FACULTY OF LAW AND CRIMINOLOGY

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25-06-2026

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To Whom It May Concern,

We welcome the opportunity to respond to the European Data Protection Board's ('EDPB') open consultation on *Guidelines 1/2026 on the Processing of Personal Data for Scientific Research Purposes* of 15 April 2026 ('Guidelines').

As academic researchers with expertise in data protection, we recognise the importance of EDPB's guidance on the processing of personal data in the context of scientific research, and appreciate the EDPB's adoption of the Guidelines. We read the draft Guidelines not only from a researcher's perspective, but also as professionals with extensive experience in the legal field. From that perspective, we would like to share our view.

First of all, we would like to stress that we **agree with the large majority** of the analysis made by the EDPB. It is a document that addresses most of the points of contention and does so in a well-substantiated way, clearly building on views shared by many despite the national differences (which do exist, given the leeway for Member States in the domain of research, and health research in particular).

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We **support** the EDPB's application of the **purpose limitation principle, the storage limitation principle** and, to a large extent, the interpretation of the **obligation to inform** and **right to erasure**. Although we noticed some inconsistencies and bigger points of attention in relation to informed consent, we would also like to commend the EDPB on its analysis of the lawfulness principle and how to apply articles 6 and 9 of the GDPR.

Hence, we appreciate the EDPB's adoption of the Guidelines and generally support the interpretative approach pursued by the EDPB.

Nevertheless, we would like to raise several **issues that**, in our opinion, **require further attention**. Some of them are particularly concerning from the perspective of ensuring adequate safeguards for data subjects and considering the application of the Guidelines in the rapidly evolving era of artificial intelligence ('AI') (see the "**Fundamental Issues**" section). In addition, we would like to highlight several aspects that, in our view, require further clarification or reconsideration by the EDPB to ensure the consistent and effective application of the GDPR in the context of scientific research (see the '**Specific Points of Attention**' section).

We would welcome the opportunity to discuss these points in greater detail.

Kind regards,

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1. Fundamental Issues

1.1. Erosion of the Concepts of Consent

Section 4.1.2 of the Guidelines introduces the possibility for controllers to rely on (1) broad consent where the purposes of the research are not fully known at the time of data collection, or (2) dynamic consent for individual research projects, or parts thereof, once the purposes of those projects become known. The Guidelines further indicate that a combination of both approaches is also possible.

While this approach appears to be based on the meaning of Recital 33 GDPR, it considerably extends its conventional reading. While Recital 33 GDPR claims that consent might cover areas of research, it was, in its conventional reading, considered to acknowledge a "staged approach", whereby, as soon as things become clearer, the controller should re-inform the data subject and, by doing so, fulfil the requirement for GDPR-consent to be specific. Allowing the reading of Recital 33 to extend beyond the staged approach suggests that the requirements for valid consent as a legal basis for the processing of personal data may differ depending on the context of processing, despite the GDPR establishing a single and autonomous concept of consent.

Additionally, the EDPB's approach seems to make the seemingly straightforward requirement of obtaining a data subject's consent (i.e. a yes/no decision) significantly more complex and potentially confusing for individuals. For example, paragraph 46 of the Guidelines appears to shift responsibility onto the data subject by emphasising that individuals should understand the consequences of the broad consent they provide and then decide whether to agree to a broadly defined processing purpose. This approach risks diminishing the data controller's responsibility and, in doing so, undermining the very rationale of consent as a legal basis for personal data processing. The responsibility to establish what it is that one should reasonably expect seems to be fully shifted to the data subject. It is our fear that such an approach to consent could substantially broaden the range of future uses that data subjects are expected to anticipate at the time of data collection, thereby weakening the role of consent as a mechanism through which individuals can meaningfully exercise control over the processing of their personal data.

In some circumstances, reliance on legitimate interests could potentially offer stronger protection than broad consent. When relying on legitimate interests, it is at least clear that the responsibility for assessing the lawfulness of the processing purpose and for ensuring respect for, or justifying limitations on, the rights of data subjects rests entirely with the controller. According to the line of argumentation advanced in the Guidelines, this no longer appears to be the case in the context of broad consent.

