EU LEGISLATION AND GENOMIC DATA WORKSHOP

10.30 am MR9, Richmond House

Isobel Atkin	PHE/ECACC
Kevin Bruce	EBiSC/Roslin Cells
Glyn Stacey	NIBSC/UKSCB
Aoibhinn McDonnell	Pfizer
Peter Mills	Nuffield Foundation
Hannah Verdin	HFEA
Sarion Bowers	Sanger
Carol Smee	Sanger/NRES
Jacqueline Barry	Cell Therapy Catapult
Rosamund Scott	MEUKSC
Phillip Quinlan	UKCRC Tissue Directory and Coordination Centre
Beth Thompson	Wellcome Trust
Dafni Moschidou	HTA
Michael O'Callaghan	Pfizer
Tim Hubbard	Genomics England/EAGDA
Ian McKay	DH
Alex Lee	DH

By phone: Jens Habermann ESBB Biobanking Society and Natural History Museum

Rosario Isas

PRESENTATION SLIDES

HFEA slides.pdf

HTA slides.pdf

Sanger slides.pdf

PHE slides.pdf

Wellcome Trust slides.pdf

THE EU DATA PROTECTION REGULATION

At present Data Protection is covered by the EU Data Protection Directive (95/46/EC) designed to protect the privacy and protection of all personal data. The Data Protection Act 1998 implements the Directive in the UK.

To revise the data protection legislation the European Commission published a draft Data Protection Regulation to replace the Directive in January 2012. As a regulation this would become binding across all member states.

The draft regulation covers all use of personal data across most sectors except law enforcement. Research is only a relatively small element of the overall legislation.

The draft proposals were reviewed earlier this year by the **European Parliament (March 2014)** and the **Council of Ministers (June 2015)** and have now reached the trilogue stage. This consists of closed negotiations where the three versions of the text become amalgamated into a single version.

The trilogue negotiations are expected to finish **late 2015/early 2016**.

The three versions of the text are freely available and it is now possible to see how the directive is likely to affect the research community. The Council's position is supportive of research with the need for added safeguards. There is the potential that aspects of the text from the European parliament may be incorporated that would contain a much more narrow definition of consent that make research more difficult to undertake.

It should be noted that irrespective of the text finally agreed the regulation will be introduced with a two year implementation period lasting until 2018.

ICO DEFINITION OF PERSONAL DATA

Personal data means data which relate to a living individual who can be identified –

- from those data, or
- from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller.

CONSENT FOR USE OF PERSONAL DATA

Current status - currently broad consent enables an individual to give consent once for their data or tissue to be used in a variety of research studies under certain conditions. The research has to be approved by an ethics committee and ongoing governance arrangements are put in place to ensure ongoing appropriate use of data and/or tissues.

- **The European Commission** – the Commissioners proposal was supportive of research through including a wide exemption for the processing of personal data for "historical, statistical and scientific research purposes". These rules

mean that specific consent is not required as a legal basis for processing personal data.

- **European Parliament** – the Parliament proposal however, would be restrictive for research as personal data for scientific research purposes could only be used with specific consent. The research exemption from specific consent is narrowed to only include pseudonymous data in "high public interest" where research "cannot possibly be carried out otherwise".
- **Council of Ministers –** The Council proposal is positive for research as key derogations of the Commission's proposal are maintained with an added emphasis on safeguards.

PSEUDONYMISED DATA

Currently researchers and related resources such as biobanks rely on broad consent where individuals give consent for their data to be shared in a pseudonymised form such as an "anonymised link" for a broad range of research processes.

If Parliament's amendments are accepted;

- Pseudonymised data would fall within the scope of the Regulation even if the key enabling re-identification is not accessible to the organisation handling the data.
- Pseudonymised data concerning health could be used without consent only in cases of "exceptionally high public interest"

RESEARCHERS AND DATA PROTECTION

The research community has a strong history of research ethics governance that goes beyond the strict legal framework. Researchers typically refer to the use of 'broad consent' but this term refers more to the ethical basis for the research rather than any legitimate basis for data processing. Broad ethical consent operates within a strict governance framework. On this basis the preferred option from the research community would be to retain the current research exemption for research activities in terms of data protection legislation.

ARE GENETIC AND GENOMIC DATA WITHIN THE SCOPE OF DATA PROTECTION LAW?

The new regulation specifically refers to "genetic data' as a category of sensitive personal data. The Council version of the text also specifically refers to genetic

information that can be obtained from an individual or analysis of a biological sample.

- Changes in law and advances in technology make the definition of ‘personal data’ not a fixed threshold.
- ICO have recognised that there is a need to accommodate the issues raised by new technologies but this could include a large amount of data that was previously outside the scope of the legislation.

It is important to recognise that the same constraints will apply to genetic data obtained from cell cultures derived from donated tissue/cells; however, consideration should also be given to the potential changes to genetic sequence during in vitro culture and derivation of cell lines. Furthermore, the new regulation potentially has boarder application to biomaterials.

DATA ACCESS ISSUES

Data access models are wide ranging from highly restrictive to relatively open. Some require high levels of accreditation in order to release personal data whilst other models require only basic certification of the requester in order to release data.

- This spectrum of data access needs to be reflected into the level of consent
- As data protection laws change even the storage of personal data may become problematic, which has ramifications for all types of data access model.

UK Expert Advisory Group on Data Access

http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/EAGDA/index.htm

Their recent report Governance of data access is most relevant.

NEXT STEPS

Until the trilogue negotiations are completed it is difficult for organisations to implement detailed plans to prepare for the new regulation, given the uncertainties regarding the final legislation.

It is possible to prepare by undertaking some simple audits of current data holdings and governance. This should consider the following elements:

- Categorisation of data
    - Is there a local data management plan?

    - Identify how data sets held sit within the current legislation; in order to create a prioritised list of data which would or may be, subject to the new regulation.
- Establish best practice
    - Does existing data governance allow data to be used for research (where currently only used for clinical purposes)

The preparation can be assisted with reference to the **MRC Regulatory Support Centre** that includes a data toolkit and confidentiality e-learning module:

http://www.dt-toolkit.ac.uk/home.cfm

http://byglearning.co.uk/mrcrsc-lms/course/category.php?id=1

- **Datasaveslives.eu Petition**

http://www.datasaveslives.eu/petition

Please contact Dr Beth Thompson (b.thompson@wellcome.ac.uk) to be added to;

1) DPR update list – focuses on following/influencing the legislation; and/or

2) EAGDA stakeholder list – to receive future reports and updates