NFU DSA

Delad Workshop

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Anne Jan Sikkema

Radboudumc

Some history

- NFU = association of the 7 Dutch academic hospitals
- Mid 2018: request from NFU Committee 'Privacy in Research':

  'Can our legal people draft one document that will allow the exchange of clinical data for research without additional hassle?'

- Consulting and writing group was formed, consisting of legal advisors from 4 academic hospitals (containing expertise in contract and privacy law).
- Deliberations concluded with answer:


No
No
No
No
No
No
No

Why not?

Too many scenarios to effectively include into one agreement:

- Joint research: will require joint controllership arrangements as stated in Art. 26 GPRP.
- Actively processing data purely on behalf of the other party: will require a service agreement and data processing agreement as stated in Art. 28 GDPR.
- Supplying existing data upon request of other party for their research: will require clauses on separate controllership

Additionally, specific non-GDPR clauses are needed to cover each specific situation, especially in the collaboration scenario.

What COULD we arrange for?

- Third scenario: *Supplying existing data upon request of other party for their research. Separate controllership.*
- Difference with second scenario '*Processing on behalf of*':
  - No service/assignment relationship: providing party acts on request, not on instructions of the other party and usually at no compensation
  - Very limited processing: provision of existing dataset, already collected for previously determined purpose
- Writing group drafted template, shared with every NFU member for input and approval. Uploaded to ELSI webpage:

Link: Waar vind ik een voorbeeld van een Material Transfer Agreement en Data Transfer Agreement? | Elsi Servicedesk (health-ri.nl)

Applicability (again):

Scope of use:
This Data Sharing Agreement template ("Template") has been set up in conjunction with legal advisors of all Dutch academic hospitals and serves to facilitate and regulate the transfer of/access to personal data that were previously collected by a Dutch University hospital ("Provider") from patients, participants and/or volunteers for the purpose of scientific research, by an external not-for-profit party ("Recipient").

This transfer/access is only permitted for *Recipient's own* investigator-initiated research (single centre). The role of Provider in this Template is solely as provider of data that is already in its possession. Provider does not (co-)initiate the research, nor does the Provider participate in the performance of the research. For transfer of personal data for the purposes of such a joint research project, a collaborative research agreement or another type of agreement with joint data controllership will be the proper document to use. If Provider is asked to actively collect data from subjects instead of providing existing data, a prospective study agreement may be the proper document to use. For such different documents, please contact your institution's legal advisors.

(taken from introductory text of the DSA)

What about legal grounds and prohibition contained in Art. 9 GDPR?

- Consent
- Possible alternative, if initially collected for different purpose based on a valid legal ground (as set out in Article 6 GDPR); purpose limitation 5.1 sub b GDPR:

> manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation');

- Apply Article 9 section 2 sub j GDPR:

> (j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

What about legal grounds plus prohibition contained in Art. 9 GDPR?

- Apply national implementing legislation in latter scenario.

Dutch implementing legislation allows for foregoing the consent procedure if a) the planned research serves a common interest, b) it can be proven that asking (additional) consent is not possible or would be too burdensome and c) sufficient precautions are taken. (Article 24 Uitvoeringswet AVG)

- Ask independent Ethics Committee ruling if possible
- Limit data and pseudonimize

Ensure that Data subjects' right can be enforced

- Add clear data description in Annex 1 to the DSA so that you KNOW where subject's data is at any time (data breaches!).
- Add clear research description in Annex 2 so that you limit use and can inform subjects
- Set up a channel through which the Data subjects can be informed of the research that their data is used in. Website?

Sending data outside EEA

- Check if EC adequacy decision applies
- If not: add EC Standard Contractual Clauses C-C and:
  - Actively check whether recipient can abide by the SCC terms (see Article 14 SCC; also document your efforts). If to USA: specifically check applicability of the “Foreign Intelligence Surveillance Act” (FISA), whether recipient has previously received government requests for these types of data and how they handle them. Also be extra strict on data minimising and pseudonymisation.
  - Check recipient’s technical and organisational measures (Annex to SCC)