

Feedback reference on the Guidelines 1/2026
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We provide some comments regarding the guidelines published on 15/04/2026 (Guidelines 1/2026), which we believe will possibly lead to a more appropriate wording of certain points and in particular to the clarification of any non-transparent positions of these guidelines. These guidelines relate to a very crucial subject in the field of protection of personal data, and it should be avoided to incorporate gray wording that will allow a "legitimate" collateral violation of the Regulation (GDPR), under the guise of scientific research purposes.

In any case, we would like to pay our respects in advance to the continuous and multi-level effort made by the EDPB to effectively protect the rights of European citizens (and not only), through, among many other things, the issuance of guidelines such as these, but also by putting them to public consultation. We highly appreciate this process and this initiative, and we thank the EDPB for giving us the opportunity to participate in it. Specifically, with all due respect, we propose the following:

1. Executive Summary & Chapter 2 / Paragraph 9 (Concept of scientific research)

1.1. The Executive summary reads "Only research that is genuinely scientific benefits from the specific rules [...]". The same is provided for in paragraph 9, where it is stated "in research activities that are genuinely scientific". Although the phrase "genuinely scientific" reflects the intention of the guidelines to speak for purely scientific purposes, we believe that it ultimately has the opposite effect. The concept of scientificity should be absolute: it either exists or does not exist. The enrichment of an absolute concept with adjective determinations leads to confusion, as in the rest of the text this terminology is not consistently followed (sometimes "genuinely scientific" and sometimes simply "scientific"), making the reader unnecessarily wonder if the omission of "genuinely" was intentional.

1.2. Suggestion: We suggest that where the word "**genuinely**" exists, it should be removed.

2. Chapter 2.1 / Paragraph 11 (Key-indicative factors)

2.1. This section lists factors that may constitute scientific research purposes. The enumeration is characterized as "key-indicative factors", implying that the contribution of some or one of them (or none of them) is sufficient. Among these, the "Methodical and systematic approach" is mentioned in I. and in III. "Verifiability ... ". These concepts belong to the core of scientific research, they are the minimum definition of scientific research, which is even found in common dictionaries. It is therefore not possible, we believe, for an element to be detached from the field of the core and characterized simply as an indication, because this constitutes a degradation of this element, and an unjustified shrinkage of the concept of scientific research. Moreover, that contradicts the EDPB's own position that "[scientific research] it may not be stretched beyond its common meaning".

2.2. In addition, point IV states: "This applies regardless of whether the research activities are carried out by an academic institution, non-profit organisation, public institution or a for-profit organisation [...]". Although independence may exist in corporate environments, the word "regardless" is unduly egalitarian. It must be investigated on a case-by-case basis, as the autonomy of a team under the direct supervision of an employer (commercial company) is not always under exactly the same guarantees as academic institutions.

2.3. Proposal: We propose to reformulate Section 2.1 to make it clear that "Key-indicative factors" are helpful in establishing a concept, "scientific research purposes". However, this concept, although it does not indeed have a commonly accepted definition, is possessed by a few components, which by their nature are contained in this concept. It may be that the EU legislator in Article 4 of the GDPR does not give an

authentic interpretation of the concept "scientific research purposes"¹, but one should not forget the so-called literal interpretation of the law, i.e. the attempt to discover the meaning of a rule of law from the meaning of the words used by the legislator. In view of the above, it would be safer not to turn this concept into a tabula rasa, but to prefer an approach in which the "Key-indicative factors" would be "built" on the core of the grammatical meaning of the phrase "scientific research purposes", which in our view consists of "Methodical and systematic approach", "Verifiability" and "Contribution to the growth of society's general knowledge and wellbeing"².

2.4. In addition, a clarification should be added to point IV on the need for a concrete assessment of autonomy when research is carried out by for-profit organisations.

3. Chapter 2.1 / Paragraph 12 (Presumption and Burden of Proof)

3.1. The wording of paragraph 12 creates the impression (due to the term "presumed") that, if all the factors in paragraph 11 are met, the controller is not obliged to substantiate the purpose of scientific research "If the research activities under assessment meet all of the factors in para. 11, they can be presumed to constitute scientific research. If the research activities do not meet all factors, the controller needs to justify and be able to demonstrate why the activities should nonetheless be considered scientific research, within the meaning of the GDPR. [...]".

