Impact of the new EU Data Protection Regulation on health research

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Background to the Regulation

- Proposal from Commission in January 2012
- Regulation = directly binding
- Will replace 1995 Data Protection Directive:
  - development in technology
  - harmonisation
  - strengthen individual rights
- Covers use of personal data across all sectors except for law enforcement

A positive outcome

- European Parliament amendments *not* included in final text
- Would have provided only an extremely narrow exemption from specific consent:
  - for pseudonymous data;
  - in “high public interest”; and
  - where the research “cannot possibly be carried out otherwise”
- Joint effort from research community to reach better outcome

Where we are now

Dec ‘15 Informal agreement

Legal-linguistic checks

Apr ‘16 Adopted in formal votes on final text

24 May ‘16 Enters into force

25 May ‘18 Takes effect

Regulation: General points

- Demonstrating compliance (A.5 & 30)
- Requirements for Data Protection Officer (A.37-39)
- Rules on data breaches (A.33-34)
- Fines for non-compliance: up to €20,000,000 or 4% global turnover (A.83)

Regulation: Scope

- “Pseudonymisation” now defined (A.4(5)) – mismatch with definition typically used in research
- Clarification needed on how pseudonymised data fits with the scope (R.26):
  - “data which could be attributed to a natural person with the use of additional information, should be considered information on an identifiable natural person” BUT
  - Taking into account “means reasonably likely to be used”

Regulation: Lawfulness of processing

- Legal basis:
  - **Consent** – more flexibility for research (R.33); or
  - **Legitimate interest** – not for public bodies (A.6(1)(f)); or
  - **Public interest** – needs MS law, but may include private organisations (A.6(1)(e))
- Special categories (inc. health):
  - **Consent;** or
  - **MS research exemption** (A.9(2)(j) and A.89))

Regulation: Research exceptions

- **Further processing:** research deemed “not incompatible”
- **Data storage:** not limited if solely research use
- **Derogations from data subject rights:**
  - Information to data subject, where data not collected directly (A.14);
  - Right to erasure (A.17);
  - Right to object – but only for tasks in public interest (A.21).

Regulation: Research safeguards (A.89)

- Only benefit from research exceptions where appropriate safeguards are in place:
  - MS to set out requirements.
  - Anonymised data must be used where possible.
  - Pseudonymisation suggested as another safeguard.
- Some other conditions apply
- MS may also create further research derogations

What happens next

- **Implementing legislation** needed in each MS e.g. on research safeguards
  - Fragmentation v. harmonisation
- **Guidance** needed for clarification e.g. pseudonymisation and scope
  - MS and/or EU (European Data Protection Board)

How can the community prepare?

- Don’t panic!
- Consider how you are applying the current law
- Don’t forget projects also need to comply with ethics framework
- Take opportunities to feed in to draft guidance and legislation

What do we want to see?

- **Clear laws for research** with safeguards and exemptions to support research while respecting privacy;
- **Guidance to promote proportionate and consistent interpretation**;
- National ministries to **work with the research community to inform implementation**; and
- Member States to work together to **promote harmonisation and compatibility between national systems** where possible.

Further information

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