populations. Hasselt University



**Dr. Alberto Rábano**  
Director, CIEN Tissue Bank and member of HBP Ethics Advisory Board



**Prof. Jo Samanta**  
Researcher at Leicester De Montfort Law School, De Montfort University; HBP Ethics and Society (SP12)



**Prof. Gunter Schumann**  
Principal Investigator and Coordinator of the IMAGEN project, Kings College



**Prof. Effy Vayena**  
Professor of Bioethics; Department of Health Sciences and Technology; ETH Zurich, Switzerland; Faculty Fellow, Berkman Klein Centre for Internet & Society, Harvard Law School



**Prof. Susan Wallace**  
University of Leicester, UK; Member of UK Biobank Ethics and Governance Council



**Prof. Henrik Walter**  
PhD, MD, neurologist, psychiatrist and philosopher; Prof. for Psychiatry, Charite, Berlin, Germany; Chair of HBP Ethics Advisory Board



**Mr. Ma'n H. Zawati**  
Executive Director, Centre of Genomics and Policy, McGill University

# Seminar: Data governance and informed consent in the Human Brain Project

December 11<sup>th</sup> and 12<sup>th</sup> 2017

European Institute for Theoretical Neuroscience (EITN), Paris, France

December 11 <sup>th</sup>		Program
12.00 – 12.45	<b>REGISTRATION &amp; BUFFET LUNCH</b>	
12.45 – 13.00	Welcome <b>Karen Riisgaard (SP12)</b>	
13.00 – 13.15	Introduction: Data protection and informed consent in big data research <b>Dr. Karin Blümer</b>	
13.15 -13.40	Data governance and informed consent in the Human Brain Project <b>Prof. Jo Samanta (SP12)</b>	
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<b>13.40-17.00</b>	<b>Ethics governance in biobanking</b> Chair: <b>Dr. Susan Wallace</b>	
13.40 – 14.00	Introduction by the Chair <b>Dr. Susan Wallace</b>	
14.00 – 14.25	Data governance in the IMAGEN project <b>Prof. Gunter Shumann</b>	
14.25 – 14.50	Alzheimer Europe Clinical Trial Database <b>Dr. Cindy Birck</b>	
14.50 – 15.15	Data governance and the CIEN tissue bank <b>Dr. Alberto Rabano</b>	
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<b>15.15 – 16.00</b>	<b>COFFEE &amp; NETWORKING BREAK</b>	
16.00 – 17.00	Commentary session <b>Chair: Dr. Susan Wallace</b>	
Plenary	HBP commentary panel: <b>Dr. Henrik Walter</b> , (EAB Chair), <b>Dr. Karin Blümer (EAB-Co-Chair)</b> ; <b>Jeff Müller (SP5)</b> , <b>Prof. Bogdan Draganski (SP8)</b>	
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<b>17.00-17.15</b>	<b>BREAK</b>	
17.15 -18.45	<b>Perspectives on the General Data Protection Regulation (GDPR)</b> Chair: <b>Dr. Simisola Akintoye</b>	
17.15 -17.30	Introduction <b>Dr. Simisola Akintoye (SP12)</b>	
17.30 – 17.50	Implications of the GDPR <b>Katrine Ore</b> (Data Protection Officer, HBP)	
17.50 – 18.45	Plenary discussion on data governance policies in the HBP	
Plenary		
<b>19.00 – 21.00</b>	<b>WORKING DINNER</b>	

## December 12<sup>th</sup>

### 9.00 – 9.30 WELCOMING COFFEE

9:30 – 9:45 Introduction of the day  
**Karen Riisgaard (SP12)**

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### 9.45-14.30 **Empowerment of data subjects in big data research** Chair: **Prof. Effy Vayena**

9.45 – 10.00 Introduction by Chair  
**Prof. Effy Vayena**

10.00-10.25 Individual rights vs big data research  
**Prof. Josep Domingo-Ferrer**

10.25-10.50 Data platforms as a form of citizen empowerment  
**Dr. Michele Loi**

### 10.50 – 11.05 BREAK

11.05-11.30 Access to data and re-contacting data subjects  
**Mr. Ma'n H. Zawati**

11:30-11:55 Informed consent and coma patients (a case study)  
**Dr. Athena Demertzi**

11.55 – 12.20 Data governance for people unable to provide consent  
**Prof. Wim Pinxten**

### 12.20-13.20 LUNCH

13.20-14.20 Chair: **Prof. Effy Vayena**  
Plenary

Expert panel: **Prof. Josep Domingo-Ferrer, Dr. Michele Loi, Mr. Ma'n H. Zawati, Dr. Athena Demertzi, Prof. Wim Pinxten**

### 14.20-14.30 COFFEE BREAK

### 14.30 – 16.30 **Options and challenges for data governance in HBP** Chair: **Jeff Müller (SP5)**

14.30-14.50 Future directions for the HBP Data Governance Working Group (DGWG)  
**Jeff Müller (SP5)**

14.50-15.45 Group discussions –Action points for HBP data governance

15.45-16.20 Plenary discussion on short and long term challenges and opportunities of data governance and informed consent in HBP  
Plenary

16.20-16.30 Concluding remarks and good bye  
**Karen Riisgaard (SP12)**