3.2. This presumes that the burden of proof is reversed to the detriment of the subject, in flagrant violation of the principle of accountability (Article 5(2) GDPR)³. The controller must always justify and demonstrate the

¹ See the Guidelines on Consent under Regulation 2016/679 of the former Article 29 Working-Party from 10.04.2018, WP259 rev.01, 17EN, page 27 (endorsed by the EDPB). Available at https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051.

² European Data Protection Supervisor, A preliminary opinion on data protection and scientific research, section 3.5, pg. 12 [It is a common assumption that scientific research is beneficial to the whole of society ...] • Study on the secondary use of personal data in the context of scientific research, section 4.1, pg. 16 [... the GDPR reintegrates a "public interest requirement" in different recitals and indirectly in Article 6 (on compatibility between primary and secondary use of personal data) ...]

³ C-60/22, 2023, para. 53, C-252/21, 2023, para. 95

lawfulness of the processing, regardless of how many indicators are met.

3.3. Proposal: "If the research activities under assessment meet all of the factors in para. 11, ~~they can be presumed this constitutes a strong indication that they qualify as to constitute~~ scientific research. ~~If the research activities do not meet all factors,~~ In any case, the controller needs to justify and be able to demonstrate why the activities should ~~nonetheless~~ be considered scientific research, within the meaning of the GDPR. When doing such an assessment, the more key-indicative factors are present, the more likely it is that the activities constitute scientific research within the meaning of the GDPR."

4. Chapter 3.1 / Paragraphs 16 & 19 (Terminology of purpose)

4.1. In section 3.1, the terms "primary purpose" (e.g. par. 16) and "initial purpose" (e.g. par. 19) are interchanged to indicate the same concept.

4.2. Proposal: For the sake of clarity and consistency with the wording of Article 5 of the GDPR, it is proposed to use the term **"initial purpose" uniformly**, as we consider it pointless to change terminology.

5. Chapter 3.1.1. / Paragraph 23 combined with 63 & 125 (Legitimate Interest & Balancing Test)

5.1. It is stated in **paragraph 23** "If a controller considers that further processing for scientific research purposes could be based on Article 6(1)(f) GDPR, the significant societal interest of conducting scientific research, as also reflected by the presumed compatibility of processing for scientific research purposes, carries significant weight in the balancing test in relation to the data subjects' interests or fundamental rights or freedoms".

5.2. Great care should be taken in invoking Article 6(1)(f) as a legal basis for processing for scientific research purposes. It is very easy to be led to the arbitrary conclusion that since an element of scientific research is "the aim of contributing to the growth of society's general knowledge

and wellbeing", then - supposedly - processing will always be allowed, because such an aim (of the good of society) will outweigh the "interests or fundamental rights and freedoms of the data subject". In other words, we consider it very "dangerous" or even inappropriate to invoke this sub-case for the legitimacy of processing, because very easily any controller could summarily oppose the "legitimate interest of society", resulting in a violation of the Regulation. We propose that this risk be highlighted, and that the specific justification required for someone to invoke this legal basis correctly should be underlined.

5.3. Proposal: Reformulate these points in order to clearly underline the risk of circumvention. The person responsible must prove with substantial evidence and data that in each specific case, the legitimate interest does indeed outweigh the fundamental rights, requiring special justification and not a simple invocation of "prosperity".

5.4. Paragraphs 63 & 125 (Legitimate interest)

5.5. Reference is made to the assessment and balancing test that the controller must carry out in order to utilize the legitimate interest as a legal basis for the processing of personal data. Given that, in common experience, scientific research promotes social well-being, i.e. serves the public interest, controllers will invoke the legitimate interest without further ado, essentially bypassing both the assessment and the balancing test, without weighing up the interests, arguing that social welfare de facto outweighs the rights of the data subject. The same is problematic in the case of the possibility of the controller to refuse the deletion of personal data, in accordance with article 21 par. 6 GDPR, on the grounds that, in the case of scientific research, the legitimate interest, which consists of social welfare, is the same as the public interest.

5.6. Proposal: rewording **paragraphs 63** and **125** to make it clear that the controller must be able to demonstrate, on the basis of substantive facts and data, that the legitimate interest outweighs the fundamental rights of the data subject, and that it is in fact in the public interest.

