Proposal for a EU General Data Protection Regulation (GDPR) – Impact on Health Research

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Opening up scientific information in Horizon 2020 and beyond: Open Access (OA)

**Goal:** optimise the impact of publicly-funded research and innovation

**Expected impacts:**
- Better science (build on previous results)
- More efficient science (avoid duplication & promote re-use)
- Economic growth (accelerated and open innovation)
- Improved transparency (involving citizens & society)

**How?**
- Open up scientific information resulting from EU-funded research (Horizon 2020)
- Work with Member States to encourage co-ordination of policies (→ Network of National Points of Reference, NPRs)
Open access to what scientific information?

1. Scientific publications:
   **Open Access (OA):** online access at no charge to the user
   Two main OA publishing business models
   - **Self-archiving:** deposit of manuscripts & immediate/delayed OA provided by author ("Green OA")
   - **OA publishing:** costs covered & immediate OA provided by publisher ("Gold OA")

2. Research Data:
   **Open Research Data (ORD):** data that can be accessed, mined, exploited, reproduced and disseminated – free of charge for any user

**Scientific information: increasingly blurred boundaries**
- **Scientific publications ... are data**
  - Text is data (text and datamining)
  - Underlying research data
- **Research data can be published (data publications)**
Open Access to Research Data Pilot in H2020
Pilot on Open Research Data (ORD): Scope

'Core areas' participating in the Open Research Data Pilot in Working Programme 2014-2015 are:

- Future and Emerging Technologies (FET)
- Research infrastructures – part e-Infrastructures
- Leadership in enabling and industrial technologies – Information and Communication Technologies (LEIT-ICT)
- Societal Challenge: Secure, Clean and Efficient Energy – part Smart cities and communities
- Societal Challenge: Climate Action, Environment, Resource Efficiency and Raw materials – except raw materials
- Societal Challenge: Europe in a changing world – inclusive, innovative and reflective Societies
- Science with and for Society

Actions in other areas can participate on a voluntary basis! by 'opting in' to the pilot, ie, health research
Types of data concerned:

- Data (including associated metadata) needed to validate the results presented in scientific publications ("underlying data")
- Other data (including associated metadata) as specified in a data management plan (DMP)
Beneficiaries participating in the Pilot will:

- Deposit a) underlying and b) "other data" as specified in the DMP into a research data repository of their choice
- Take measures to make it possible to access, mine, exploit, reproduce and disseminate free of charge (using e.g. Creative Commons licences)
- Provide information about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (where possible, provide the tools and instruments themselves)

**Note:** Actions participating in the Pilot are not obliged to make all datasets open (details described in DMP)
Pilot on Open Research Data: opting out

Actions may opt out of the Pilot on Open Research Data in Horizon 2020 in a series of cases (submission stage):

- If the project will not generate / collect any data
- In case of conflict with the obligation to protect results
- In case of conflict with confidentiality obligations
- In case of conflict with (national) security obligations
- In case of conflict with rules on protection of personal data (i.e., privacy)
- If the achievement of the action’s main objective would be jeopardised by making specific parts of the research data openly accessible
General Data Protection Regulation (GDPR)

- Strengthens individuals' rights to personal data protection
- Helps people better manage risks to personal data protection online
- A harmonised approach: one single law directly applicable to all EU MS, whereby a 'one-stop-shop' mechanism is established
  - to simplify the way businesses interact with data protection authorities (DPAs)
  - to facilitate cooperation between DPAs via 'cooperation' and 'joint-decision/co-decision' systems and the establishment of the European Data Protection Board (EDPB) as the body in charge of resolution of potential conflicts amongst DPAs
General Data Protection Regulation (GDPR)

- Commission proposal January 2012
- Parliament’s first reading March 2014
- During 2014 Council reached partial general approach (PGA) on international transfers, obligations of controllers and processors and last December on Chapter IX for provisions relating to 'specific data processing situations', including scientific purposes (along others such as archiving in public interest, historical and statistical)
- Council expected to reach general approach (Common Position) during the Latvian Presidency
- Trilogue to start in the summer?
GDPR and Scientific Research

• Currently, Directive 95/46/EC contains provisions for processing of personal data for scientific research purposes but MS shall implement their concrete application and legislate the possible limitations for research.

• Thus divergencies in implementation exist which create a complex, fragmented and legally uncertain landscape of national data protection laws, as well as high administrative costs.

• The Regulation would introduce a single set of rules on personal data protection, thereby affording a better harmonised EU legal framework.
Commission Proposal for a GDPR—key provisions on health & research

- **Lawfulness of processing**: art. 6.1 (consent, performance of a contract, compliance with legal obligation, tasks in public interest or with official authority, legitimate interests of data controller) and 6.2 (processing for archiving in public interest, historical, statistical or scientific purposes) which refers to conditions and safeguards in art. 83

- Article 83 is based on **principles of proportionality, necessity and data minimisation**, as well as **anonymisation/pseudonymisation** as long as the processing purpose allows

- Article 81 - personal data concerning Health: Art 81.2 clarifies that **processing of personal data concerning health for scientific research purposes** is subject to the conditions and safeguards in Art 83

- **Special categories of data** (so-called 'sensitive data' such as 'genetic data or data concerning health') – general prohibiton for processing, with exceptions - Art. 9.2. (h) and (i): Exemption from general prohibiton for health and historical, statistical and scientific research purposes (art. 9.2(h) refers to art. 81 (i) which in turn refers to conditions and safeguards in art. 83)
Parliament’s amendments to Chapter IX

- Introduce the requirement of consent and pseudonymisation in Arts. 81 and 83
- However, “Member States law may provide for exceptions to the requirement of consent for research, ..., with regard to research that serves a high public interest, if that research cannot possibly be carried out otherwise” – Art 81.2a
- Seems to introduce ‘broad consent’ in Art 81.1b “consent may be given for one or more specific and similar researches”...BUT also those "similar researches" must be specified and be subject to the information requirement
- It is highly interested in leading the legislative process to its conclusion (according to recent comments by EP LIBE rapporteur Albrecht at the 'Computers, Privacy and Data Protection 2015' Conference)
Council’s Partial General Approach (PGA) on Chapter IX

- Art 83: Introduces “Derogations applying to processing of personal data for archiving, scientific, statistical and historical purposes”

- Art 83.1: “...Union or MS law may, subject to appropriate safeguards for the rights and freedoms of the data subject, provide for derogations from Articles 14a(1) and (2), 15, 16, 17, 17a, 17b, 18 and 19,...” (rights to rectification, objection, restriction of processing and data portability) > Potential impact on cross-border research?

- Art 83.2. refers to safeguards: “...to minimise the processing of personal data in pursuance of the proportionality and necessity principles, such as pseudonymising the data, unless those measures prevent achieving the purpose of the processing and such purpose cannot be otherwise fulfilled within reasonable means.”

- Art 81 deleted and displaced to article 9

- COM delegated acts suppressed for Arts. 81 and 83
CONCLUSION

• Main role now for co-legislators to decide on this proposal (EP and Council in co-decision)

• Commission's role as facilitator in trying to strike the right balance between high level of personal data protection and fostering other public interest goals such as the promotion of health, research and innovation