



AGENDA WORKSHOP 2  
13 – 14th November 2008 Coimbra, Portugal

Wednesday 12<sup>th</sup> November: arrival and informal evening meal

Thursday: Regulation

am: regulation of privacy

9.00 Welcome and Introduction: discussion of Stage Two (and Stage Three) and Workshop 2 activities

9.30 Paper: David Townend and Mark Taylor (Stage one project report) (20 mins)

Response by Simone Fennell, Tilburg Institute for Law, Technology and Society (20 mins)

Discussion (20 mins)

10.30 Coffee Break

11.00 Professor Graeme Laurie, University of Edinburgh and Chair of Ethics and Governance Council of UK BioBank

12.00 Lunch

pm: regulation of biobanks

13.00 Presentation by each of the RC's on their draft stage Two reports (20 mins each) Breakout in Regional Groups with Regional RCs to lead

	Data Protection	Other Regulation	Practical Guidance	Overall Position
What is the scope of the protection? What biobank activities are (not) covered? 1. How is the sample/ data distinction drawn within regulation? (Asking the question how these different things are regulated across Europe from both a data protection perspective but also how the data protection position is	What is the coverage and practice?	Does this modify the position?	Does this modify the position	...

<p>modified by other regulation and professional guidance)</p> <p>2. How identifiable does data need to be to be covered? (Asking questions about the kind of anonymisation capable of taking data outside the scope of regulation but also considering the issue of individual cf. group identifiability)</p> <p>3. What is the nature and extent of the research exemption?*</p>				
<p>What is the nature of the protection?</p> <p>4. What is the nature of the consent? (Asking questions about how narrow consent needs to be to satisfy the regulations (or alternatively how broad it <i>can</i> be) but also considering questions of re-contact and or withdrawal)</p> <p>5. Research and the vulnerable (asking 'From whom must consent be sought?' e.g. in the case of children but also considering further implications of research and the vulnerable e.g. whether information needs to be provided on possibilities of withdrawal when children come of age)</p> <p>6. The provision of Information (Asking what information must be provided prior to participation and what information must be provided <i>post</i> participation, including questions about potential discrimination, benefits, and dissemination of research results)</p>				

15.30 Coffee Break (30mins)

16.00 Rapporteur's report conclusion; complete 'spread-sheet'

17.00 Pre-Dinner Seminar

Presentations by:

- Prof. Dr. Lisbeth Ehlert Knudsen

- Dr. Atina Krajewska

- Dr. Pierre Mallia

- Prof. Dr. Peter Rehak

18.00 Close

[18.30 –20.00 Steering Group]

20.30 Dinner

### Friday: Implications of Regulation

#### am: Implications of regulation for science

9.30 Dr Vilmundur Gudnason, director of the Icelandic Heart Association's Heart Preventive Clinic and Research Institute.

10.30 Coffee Break

11.00 Panel discussion on consequences of regulation for science (and privacy protection)

12.00 Lunch

#### pm: Implications of regulation for privacy

13.00 in self selected breakout groups with an RC for each group.

What are the implications for privacy protection (taking into account impacts upon science) of yesterday's (spread sheet) conclusions?

*vis a vis*

1. Scope;
2. nature; and,
3. research exemption from protection offered.

Focus upon determining the privacy implications of alternatives identified (yesterday) under each of these headings.

15.30 Coffee (30mins)

16.00 Rapporteur's report back to plenary.

17.00 Recapitulation: the work in Stage Three.

18.00 Close

20.30 Formal Dinner