6. Chapter 3.1.1. / Paragraph 24 (Exceptions to Article 9 par. 2)

6.1. It is stated that the person responsible may invoke the exceptions of article 9 par. 2 GDPR, specifically states that "Nevertheless, the controller must still assess which derogation to the prohibition to process special categories of personal data, pursuant to Article 9(2) GDPR, that applies when further processing such data for scientific research purposes". However, not all legal bases/exceptions are suitable.

6.2. Proposal: We consider that not all the legal bases/exceptions provided for in Article 9 (2) of the GDPR are appropriate and we propose that paragraph 24 be reworded in such a way that it is clear that it is not appropriate to invoke in particular cases (b) and (f) of Article 9 (2) of the GDPR.

7. Chapter 3.1.2. / Paragraph 26 (Compatibility Assessment)

7.1. It states "When providing personal data to another controller for scientific research purposes, neither the providing (controller A) nor receiving controller (controller B) needs to undertake a compatibility assessment, pursuant to Article 6(4) GDPR".

7.2. The position that the transfer to a third-party controller (controller B) for research purposes is exempt from the compatibility assessment (Article 5 par. 1 par. b' last subsection and Article 6 par. 4 GDPR) is highly problematic. It recognises unrestricted freedom of transfer, reducing data to uncontrolled transactions, indirectly circumventing transfer guarantees (e.g. to third countries, Articles 44 et seq.).

7.3. The controller providing the information is bound by its obligation to be able to demonstrate that it has taken appropriate measures and has requested appropriate safeguards from the requesting data controller to establish that the requester does indeed have scientific research purposes. The unconditional transfer of data from controller to controller without even a compatibility check, because all parties rely on further

scientific research, It is tantamount to a loss⁴ of subjects' control over their data.

7.4. The risk for the data subject is even more intensified, given that the controller may refuse the data subject's request for erasure of his or her personal data, citing the public interest, which, in common experience, scientific research serves.

7.5. Given the exceptional nature of article 5 par. 1 par. B' last subpar. of GDPR, this must be interpreted narrowly. Thus, in order for the exemption from the compatibility assessment to apply, according to the aforementioned article, the further processing for scientific research purposes must be carried out by the same/original controller and not by another to whom the data are transmitted⁵. That is, for the purposes of article 5 par. 1 par. b', the transfer of personal data to another controller, who will process them for scientific research purposes, must be considered not to fall under article 5 par. 1 par. b' GDPR. Therefore, in the latter case (transfer to another controller), the compatibility assessment must be carried out, when required by the GDPR, in accordance with the provisions of Article 6 par. 4 GDPR, and, in particular, in order to check that the processing is indeed carried out for the purpose of scientific research and that safeguards pursuant to Article 89 par. 1 GDPR are established.

7.6. Proposal: **delete the last sentence** of the paragraph **or add** the following sentence **"When transferring personal data to another controller for scientific research purposes, the absence of a compatibility assessment under Article 6(4) GDPR does not relieve the transferring controller of**

⁴ C-667/21, 2023, para. 66 and introductory remarks (7) and (85)

⁵ It is also interesting to follow the decision to be issued by the CJEU on a relatively similar question recently raised by the Austrian Supreme Court (OGH) in 6Ob69/25b/26.05.2026, which in short asks "1. Does the transfer of personal data from a controller to a processor require an independent legal basis in accordance with Article 6(1) of the General Data Protection Regulation? 2. If the answer to the first question is in the negative: Does the consent, which has been given 'in full knowledge' within the meaning of Article 4(11) of the GDPR, in accordance with Article 6(1)(a) of the GDPR, presuppose that the data subject knows, before giving his or her consent, that the controller intends to use: for the specific processing of data (the sending of a prospectus), the processor within the meaning of Article 4(8) of the GDPR established in a third country?" Obviously, if it is deemed necessary to have a separate legal basis for the transfer of data from a controller to a performer, the same should apply mutatis mutandis in the case of a transfer of data from a controller to a third party controller.

its obligation to verify that the recipient is genuinely pursuing scientific research purposes and that the transfer complies with the applicable GDPR requirements, including, where relevant, the provisions governing international data transfers".

