COREON Statement[1]
Scientific research

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Summary

Scientific research has a special status in the GDPR but is not defined further in the GDPR. This statement elaborates on the definition of the term scientific research. This definition is important in justifying the special status of scientific research. Aimed specifically at the observational care and health research carried out by members of COREON, scientific research needs to meet the following criteria (some of which overlap):

1. Scientific research aims towards new, generally applicable insights (a hypothesis, a correlation, a theory or a combination of these).
2. It is carried out according to the accepted methodological standards applicable to that kind of research.
3. The data processing for the purposes of the research doesn't directly lead to conclusions regarding the subjects involved. There is always a 'translation' of the results into practice (measures for the organisation of the healthcare system, guidelines for prevention or treatment)[2].
4. The research is capable of being replicated[3].
5. The research complies with generally recognised criteria for scientific integrity[4].
6. The results are always eventually published[5].
7. The underlying data are available according to the FAIR principles[6].

[1] For more on the COREON statements see the justification at the end.
[2] This also applies to the reporting back of 'findings'. Then an appraisal will be made which does not lie with the researchers. See the Human Tissue and Medical Research: Code of conduct for responsible use (2011), the English translation of the Code Goed Gebruik 2011.
[3] http://stm.sciencemag.org/content/8/341/341ps12
[4] https://www.knaw.nl/shared/resources/actueel/bestanden/nederlandse-gedragscode-wetenschappelijke-integriteit-2018-nl
[5] A certain term (period of grace) to allow submission of a patent is acceptable. A patent is also a form of publication but the majority of research does not lead to a patent or research dossier for the admission of a medicine or medical implant onto the market.
[6] https://www.dtls.nl/fair-data/fair-data/ Fair data is not the same as 'open data'. That refers exclusively to the catalogue of metadata which doesn't contain personal data. Conditions can certainly be imposed on the availability of data where personal data is involved. For examples of good processes in this connection, see: Ohmann C, Canham S, Banzi R, Kuchinke W, Battaglia S., Classification of processes involved in sharing individual participant data from clinical trials, F1000 research, https://f1000research.com/articles/7-138/v2

8. Researchers need to be able to justify why this research could *eventually*[7] contribute to better healthcare schemes, prevention or treatment[8].

The choices inherent to these criteria and refinement of the wider term of scientific research are explained below.
To be clear, these criteria only aim to define when an activity can be regarded as scientific research in the context of the GDPR. They say nothing about whether such an activity is permissible (although it could simplify the review procedure).

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[7] This means that fundamental research is not excluded. Fundamental research not involving personal data is not included in this specification of scientific research. The special status in the AVG is not then applicable.
[8] See further by point 6 of the explanation.

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1. **The question**
   What does the term scientific research mean in the context of the GDPR?

2. **Why is the answer to that question important?**
   The GDPR recognises a number of exemptions for scientific research to the general regimen of the GDPR. Some of these apply directly (such as 5.1b GDPR, see the COREON statement on 'further use'), others require implementation in national legislation.

3. **What does the GDPR say?**
   The GDPR does not define scientific research. Consideration 159 shows that scientific research should be interpreted broadly. By referencing article 179.1 of the Treaty on the Functioning of the European Union, commercially driven scientific research is also covered, for example.
   In the Netherlands the Implementation Act (UAVG) similarly does not define scientific research. Article 24 of that Act (implementing article 9.2.j GDPR) does state that in the case of an exception to the principle of consent, the research must be in the public interest. Dutch civil law also refers to public interest but does not define what that is, although in the proceedings over the Dutch Bill on healthcare treatment contracts this was gone into. This will be referred to later.
   Article 44 of the Dutch implementation legislation limits the exemptions to the general regimen to institutions or services for scientific research and statistics. A definition of these institutions or services is not given.

