Public Consultation

Guidelines 1/2026 on processing of personal data for scientific research purposes

Part 1

Governance, compatibility and broad consent in scientific research under GDPR

1 Contributors

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2 Introductory note

This is part 1 of Contributors' response with respect to the public consultation concerning these Guidelines, and this part 1 addresses central concepts in GDPR. Part 2, submitted simultaneously, addresses technical safeguards and Part 3 contains the clinician's perspective.

The Guidelines are complete and will be helpful in assisting Data Protection Officers, controllers and all stakeholders to better understand, apply and comply with the GDPR. We believe that their final adoption will be instrumental in facilitating the approval and the management of scientific research projects, particularly in the area of health.

We note that these Guidelines introduce a positive change in attitude. The genesis of the GDPR was influenced by its time, characterised by the presence of new technologies, particularly social media, where the access to free information services turned the person into a willing product, and where persons accepted that the access to their personal data was the price to pay for such services. In this context, the GDPR was a courageous initiative, which brought the European Union to the forefront of the ethical processing of personal data and the protection of privacy rights.

But this complex law, focused on the protection of individual rights and on the imposition of severe penalties in case of non-compliance, caused a slowdown in research involving personal data. The European Commission reacted with the publication of the European Health Data Space Regulation, building on the requirements of the GDPR and making personal health data more shareable, access more agile and research more efficient.

These Guidelines clearly seek the same purpose and they focus less on the dangers of using personal data and more on the benefits of doing so. In that respect, they bring clarity and will greatly assist DPOs and regulators in finding more motives to accept a project, than to delay its approval or even reject it. For this reason, we broadly support these Guidelines.

The thesis of this Part 1 is that in complex scientific research ecosystems, compatibility, broad consent and further processing should be interpreted through governance, proportionality and structural equivalence of safeguards, rather than narrow thematic similarity between studies.

3 The fundamentally important concepts

3.1 On the benefits of scientific research

The Guidelines are explicit in presenting scientific research as a benefit to society (Executive Summary; paragraphs 56 and 61), in allaying concerns about the commercial uses of research information (paragraphs 11 [Key-indicative factor v] and 61), and in stating that such uses do not invalidate legitimate interest (Executive Summary). The case is well presented.

3.2 On the need for specific consents

Paragraph 54 makes an important point in these Guidelines, distinguishing, where consent is possible to be obtained, between:

- consent to participate in scientific research, which follows different models depending on the level of intervention on the patient, as per the World Medical Association's Helsinki Declaration, the Council of Europe's Oviedo Convention, or the European Union's Clinical Trials Regulation (EU) 536/2014, and

- consent to the processing of personal data, as is the case under article 9(2)(a) of the GDPR.

This distinction could be communicated to the data subject, to controllers and other stakeholders in a more unambiguous way if the Guidelines always used precise expressions, such as “consent for data processing” and “consent for research”.

3.3 On structural equivalence

The requirement of compatibility between an initial study where the data subject has given consent for data processing and a new study involving further processing has led to semantic debates whether two studies are “similar enough” However, it is the position of this Contribution that the debate should not focus on compatibility or similarity but whether scientific studies are structured in an equivalent manner and assess proportionality of impact on the data subject

Structural equivalence refers to the continuity of governance, safeguards, proportionality, research scope, security controls and data subject impact between the original and subsequent processing activities. This concept may provide an alternative to compatibility assessments based primarily on thematic similarity between studies and result in consent forms that are shorter and easier to read.

4 Requests for clarification and improvement

4.1 On further processing – compatibility, structural equivalence and the right to object

The Guidelines give considerable attention to the easing of constraints on further processing. We address here the special case where personal data has been obtained under consent for data processing for research study A and there is a scientifically legitimate reason to use the data in research studies B and C.

4.1.1 Issues

The Guidelines formally allocate compatibility assessment to the controller but operationally rely on the data subject’s ability to understand and evaluate the thematic and ethical relationship between future research activities and the original study. In complex health research ecosystems, this expectation may not be realistic or meaningful for most participants.

We are of the opinion that the emphasis on the person’s right to allow or object to personal data being used in Studies B or C should not be dependent only on “compatibility” between the three studies, which is difficult to assess, but on the structural equivalence between studies A, B and C. To illustrate this point, it is useful to place these three example studies in a specific context:

- Study A: “Assessing and comparing the efficacy and safety of angiotensin-converting enzyme and beta-blocker therapies in moderate to severe hypertension”;

- Study B: “Predicting the risk of myocardial infarction in hypertensive patients “.
- Study C: “Identifying diabetes biomarkers”.

Studies A and B are visibly “compatible” and the data subject may have no reason to object to having their data used in further processing in Study B, but may not be so willing in relation to Study C – because, say, the data subject is not diabetic and does not know what biomarkers are.

The right to object to further processing on the basis of compatibility or incompatibility of purposes between the various studies may lead to important research not being executed. Assessing the value of these studies purely on their titles, studies B and C are as useful to participating data subjects and to society at large as study A was.

Justifying further processing on the basis of compatibility between different studies may also be difficult to establish, being a highly technical matter and repeated compatibility assessments may not be realistically meaningful to the participant.

Moreover, considering the level of risk to which data subjects are subjected should be a material factor in the controller’s use of broad consent to justify a new study. Lower risk may justify broader purpose framing where safeguards compensate for reduced specificity.

4.1.2 Proposal

It is recommended that the Guidelines allow DPOs and ethics committees to verify that further processing remains within the legitimate, structurally equivalent research framework. It will be the controller’s responsibility to demonstrate and satisfy the DPO and the ethics committee that Studies B and C are equivalent to Study A in the dimensions described here.