8. Chapter 3.2. / Paragraph 29 (Future projects and timetables)

8.1. It is stated that the person in charge must document how he intends to use the data in the future, without the need for a full research plan. Specifically, it is stated that "This means that the controller should substantiate how it intends to use the personal data in future scientific research projects, although it should not be required to draft a complete research plan".

8.2. This wording leaves room for vague documentation, allowing for abusive, indefinite retention of data simply because "it may be useful at some point".

8.3. We believe that the proposal as it stands leaves open the possibility of very vague documentation on how the data will be used in future projects. In particular, we consider that it is not enough to describe the method of processing, but it is also necessary to at least indicate an indicative timetable on its part, with an ultimate limit at which this processing will be justified. As time goes by, it is a given that the right of the person in charge to keep and process the same data is weakened. In other words, we believe that it is abusive to retain this data only because it may somehow be useful, without at least a maximum estimated time point having been set by the controller, because the setting of a schedule immediately limits the possibilities of arbitrary data retention. And the timetable will obviously be able to be renewed by the person in charge if there is a well-founded and foreseeable need.

8.4. Proposal: we propose the reconfiguration as follows "This means that the controller should substantiate not only how the personal data will be used in future scientific research projects, but also provide an indicative timeframe for such use, including an estimated long-stop date, so as to prevent the indefinite retention of personal data on the basis of unspecified future research needs."

9. Chapter 3.2 / Paragraph 31 (Data retention - Article 5(1)(e) & 89(1))

9.1. Proposal: "Controllers storing data in accordance with Article 5(1)(e) lit 2 GDPR must also adopt appropriate safeguards, pursuant to Article 89(1) GDPR⁴⁷. In particular, when controllers store personal data for prolonged periods of time, they must regularly review the necessity of storing personal data – including **which personal data and** in which format the data should be retained (i.e. whether the personal data should be anonymised or pseudonymised) – in light of the envisaged further processing for scientific research purposes."

10. Chapter 4.1.1. / Paragraph 37 (Patient Consent and Vulnerability)

10.1. The paragraph states that the status of a patient does not in itself affect the capacity for free consent, as long as he does not suffer from a serious medical condition. Specifically, it is stated that "Conversely, the fact that a data subject is a patient receiving health care does not in itself affect the data subject's capacity to freely provide consent, in so far as the data subject is not severely affected by a mental or physical medical condition".

10.2. However, the freedom of consent may also be affected by social or economic circumstances.

10.3. Proposal: We consider that the phrase "Conversely, the fact that a data subject is a patient receiving health care does not in itself affect the data subject's capacity to freely provide consent, in so far as the data subject is not severely affected by a mental or physical medical condition **and there are no surrounding circumstances, including social or economic vulnerabilities, that may unduly influence the data subject's decision.**" shall be added.

11. Chapter 4, Paragraphs 40, 41 (Broad consent vs. Dynamic consent)

11.1. The introduction of the neologisms "broad consent" and "dynamic consent", which are not provided for by the GDPR, causes serious confusion and unduly shifts responsibility to the subjects (contrary to Article 12). The so-called "dynamic consent" is essentially the simple

"consent" of GDPR, while the "broad consent" invalidates the concept of consent of Article 6 (for specified purposes).

- 11.2. Proposal:** we propose the abolition of the distinction between "broad consent" and "dynamic consent" and the circumscriptive wording where necessary, as the regulation provides for the legal basis for consent to be the clear wording in Article 6 'the data subject has given **consent** to the processing of his or her personal data for one or more specific purposes'.

12. Chapter 4.1.2.1 / Paragraph 44 ("as clearly as")

- 12.1.** "Therefore, controllers intending to process personal data for scientific research purposes on the basis of broad consent should define the purposes of future research as clearly as possible."
- 12.2.** We consider the wording "as clearly as possible" to be very conciliatory and lenient, because what would happen if a researcher claimed that the determination of the purpose despite every effort had been made was impossible to determine? It seems that a more careful formulation is needed, since researcher must in principle define the purpose completely and clearly, and only by absolute exception as clearly as possible, and in any case never completely vaguely.
- 12.3. Proposal:** We therefore propose the amendment of the sentence as follows "Therefore, controllers intending to process personal data for scientific research purposes on the basis of broad consent should define the purposes of future research **clearly and specifically. Recourse to broader descriptions should be limited to exceptional cases where a more precise definition is not reasonably possible, and should never result in purposes that are vague or indeterminate.**"

