COREON Statement[1]
'further use' of personal data for scientific research

Secretariaat COREON
Annemarie Janse – Virtual Assistant t.b.v. secretariaat Coreon
T: 0654695708
E: coreon@federa.org
W: www.federa.org/over-coreon

Summary

One of the principles of the GDPR is the purpose limitation principle (article 5.1b GDPR). Personal data may only be collected for clear, specified and explicit purposes and may not be further processed in a manner incompatible with these purposes.

The second part of this article states that further data processing for scientific research or statistical purposes is not incompatible with the original purpose.

This further processing for this purpose is permitted in principle, even of the first purpose is a different one such as a medical treatment contract. A new basis is not required. But this is not a licence:

1. It must concern scientific research as defined in the COREON Statement on scientific research.
2. The exception does not create a new independent basis. It concerns 'further use' by the controller (or their processor) of data already obtained on a legitimate basis.
3. The dataset obtained through the 'further use for the purposes of scientific research' may only be used for scientific research, whether by the controller themselves or by a third party to whom the dataset is made available.
4. In the latter case that third party also requires a legal basis to process the personal data if the dataset still contains personal data. Such a third party has become a new controller.
5. Each 'further use' of personal data for scientific research must comply with the principles of data minimising and data protection by design and default. In the context of health research the protocol must make clear why which data in which stage of the research are necessary and what privacy measures such as pseudonymisation or possibly anonymisation are to be used.
6. For personal data which in a treatment relationship are only accessible to those directly involved in the execution of the treatment contract, that access limitation continues to apply to 'further use'.

[1] For more on the COREON statements see the justification at the end.

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1. **The question**
   What is the implication of purpose limitation (article 5.1b GDPR) for scientific research[2]?
   Article 5.1b, first part, states in short that personal data should be collected for specified, explicit and legitimate purposes. Further use must not be incompatible with this.
   The second part states however that further processing for scientific research is not deemed incompatible.

2. **Why is the answer to that question important?**
   'Further use' of patient data for quality improvement and scientific research is an extremely important element for a 'learning healthcare system'.[3] A very large number of registries and research is based on this 'further use'.
   That 'further use' for the purposes of scientific research and statistics was not in principle incompatible had already been legislated for in the Netherlands in the Personal Data Protection Act. The question there was whether it was still possible under the GDPR or if there were additional conditions which were not applicable earlier. In a number of countries the second sentence of article 5.1b is new and there appeared to be a reluctance to apply this provision.

3. **What does the GDPR say?**
   Refer to the question above for the relevant article. In addition to the second part of article 5,1b there is also article 6.4 GDPR which contains specific criteria for the compatibility test.

4. **Discussion and interpretation**
   The first juridical question is if one cites article 5.1b as the legal basis, does one also need to apply the compatibility test in article 6.4 GDPR? A positive answer would be absurd. That would render the second part of article 5.1b superfluous. Consideration 50 (which contains an explanation of article 6.4) also refers first to that second part of 5.1b and only if that or another argument doesn't apply, to the criteria in 6.4.
   A less far reaching view is that the second sentence of 5.1b gives scientific research a preferential status in the context of the compatibility test in article 6.4 GDPR but that the test is still important.
   In that respect the definition of scientific research is important in order to

[2] For more on this term, see the COREON Statement about scientific research.
[3] See amongst others E.B. van Veen, Big Data voor een lerend zorgsysteem, in Big data in de zorg, Preadvies Vereniging voor Gezondheidsrecht 2017.

qualify for the exception. See the COREON statement on scientific research for more on this. If the criteria for scientific research in that statement are met and the limitations on this 'further use' for scientific research mentioned in this statement are followed, then in practice the criteria in article 6.4 GDPR will also be met.
The second point in the summary originates from article 5.1b but there appear to be misunderstandings about it. The principles are directed to the controller that collected the data for a certain purpose and aim. That controller may further use the personal data for scientific research without requiring a new basis. The exception to the purpose limitation principle does not create a basis for the collection of personal data.
There first needs to be a basis, then processing (collection) and then possible 'further use' of the data processed on that basis for scientific research and statistics.
The third point means that the exception to the purpose limitation principle for scientific research needs to be maintained throughout the lifecycle of the dataset so collected. That is implied in article 5.1b (and 6.4) and was, for example, already embedded in Dutch law. Should that dataset be made available to a third party, this condition can be incorporated in a data transfer agreement.
The fourth point in the summary clearly states that should a third party receive such personal data, they need a basis under the GDPR and the relevant national implementation thereof to process the personal data (as does the provider in order to make them available). For example, article 24 of the Dutch Implementation Act of the GDPR (exception to the principle of consent) could be such a basis.
The fifth point in the summary follows from article 89 paragraph 1 GDPR. A large number of research exceptions point to this article.
The sixth point in the summary ensues specifically from the Dutch legislation on healthcare contractual obligations (other countries may have differing legislation). Further processing for the purposes of scientific research does not imply that people unauthorised to access personal data collected for the purpose of treatment and healthcare are suddenly granted access.
Modern digitised patient files in hospitals and general practice afford new possibilities for providing access to data. Automated systems employing privacy by design can make data available without the need for a healthcare professional to select the data by hand. ICT support will probably be needed. If such ICT support was involved in setting up the primary system, dealing with healthcare records and the healthcare facility's access systems, this would not be regarded as third party involvement and thus not a breach of patient confidentiality.

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Naturally all data processing (also for 'further use') needs to comply with all relevant EU and national standards applicable to the processing of healthcare data. These COREON statements do not go into these preconditions. They deal only with particularisations.

5. What has changed?

In the Netherlands, nothing has changed. National legislation had already implemented article 6.1b of Directive 95/46/EG, but not all member states had done so. The GDPR is now in force in all member states including the European Economic Area[4]. This wasn't apparent to all Data Protection Authorities however.

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[4] Including Norway and Switzerland.

Justification

Through the COREON GDPR Statements, COREON intends a clarification of the terms used in the GDPR.
The following criteria qualify a Statement:

- The statement refers to a limited defined subject from the GDPR
- It should be relatively simple to reach a consensus
- It should be relevant to members of COREON.

COREON is a Dutch commission for regulations in (observational) research. A large number of research groups and institutions in healthcare is represented by COREON. For more over COREON, see: https://www.federa.org/over-coreon .

The initiative for the Statements was given at the general meeting of COREON on 24th November 2017. The coordinating author of this Statement was Evert-Ben van Veen. The Standing Committee of COREON were critical co-readers and supplied input. Alongside them were three members of COREON: Remy van den Boom (TNO), Jasper Bovenberg (BBMRI-NL) and Remco Coppen (NIVEL).

Although the Statement represents the present consensus of a wide group of those involved in the field, new insights can give cause for amendment. Take note therefore of the date and version number. The first digit represents the most recently published version. Naturally neither COREON, the Standing Committee of COREON nor any of the contributors can be held responsible in the event that you follow the Statement but another party thinks differently about what is postulated in the Statement.

NB: English translation made by Graham Kennett.

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