Consultation Response of the Central Committee on Research Involving Human Subjects (CCMO, The Netherlands) regarding EDPB Guidelines 01/2026

The Central Committee on Research Involving Human Subjects (CCMO) is responsible in the Netherlands for the review of medical-scientific research involving human subjects and, in doing so, oversees the protection of research participants. In addition, under the Medical Research Involving Human Subjects Act (WMO), the CCMO acts as the supervisory authority for all accredited medical research ethics committees (METCs) in the Netherlands and holds the statutory authority to establish guidelines that provide direction for the assessment of such research. In this context, the CCMO assesses, among other things, the safeguards for the processing of personal data in accordance with the General Data Protection Regulation (GDPR).

The CCMO has reviewed Guidelines 01/2026 of the European Data Protection Board and, in response, wishes to bring the following remarks to your attention.

Regarding Chapter 3:

Comment point – reuse of research data for AI training

In practice, participants in medical-scientific research projects are increasingly being asked whether the personal data collected for the study may be reused after the study has concluded for the purpose of training AI models. Although the draft guidelines provide valuable clarifications on further processing for scientific purposes, they currently lack a concrete explanation of how these rules apply when research data are used for AI training.

Given the rapid growth of AI applications within the scientific domain and the specific risks associated with them (such as model leakage, challenges in applying data minimisation, and the limits of pseudonymisation), it would be helpful if the guidelines included an explicit example or case study illustrating how such reuse should be handled.

Such clarification would contribute to a uniform interpretation within research practice and would provide both researchers and participants with greater certainty regarding the conditions under which research data may be processed for AI-training purposes.

Regarding Chapter 4:

Comment point – application of legitimate interest in further processing for scientific research

The EDPB acknowledges that scientific research may, under certain circumstances, be based on a legitimate interest (Art. 6(1)(f) GDPR), in combination with the exception for processing special categories of data for scientific research purposes (Art. 9(2)(j) GDPR). In practice, this may concern, for example, research on rare diseases, epidemiological research, or research on medication safety, where the societal interest in scientific progress carries significant weight and consent is not always feasible or reliable.

However, it remains unclear how controllers should assess whether reliance on legitimate interest is appropriate in situations where research data are reused for new, additional, or broader research purposes within the same research domain. In particular, further clarification is needed regarding how the balancing test should be conducted and which safeguards are considered minimally necessary in this context. Until now, 'consent of the data subject' has been the default basis for such further processing.

Given the importance of legal certainty for researchers, institutions, and participants, it would be especially helpful if the guidelines included a concrete example or case study illustrating how legitimate interest may be applied in the further processing of research data for additional scientific purposes.

Regarding Chapter 5

Comment point – Provision of contact details

In §5.1 of the guidelines, it is rightly emphasised that data subjects should be given the opportunity to voluntarily provide contact details in order to receive updates about the processing of their personal data. However, in the context of medical-scientific research, this passage may inadvertently be interpreted as an obligation or possibility for sponsors to process these contact details themselves.

According to ICH/GCP standards (including E6(R2)), a sponsor may not receive directly identifiable personal data of research participants. Contact details may only be managed by the research site or another authorised party. To avoid misinterpretation, we kindly request that §5.1 explicitly clarify that this requirement does not imply that contact details may be disclosed to the sponsor, and that standards such as ICH/GCP must be fully respected.

Regarding Chapter 7

Comment point – qualification of processing roles between sponsors and research centres

We note that, in practice, there are significant differences in how data-processing roles between sponsors and research centres are classified in medical-scientific research. Despite comparable starting points, centres are in some cases designated as processors and in others as joint controllers. This regularly leads to delays in concluding Clinical Trial Agreements and, consequently, delays in the initiation of research.

Guidelines 01/2026 do not provide sufficient clarity on this point:

Paragraph 140 appears to point towards joint controllership, as the processing cannot take place without the simultaneous involvement of both parties.

Paragraph 142, however, leaves room for a processor relationship when the centre is not involved in determining the purposes and means of the processing.

The factual situation is more complex than this dichotomy suggests. Although the sponsor typically drafts the study protocol, the research can only be conducted through the involvement of the research centres, which treat and enrol participants and also provide the sponsor with (pseudonymised) treatment data that were already collected in the context of care. This is not merely a transfer of data to a third party; it also involves a breach of medical professional

secrecy. In addition, both study-specific and routine care data are often used for the research database. Researchers are also bound by ICH/GCP and the Declaration of Helsinki, which require professional autonomy. Certain elements of the processing — such as management of the coding key; management of source data under their own legal obligations; their own retention periods; their own publication authority; and their own incident and data-breach obligations — can only be carried out by the centre.

It is therefore neither appropriate nor legally correct to classify participating centres solely as processors. This does not reflect their role and provides insufficient safeguards for the protection of research participants, particularly when sponsors are established outside the EEA. Given the indispensable role of the centres and the interdependence of their processing activities with those of the sponsor, joint controllership would be the most accurate qualification.

We therefore request the EDPB to provide explicit and unambiguous guidance on this matter and to limit the interpretative space currently left by paragraph 142, in order to prevent divergent interpretations and delays in practice.

Regarding Chapter 8

Comment point – anonymisation of research data

In general:

> We are concerned about the implicit assumption that anonymisation in medical-scientific research would be a feasible and appropriate standard. A valid assessment of anonymisation requires in-depth, specialised expertise, which is often lacking in medical research ethics committees in practice. As a result, there is a risk that datasets containing health data are too readily and incorrectly classified as "anonymous," leading to the erroneous conclusion that the GDPR is "no longer applicable."
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> Given the rapid development and use of AI techniques in scientific research, the risk of re-identification is increasing, and it is highly questionable whether data — particularly when managed together with biological material — can still be considered anonymous. For this reason as well, the message should be that anonymisation is usually not possible and that the GDPR will generally apply.

And specifically:

> In medical-scientific research, it is common for sponsors to state that data collected during a clinical trial will be anonymised after the study and used for follow-up research, while at the same time retaining the pseudonymised dataset from the same trial. In such situations, it is crucial to determine whether the dataset has in fact been anonymised within the meaning of the GDPR.
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> We therefore request that the EDPB more clearly describe in the final guidelines the conditions under which anonymisation is possible in this context, particularly because expertise in anonymisation is often lacking within medical research ethics committees.

In addition, the current guidelines do not explicitly describe cases in which anonymisation is, by definition, not feasible, such as genome data, medical imaging, rare diseases, small cohorts, and datasets used for or generated by AI models.

As AI is expected to become a structural component of scientific research, we consider it essential that the guidelines provide guidance on the conditions under which a dataset can still be regarded as anonymised in an AI context, given the increased risks of re-identification. After all, a dataset that appears anonymous on its own may still become identifiable once an AI model is combined with other datasets concerning the same individuals.

Finally, it may be worth considering the establishment of a certification system (confirming that data are GDPR-anonymous), issued by an independent body, enabling a sponsor or researcher to demonstrate — on the basis of such a certificate — that the dataset can indeed be regarded as GDPR-anonymous.