While the Guidelines require controllers to process personal data in accordance with ethical standards for scientific research and to put additional safeguards in place to compensate for the lack of purpose specification, these safeguards may not be sufficient. Ethical standards for scientific research are not necessarily uniform, legally binding, monitored, or applied consistently across different disciplines and jurisdictions. Likewise, the requirement to implement "additional safeguards" remains open-ended and provides little guidance as to which measures would be sufficient to compensate for the absence of a sufficiently specified purpose. As a result, these safeguards may not adequately

mitigate the uncertainty faced by data subjects regarding the future use of their personal data when providing broad or dynamic consent, nor fully compensate for the reduced ability of individuals to assess the implications of consenting to broad and evolving research purposes.

As a minor point of attention, we would like to advise the EDPB to move important clarifications, such as the comment in footnote 72, to the body of the text.

In relation to other regulatory frameworks applicable to certain areas of research, especially healthcare, Example 8 of the Guidelines reveals how complicated the relationship between the GDPR and the European Health Data Space Regulation ('EHDS') might become. The Guidelines, however, miss the opportunity to explain the interplay between these legal frameworks. In particular, in a situation where a data subject is presented with a request to provide broad consent, but refuses to do so, the data subject's refusal risks being bypassed by obtaining the data via the EHDS as an "alternative route". The question arises whether the researcher is obliged to inform the data subject that there is another "route" for obtaining the data? Can the researcher leave the data subject unaware of this alternative route? Or should the researcher, conversely, warn the data subject that, unless they explicitly opt out of the EHDS, their data might still be available despite their refusal to provide broad consent? These pressing questions remain unanswered.

1.2. Lack of Sufficient Focus on the AI-enabled technology

While the Guidelines open by referring to "recent advances in artificial intelligence", they do not elaborate on the impact of AI. In the context of the widespread adoption of AI-enabled systems in scientific research across different fields, the discussion of the application of scientific research-related rules to personal data processing should be considerably expanded. In particular, the Guidelines would benefit from clarifying whether AI model training and refinement should be considered "genuine scientific research", and, if so, in which cases.

This clarification would also be important in the context of the interplay between the GDPR and the EHDS Regulation regarding the training, testing, and evaluation of algorithms, including those used in medical devices, in vitro diagnostic medical devices, AI systems, and digital health applications, which constitute a permitted secondary use purpose under the EHDS only when carried out as scientific research related to the health or care sectors (Article 53(1)(e)(ii) EHDS).

The Guidelines also lack several relevant references to the interplay between the GDPR and the AI Act ('AIA'). For instance, footnote 115 of the Guidelines refers to examples of Union and Member State laws that provide derogations for the processing of personal data for scientific research purposes, yet it does not refer to Article 10(5) AIA concerning bias detection and correction. Additionally, no reference is made to the concept of 'informed consent' under the AIA (e.g. Articles 3(59) and 61 AIA). It therefore remains unclear whether this constitutes an additional requirement that should be considered in this context. The Guidelines would also benefit from more examples relating to the development and use of AI models and AI systems in the context of scientific research.

2. Specific points of Attention

2.1. Section 2 of the Guidelines:

2.1.1. Simplicity of some examples versus complexity of the reality

While we warmly welcome the examples that are included throughout this section, we are wondering whether they sufficiently reflect the complex reality researchers are facing. Example 3 of the Guidelines, for example, does not reflect the level of ambiguity that is quite often experienced when distinguishing scientific research purposes from other purposes. It is rather obvious that analysing sales data to develop a marketing strategy does not constitute scientific research. However, there are many other situations in which the distinction is much less clear.

For example, how should a request for secondary use be qualified when the data are used to assess the frequency with which certain product features are used by its professional users? The requestor wants to investigate the usage, in essence, to improve the product. The requestor probably hopes to increase its market share by improving the features of the product. At the same time, assessing the usage of the features may also make the product safer and increase knowledge on the safety or quality of a certain category of products. This scenario is not specific to one sector. One might, for example, analyse teachers' use of school software, nurses' use of a hygiene management application, or CISOs' use of SIEM software. In such cases, the delineation between scientific research and product improvement, commercial interests, or quality enhancement is considerably less straightforward.