13. Chapter 4.1.2.1 / Paragraph 47 (reasonable expectations)

- 13.1.** It is stated that "Broad consent can be relied on for the processing operations of – inter alia – collection, curation, storage and provision of data (e.g. by way of transmission or giving access through a secure processing environment), as well as subsequent processing operations

in individual research projects or parts thereof, as long as the processing of personal data remains within the relevant research area and the reasonable expectations of the data subjects. For example, patients that have had their genome sequenced as part of personalised medical treatment can consent to making their personal data available for the purposes of scientific research in the field of medical genetics for multiple research projects. Broad consent can also be relied on if a research project progresses towards a direction that was not anticipated or expected at the time when the personal data was collected, as long as it remains within the relevant research area.”.

13.2. Initially, it is set as a condition in the "broad consent" for subsequent processing operations, that the processing "remains within the relevant research area and the reasonable expectations of the data subjects", and a few lines later the guidelines contradict themselves by writing "Broad consent can also be relied on if a research project progresses towards a direction that was not anticipated or expected at the time when the personal data was collected, as long as it remains within the relevant research area.". It is questionable why conditions are set when immediately afterwards it is stipulated that it is done and not met. In any case, we consider this period to be completely dangerous and misleading, as if something could not even be foreseen or was not expected, then de facto no "form" of consent of the subject can cover it, because it is simply excessive to consider that the subject gave any consent for something that could not even be foreseen. In this case, consent from the subject is simply needed.

13.3. Proposal: We propose to replace the sentence with the following "Broad consent can be relied on for subsequent processing operations only insofar as such processing remains within the relevant research area and within the reasonable expectations of the data subjects at the time consent was obtained. Where a research project develops in a direction that could not reasonably have been anticipated by, or communicated to, the data subjects when their personal data was collected, the controller should obtain renewed consent before relying on the data for such further processing.".

14. Chapter 4.1.2.1 / Paragraph 49 (Independent data trustee)

- 14.1. The concept of "independent data trustee" is innovative, and a footer explanation is not enough.
- 14.2. For example, it would be appropriate to determine whether the provisions on the processor are analogous to that concept.
- 14.3. Who ultimately appoints the independent data trustee, the data controller or e.g. the independent authority or can the "independent data trustee" be the independent authority itself?
- 14.4. **Proposal:** to clarify the concept further and on a practical level.

15. Chapter 4.1.3 / Paragraph 55 ("clearly distinguishable")

- 15.1. It is stated that the request for consent from the data subject may be cumulated with a request for the participation of the subject in a research project carried out by the controller, provided that these requests are sufficiently distinct.
- 15.2. The term "clearly distinguishable" is vague and is not specified either by reference No. 82 to the Guidelines on transparency under Regulation 2016/679 (WP260 rev.01) nor by citing examples. In addition, there are issues of a technical nature (such as, but not limited to, the font size, the font color, the layout, etc.) which, although important for the authenticity of the data subject's consent, are not referred to in **paragraph 55**.
- 15.3. **Proposal:** We suggest that relevant examples be given, as well as reference to technical issues of the form/request, such as the font, font size, etc⁶.

16. Chapter 4.4.1 / Paragraph 67 (Sensitive data and broad consent)

- 16.1. It is stated that broad consent can be used for special categories of data. Specifically, it is stated that "Controllers may also assess whether they can rely on the explicit consent of data subjects, including

⁶ Similarly to the Guidelines on marketing communications under the Regulation on cross-border distribution of funds (ESMA34-45-1272).

broad or dynamic consent, pursuant to Article 9(2)(a) GDPR, to process special categories of personal data for scientific research purposes".