4. **Discussion and interpretation**
   A broad transdisciplinary definition of scientific research quoted in the Dutch code of conduct for scientific integrity is taken from ALLEA: "the quest for knowledge obtained through systematic study and thinking, observation and experimentation"[9].
   This code of conduct doesn't leave it there. It delves extensively into the general transdisciplinary normative principles regarding the how of scientific research.
   The Article 29 Working Party, now the EDPB, states in its Guidelines on informed consent that, despite the broad meaning in Consideration 159, "the notion may not be stretched beyond its common meaning and understands that 'scientific research' in this context means a research project set up in

[9] ALLEA – All European Acadamies: European Code of Conduct for Research Integrity (https://www.allea.org/publications/joint-publications/european-code-conduct-research-integrity/)

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accordance with relevant sector-related methodological and ethical standards, in conformity with good practice".
That last bit is a little unclear but at least means that the criteria do not only describe *what* scientific research is but also, even though quite globally, *how* it should be carried out according to current opinions.
This statement goes into that further, also with reference to the literature.
The Article 29 Working Group comment is incorporated in the second point of the summary above. The methodology of big data hypothesis generating research will naturally be different when the aim is to confirm or exclude a causal relationship.

5. The interpretation by COREON

In order to justify the exception laid down in the GDPR to a number of specific provisions of the GDPR and the fundamental rights to data protection, a substantive normative definition of scientific research is required.
That definition is provided here for COREON. Its application is aimed at observational health and healthcare research. These terms do not have generally applicable definitions, either. Healthcare research concerns the functioning of the healthcare system, and health research concerns the factors that influence health and illness including factors which influence treatment once illness has occurred, but, in the Netherlands, not research covered by the Medical Research Involving Human Subjects Act (WMO) which has a special legal regime. The third criterion would not automatically apply to such non-observational research. Sometimes healthcare research and observational health research will overlap. There are also extremes. Healthcare research can involve political decision making and the resultant consequences for the healthcare system. Health research can also be concerned with fundamental underlying biological processes.
From the substantive normative point of view it is not enough to define this research by what it concerns and how it is carried out but also by what purpose it serves. That is apparent from the eighth criterion which COREON didn't come up with themselves but had already been suggested in the literature[10]. The eight criteria taken together have also been previously suggested in the literature (although comprising only seven then)[11].

[10] Floridi L, Luetge C, Pagallo U, Schafer B, Valcke P, Vayena E, et al. Key ethical challenges in the European medical information framework. Minds Machine 2018. https://doi.org/10.1007/s11023-018-9467-4
[11] E.B. van Veen, Observational health research in Europe: understanding the General Data Protection Regulation (GDPR) and underlying debate, EJC 2018, https://www.ejcancer.com/article/S0959-8049(18)31402-3/pdf

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This substantive definition does not exclusively apply to the exemptions in the context of the GDPR. When someone is invited to take part in scientific research and that research is based on informed consent, the potential participant has a certain expectation. The criteria cover the expectation that people in general have about scientific research in healthcare.
Of the eight criteria in the summary, the last one is the most complex. Hence the following separate paragraph. The explanation of the other criteria, in as much as they are not self-evident, can be found in the footnotes.
Of course a good number of these criteria also apply outside the more defined COREON research domain.

6. Relationship of the criteria to the term 'public interest'

Many books have been written about 'public interest'. A summary of these is not intended here.
The following benchmarks are important to the discussion.
The first is that public interest as intended in the GDPR and the exemptions (or particularisations) for scientific research in the GDPR do not coincide, neither do they have to. It occurs only in one case in the GDPR that the research exception for scientific research is linked to public interest[12]. Apart from that they are two different basis for an exception to the general regimen of the GDPR: either public interest[13] or scientific research. The terms public interest and scientific research are distinct from each other. In the Dutch Implementation of the GDPR they don't coincide either. It is firstly scientific research and then also in the public interest.
Public interest in the GDPR presupposes an Act of Parliament determining that activities of a certain organisation are in the public interest. The majority of the members of COREON do not fall under public interest in that specific GDPR meaning, even if they are subsidised by public means.
The second benchmark is that the term 'public interest' also has a wider meaning. In many discussions in political philosophy and in politics it is a benchmark for a just society. What that is exactly is open to discussion of course. But according to many it means that the rights of minorities are also protected. Public interest and the interest according to the current opinion of the majority do not necessarily coincide.
The third benchmark is that the special status of scientific research in the context of the discussion about public interest has a much wider reach than the particular groups which could possibly benefit from it. Scientific research

[12] Namely in article 21.6.
See http://www.medlaw.nl/wp-content/uploads/2018/01/GDPRrshexemptionsv.1.4.pdf
[13] A term which occurs 23 times in the GDPR but which is not defined.