2.1.2. Specific point of attention in relation to key indicative factors

- ***'Adherence to ethical standards'***

The way in which adherence to ethical standards is reflected in Example 4 of the Guidelines is, in our opinion, more problematic than the general description on page 8 of the Guidelines.
Example 4 of the Guidelines states that *"if a researcher wants to access special categories of data [...] pursuant to Article 9(2) GDPR, it also needs ethical approval, in line with factor (ii)"*. While this is true in the context of clinical trials at the EU level, it is less clear whether such a requirement exists for other types of research. The submission of research projects for ethical review is not systematically required by law, even where special categories of personal data are processed. In many cases, this remains a matter of institutional policy or publisher requirements, with the latter often serving as an important driver for institutions to establish additional ethics review procedures.

- ***Verifiability and transparency'***

In this indicative factor description, the Guidelines state that *"the results of the research are shared with other parties, for example by publication, or will be shared in the future, with due regard to legitimate limitations to access such as protection of intellectual property and trade secrets"*. We would like to comment on this wording.

In particular, in the exact sciences, it is not sufficient for only the results of research to be made available. For research to be verifiable, the underlying data – sometimes even raw data – must also be made available. This creates a specific but challenging dilemma: while the results themselves are not

personal data, the underlying datasets may be. This raises the question of how to balance verifiability and privacy, and whether verifiability should, in certain contexts, be given greater weight than data protection considerations.

- ***'Autonomy and independence'***

In this indicative factor, we would like to emphasise the importance of the Guidelines' reference to the research team's *"freedom to define research questions, identify methods by which problems are solved, choose and develop scientific theories, as well as the freedom to disseminate and publish the results of their research"*. From our experience, it is clear that researchers will always seek to publish their results in peer-reviewed journals, even when conducting research in collaboration with a commercial company. However, where research is unsuccessful, neither academic researchers nor researchers in companies are generally inclined to publish.

From a fairness perspective, the question therefore remains whether, in addition to remaining uncertainties and knowledge gaps, research failures should also be published. This could be considered as a preventive measure against the duplication of research activities, thereby preventing new processing operations.

- ***'Objectives of the research'***

Typically, the line between purely commercial interests and research activities is characterised not only by an aim to contribute to society's general knowledge and wellbeing, but also by a certain level of uncertainty in relation to the outcomes. While the objective is clearly formulated, it is uncertain if that objective can be achieved.

2.2. Section 4 of the Guidelines, Lawfulness:

In section 1.1 of this letter, we already raised fundamental criticism on the concepts of broad and dynamic consent. Below, we focus on other, more specific, points of Section 4 that require further attention.

- ***Incomplete assessment of potential legal bases***

The Guidelines elaborate on consent, legitimate interest and public interest as potential legal bases for the processing of personal data for scientific research purposes. In footnote 50, 'vital interests of the data subject' is also mentioned as a viable legal base. It seems advisable to furthermore explain why the two remaining legal bases, performance of a contract and legal obligation, are not considered.

The phrasing creates the impression that these legal bases are excluded by default, unless the controller can prove the contrary. In particular, further elaboration regarding the performance of a contract as a legal basis would be beneficial. One might consider the possibility of a research institution and the data subject entering into a contractual agreement for the purpose of processing the personal data of the data subject.

- ***Explicit consent***

Paragraph 67 of the Guidelines briefly addresses the concept of explicit consent. However, the expectations of the EDPB with regard to its practical application are unclear. While it is clear that controllers should offer multiple checkboxes when processing data for several purposes, it is, for instance, not clear if controllers must also include multiple checkboxes when requesting consent for one purpose, but referring to different legal and ethical requirements: a first checkbox to provide consent as a legal basis under Article 6(1)(a) GDPR, a second checkbox to provide explicit consent under Article 9(2)(a) GDPR, and a third checkbox to provide distinguishable consent to participate in scientific research pursuant to ethical or legal requirements not stemming from the GDPR (as mentioned in Section 4.1.3 of the Guidelines). In the event of multiple checkboxes being required, the practicality of this method could be called into question, as the research cannot continue if any of the checkboxes is left unselected. In the event that separate checkboxes are not required, it would be advisable to explicitly state that one checkbox could suffice, on the condition that the data subject is informed that ticking the box provides different types of consent. This could also be clarified by including an additional example.

- ***Freely given consent***

A first concern relates to paragraph 36 of the Guidelines. In this paragraph, it is indicated that a power imbalance may arise in cases involving research projects with *convicted persons, pupils, unemployed persons or disenfranchised persons*.