The controller would be required to notify the participating data subject that the conditions of the further use of their personal data have been verified by competent and independent entities as being equivalent to those of the original study, and that they have the right to object, presented as an opportunity to opt-out from the new study.

A new paragraph is proposed:

> 23b. *When further processing for research purposes has been assessed by the ethics committee or other appropriate authority as maintaining equivalent safeguards, governance, scientific scope and risk relative to the original processing, the controller should so notify data subjects and offer them the opportunity to object with an opt-out mechanism.*

Finally, the Guidelines should de-emphasise excessive detail and encourage the layered approach currently suggested in footnote 82, page 27, by moving it to the main body of the text.

4.2 On further processing – using Personal Health Records in research studies

Paragraph 38 states that personal health data may be used for two interrelated purposes – providing healthcare and conducting scientific research – and this processing may be covered

by a single consent. Medical records generated in routine clinical practice normally contain the complete clinical history of persons and are an ideal source of data for real-world data research studies, as well as a readily available source for the precise selection of candidates for clinical trials and studies.

4.2.1 Issues

Where controllers store personal health data to assist in healthcare, they may use this master dataset to make a data subset available for scientific research use. When relying on article 9(2)(j) of the GDPR as the legal basis for scientific research, when the study ends and the purpose is exhausted, the controller is required to delete the study data, an action which ensures compliance with article 17(1)(a) of the GDPR. There are exceptions and mechanisms to facilitate keeping records for long periods of time: the opportunity of further processing already referred to, and the long-term retention of records for archival or statistical purposes. Article 89(1) of the GDPR covers this point adequately.

4.2.2 Proposal

However, if relying on article 9(2)(a) of the GDPR, the controller can obtain a broad consent for further data processing from the data subject which addresses data re-use in specific studies, always subject to the assessment of the protective framework being equivalent to the original processing. In this case, when the study is concluded, the controller would only be required to delete the data subset, and the master dataset would remain operational.

A new paragraph is proposed:

> 38b. *When a personal data subset used in scientific research originates from a master dataset of personal health records used for healthcare, the deletion of the subset when a study is concluded is without prejudice to the continued storage and processing of the master dataset.*

This supports the view that conditions for the processing of personal data for health care and for scientific research are distinct. They are subject to specific legal requirements, as the EHDS Regulation imposes a separation between primary and secondary uses.

4.3 On broad consent

Paragraphs 43 and 47 explain the concept of broad consent as a means to render access to data more agile and ensure continued support for further processing. Broad consent arose as a compromise to reconcile participant autonomy and scientific utility, but the concept is novel in the GDPR environment and is a welcome addition to it. However, further clarification is desirable in the Guidelines.

4.3.1 Issues

Paragraphs 44-46, 49 and 50 detail conditions to compensate the inherent openness of broad consent. In particular, EDPB has stated that broad consent cannot be interpreted as a means of circumventing the clear definition of purpose. The key issue lies therefore on the specificity

and clarity of the purpose in further processing, whether by delimiting the field, or detailing the expected outcomes, or possibly interacting with representative patient groups for confirmation. The current formulation risks narrowing the practical utility of broad consent, which could confuse all stakeholders.

Moreover, these paragraphs make no reference to the risk to data subjects who may be involved in further processing, which varies with the type of research – high in the case of a clinical trial investigating an experimental drug, lower in a prospective observational study, and very low in the case of real-world data obtained in routine clinical practice. Including a reference in the Guidelines to the risks involved in the structural equivalence assessment as means to modulate the broadness of consent would also be helpful.

4.3.2 Proposal

The Guidelines should provide for greater flexibility in accommodating broad consent to enable further processing. An innovative approach to the broadness/narrowness dilemma would be to combine the functionality of the consent for data processing with the protection of the ethics committee. Data subjects could be offered the opportunity in the consent for data processing to accept to have their data used in scientific research including further processing, provided:

a) Each scientific study is approved by the ethics committee, and
b) The research results are communicated to the attending doctor and to the data subject who has indicated a wish to receive them.

This approach could operate with a common data governance, where a controller provides interrelated primary and secondary uses of data, and allow the data subject to give consent just once, in the consent for data processing. This would combine with the new paragraph 23b proposed above in section 4.1.2 on the right to object by opting out of the new study.

A new paragraph is proposed:

> *38c. Where a controller manages a health data infrastructure for interrelated primary and secondary uses, the consent for data processing may support scientific research, provided the ethics committee or other appropriate authority has assessed the consent for data processing as adequate for scientific research, including further processing where the controller has demonstrated structural equivalence, and the research results, when relevant to health care, are communicated to the attending doctor and to the data subject who has indicated a wish to receive them.*

5 Conclusion

The Contributors broadly support the Guidelines and welcome the EDPB's effort to facilitate the responsible use of personal data for scientific research purposes. In particular, the Guidelines correctly recognise the societal value of scientific research, the legitimacy of broad consent, and the importance of facilitating further processing under appropriate safeguards.

This contribution proposes that, in complex scientific research ecosystems, compatibility assessment should increasingly rely not only on thematic or scientific similarity between studies, but also on the structural equivalence of governance mechanisms, safeguards, proportionality and data subject impact. Such an approach would reconcile the operational realities of longitudinal health research with the privacy rights of citizens and the architecture of the European Health Data Space.

The Contributors also propose that the Guidelines more clearly distinguish between consent to participate in research and consent for personal data processing, and provide additional guidance on consent mechanisms, broad consent and governance-based safeguards in further processing.

The objective of these proposals is not to reduce data protection standards, but to support a scientifically effective, ethically governed and operationally workable interpretation of the GDPR, capable of enabling trustworthy health research while continuing to protect the rights and freedoms of data subjects.

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