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serves a public interest because this implies an open democratic society where open debate can take place. Hence scientific research should sometimes dare and be allowed to swim against the current. Otherwise, to use an extreme example, the sun would still be turning around the earth.
It is therefore up for debate whether all scientific research should meet all the criteria in this Statement. The GDPR also contains a provision on the freedom of expression and information (article 86). This provision is more open ended and also more dependent on national implementation. It would seem that in order for scientific research to be classified as such rather than just opinion[14] or journalistic expression that within certain boundaries deserves protection, it should meet at least the second, fourth and fifth criteria. Dishonourable science cannot be in the public interest in that wider sense. In the context of COREON, the seventh and eighth criteria are also important. Alongside the sixth, but that doesn't distinguish them from opinions and journalistic expression.
The fourth benchmark is that the discussion about public interest in the light of a provision in the Dutch civil code the government determined that research was in the public interest when it was anticipated that 'large groups of patients' could profit from it. This would seem to conflict with the second benchmark. Back then (1992-1994) rare diseases were seldom considered. The discussion about extending the possibilities for 'orphan drugs', for example, came much later.
Here the discussion of this benchmark leads to the conclusion that the parliamentary papers of the time should not be taken too literally. It is not acceptable that public interest should mean that we disregard certain minorities of patients. The discussion does however mean that you have a more or less concrete perspective of how the research can contribute to better healthcare, treatment or prevention (courses of action in general).

What do these considerations mean for the exemptions?

- Each scientific research is in the general interest of an open democratic society. It must meet certain criteria to distinguish it from other activities in the public debate. It does not have to concern gratifying subjects or results in the eyes of the majority of the population (however that may be determined).
- Some research needs to be more in the public interest than all the other scientific research already is[15]. In that case researchers need to provide a

[14] Such as those of opponents of vaccination.
[15] In the Netherlands, for example, research falling under article 7:458 of the Civil Code and article 24 UAVG or article 28, paragraph 2 under b UAVG. This article determines that scientific research using genetic data, even with consent, should be in the public interest.

concrete response to the eighth criterion. That still might not be gratifying for the majority, but researchers need to show how they think this research can improve the position of certain groups in terms of courses of action (possibilities that these groups can make use of themselves or can be offered to them or contribute to the debate about further courses of action)[16].

- Certain organisations are designated research institutes that conduct research in the public interest. That is a specific designation laid down by law. The 8 criteria apply to them just as much. Whether their research in terms of the choice of research can also be ungratifying will depend on the degree of freedom the organisation has according to its constitution (for example, possibly requiring approval of an annual plan). Once the research is under way it needs to meet all the criteria and the results might sometimes be uncomfortable. To qualify under the provision in the GDPR referred to in the second point above, these organisations will also have to meet the requirement of the eighth criterion.

7. What has changed?

The premise is that the criteria were already implicitly being met by members of COREON. In that sense little has changed although any elucidation can give cause for reflection. When collaborating with commercial partners, care needs to be taken that written agreements with these partners guarantee the application of the various criteria. The EU IMI[17] projects (with public-private partnerships) are a case in point. Thus in that context is why the basic principles of 'bona fide research' were mentioned (note xx). This Statement dovetails with that, just as with the principles from the Dutch Code of Conduct for scientific integrity.

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[16] It will often be of extra importance how the results are communicated. Article 3.6 of the Dutch Code of Conduct on scientific integrity (see note 4) summarises this.
[17] Investigational Medicines Initiative.

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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