GDPR and medical research

ICCD 2022 – part II "How to optimise the GDPR to facilitate childhood cancer research" 02/02/2022

Owe Langfeldt
Directorate-General Justice and Consumers – Data Protection

GDPR and medical research

Data protection rules as ‘code of the road’

- Ensuring protection of people against overreach by organisations;
- What for? To protect dignity and autonomy of individuals, while also ensuring that fair and lawful processing can take place;
- GDPR is evolution, not revolution - most principles date back to the former data protection directive 95/46/EC, if not all the way to Council of Europe Convention 108 (1981).

GDPR and medical research

Quick recap of (some) main rules

- Lawfulness/conditions of processing (Articles 6 and 9 GDPR)
  - Role of different lawful bases for processing – not only consent!
  - Difference between “data protection consent” to processing and “informed consent” to medical intervention (see EDPB Opinion 3/2019);
  - Recital 33 on “broad” consent – interaction with information obligations;
  - See also 9(2)(j): processing which is “necessary for […] scientific or historical research purposes or statistical purposes”, based on laws which “provide for suitable and specific measures to safeguard the fundamental rights” of the data subject.
- Possibility for additional MS rules in the health field (Art. 9(4)) (study for EC on implementation)

European Commission

GDPR and medical research

Quick recap

- Presumption of compatibility and safeguards (Articles 5(1)(b), 89(1))
  - certain privileging of research over other secondary uses, but safeguards required, e.g. reference to pseudonymisation in Article 89.
- Transparency and data subject rights (Articles 12-22, recitals 33, 57)
  - People have a right to know (NB: possible exemptions from information obligations in indirect collection scenarios), to have incorrect data rectified, etc.
  - Possibility to lay down (by law) derogations from data subject rights (e.g. access) under certain circumstances (Article 89(2)).

What's next?

EDPB Guidelines on scientific research

- EC invited EDPB to provide guidance in 2020 GDPR report; first indications in reply to EC questionnaire;
- EDPB is working on Guidelines:
  - Stakeholder event 30/04/21;
  - likely to cover e.g. "broad" consent, secondary use, indirect collection and information obligations in that situation, Article 89 GDPR safeguards;
  - Timing: expected this year;
- Standard procedure: publication of a version for public comments, finalisation after feedback.

Thank you

European Commission