We wonder if the mere inclusion within such a category does inherently result in a power imbalance. While the imbalance of power clearly exists between the data subject and the prison, school, employment agency or even a grassroots organisation, and the situation might be problematic (depending on the concrete circumstances) when these organisations operate as an intermediate organisation facilitating the research with research participants, the same imbalance does not necessarily exist between the research organisation (i.e. the controller) and the data subject. This prompts a question that is unaddressed by the Guidelines. It would therefore be beneficial if the EDPB clarified whether, and how, pressure originating from an intermediary party is to be taken into account when assessing whether consent is freely given between the data subject and the controller.

Furthermore, it is not clear why a data subject in a difficult personal situation would, for that reason alone, be in a position of imbalance vis-à-vis the controller. The same reasoning would, in our opinion, not extend to other groups, such as elderly or disabled persons.

A second concern relates to paragraph 38 of the Guidelines. It should be noted that the effect of including several checkboxes for different purposes is likely to have a rather modest effect. In practice, a patient is likely focused on receiving the best possible care and will be less likely to give careful, separate consideration to each checkbox, making it especially difficult to verify that consent has been freely given. The implementation of a waiting period between the consent for healthcare and consent for scientific research is more likely to truly acknowledge the voluntariness that is required for a consent to be valid.

- ***Derogations laid down in Union or MS law***

In relation to paragraph 75 specifically, it is remarkable that a reference to article 9(2) is made without specifying the relevance and irrelevance of article 9(2) (a) to (j) one by one.

2.3. Section 5 of the Guidelines, Obligations to Inform

In Example 12 of the Guidelines, we advise not to suggest a "central" contact number. In practice, a central helpdesk is often not in a position to respond to specific or technical questions from data subjects, particularly where queries relate to a particular research project or dataset. A more appropriate and efficient solution would therefore be to refer data subjects directly to the secretariat of the principal investigator (PI).

In paragraph 100, bullet point 3 of the Guidelines, it is unclear whether the example of a dataset being 10 years old is particularly representative or relevant in this context. In general, individuals do not change email addresses with such low frequency; changes typically occur sporadically and are not tied to fixed time intervals such as a decade. By comparison, the frequency of email address changes is likely significantly lower than, for example, changes of residential address, and therefore may not provide a realistic basis for the illustration given.

2.4. Section 7 of the Guidelines, Attribution of Responsibility

In the last sentence of paragraph 134 of the Guidelines, we think it might be useful to add that funders, consulted experts,… are indeed not a controller because they do not decide on the purposes of the processing; rather, they have an advisory role and do not bear responsibility for the final decision. Additionally, they are not typically subject to instructions, as they are often explicitly required to act independently.

In paragraph 136 of the Guidelines, while the first example is clear, we find the wording of the second is confusing. We believe that the trusted data holder will be qualified as a processor. The attribution of responsibility referred to in paragraph 135 of the Guidelines does not appear to align with this second example.

Regarding Example 21 of the Guidelines, it is unclear how this example should be interpreted and how it relates to Example 22 of the Guidelines. It should be clarified whether, in Example 22, the university should be considered the controller for the decision to allow a specific researcher to access data from the database (noting that this researcher would have to be someone other than an employee of the university). Additionally and more generally, the rationale behind this step in the chain of processing activities is unclear (see also the CNIL decision in *IQVIA*). It does not appear meaningful to create a separate controllership under the GDPR for the "decision to allow access". Beyond the question of whether such a decision constitutes a "processing" of personal data at all, it is, in any event, intrinsically linked to the determination of the purposes and essential means by the requestor. Such a decision cannot be taken independently unless that party has already defined the purpose and means.

The requestor should therefore be considered the sole controller for the entire chain of processing for secondary use, unless the original data controller is involved in the secondary use, for example, in the context of a collaborative project where it also contributes to defining the purpose of processing.

2.5. Section 8 of the Guidelines, Appropriate safeguards

In relation to the guidance on anonymisation and pseudonymisation of personal data, a first concern arises in relation to paragraph 159 of the Guidelines. In the last sentence of this paragraph, it is indicated that “the controller should always opt for using anonymised data or pseudonymised personal data, if the purpose of the scientific research does not require the use of personal data that can be used to directly identify data subjects”. We are wondering why the EDPB opted to mention “direct” identification while not mentioning indirect identification?