16.2. However, Article 9(2)(a) requires **explicit** and specific consent (for one or more specified purposes). As one observes in the GDPR, the reference in Article 6 as a legal basis to "the data subject has given consent to the processing" is tightened up in a narrower wording in Article 9 which speaks of special categories of data and in which it is stated as a legal basis that "the data subject has given explicit consent to the processing of those personal data". In other words, it is directly apparent from the literal and systematic interpretation of the two articles that the legislator's wording is narrower regarding consent for special categories of personal data, which provides for **explicit** consent. In view of the above, we consider that the concept of "broad consent" as analysed in the guidelines is by definition in contradiction with Article 9 of GDPR because explicit consent is referred to "for one or more specified purposes", whereas "broad consent" refers to "not fully known at the time of collecting the personal data purposes".

16.3. In summary we consider that broad consent can in no way constitute a legal basis for the processing of sensitive personal data. This is because according to the letter of article 9 par. 2 par. a', which, due to its exceptional nature, is interpreted strictly⁷, the consent of the subject must be explicit and specific.

16.4. Proposal: We therefore propose that, if the distinction in broad and dynamic consensus is to be maintained, the paragraph should be reworded as follows "Controllers may also assess if they can rely on the explicit consent of data subjects, including ~~broad or~~ dynamic consent, pursuant to Article 9(2)(a) GDPR, to process special categories of personal data for scientific research purposes."

17. Chapter 4.4.2 / Paragraphs 70 (active choice)

⁷ By analogy C-252/21, para. 76

- 17.1.** In par. 70 It is required that the posting of personal data results from an "active choice". Specifically, it states that "A controller that wants to process special categories of personal data in individual posts on social media for scientific research purposes should make sure that the data was posted following an active choice by the data subject. The controller should check the settings available to users on the social media platform. The controller should also verify that users".
- 17.2.** Analysis is made in this paragraph as well as in previous ones on the issue of the publication of data by the subject himself on the internet. First of all, we would like to point out that it is not enough for the publication to result from the "active choice" of the subject but also from "free choice", by analogy with the conditions for valid consent, because a post by a person, for example, who suffers from mental illnesses cannot be considered active and free and therefore cannot be relied on by a person responsible to legally carry out processing.
- 17.3. Proposal:** We propose to revise the paragraph as follows: "A controller that wants to process special categories of personal data in individual posts on social media for scientific research purposes should make sure that the data was posted following an active **and freely given** choice by the data subject. The controller should check the settings available to users on the social media platform. The controller should also verify that users".

18. Chapter 4.4.2 / paragraph 72 (public)

- 18.1.** It states that "Finally, the EDPB reiterates that the fact that a data subject has made special categories of personal data public at a certain point in time and in a certain context, does not mean that the data subject has also made other personal data – within the same category of data – public".
- 18.2.** We do agree with the above position, but we would like to raise a further issue. What happens in a case where a person made a post, which afterwards (even within the same day, for example) they have deleted? Does this minimum period of time in which this data has been posted, give the legal basis to the controller to process this data in

perpetuity? We consider that the act of the subject by which he deletes this data from the internet expresses his will to "revoke" this implicit legal basis for processing, since his intention is clear to "delete" this data from the internet.

- 18.3. Suggestion:** we would like to analyse this concern and perhaps mention that the controller should be very careful when collecting data in this way. It would be useful for him to take as a measure to ensure data protection the regular re-checking of his or her online sources.

19. Chapter 4.4.3 / Paragraph 75 (EHDS)

- 19.1.** Reference to the EHDS Regulation is made. First of all, we would like to comment that more focus should be given to the analysis of this regulation, and this is because it involves the concept of secondary use of health data, from which targeted analogies could be drawn with the concept of the further processing of data in general.

- 19.2. Proposal:** We propose in any case to highlight the relationship between the EHDS and the GDPR, and this is because even in the text of the EHDS the legislator takes care to point out the primary role that the GDPR continues to play, to which references are constantly made, the paragraphs (5), (8), (9), (10), (15), (23), (52) are characteristic. While the reference to the "EDPB-EDPS (2022) Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space" is also useful.

20. Chapter 6.2.2 / Paragraph 120 (over a longer period of time)

- 20.1.** "A request for erasure of personal data may also make it impossible or seriously impair the achievement of the scientific research purposes if the controller researches developments or trends over a longer period of time and the request is received while the research is still in progress."

- 20.2. Proposal:** We consider that given the weighing of the legal interests at stake, the wording "over a longer period of time" is particularly broad and it would be more correct to rephrase "A request

for erasure of personal data may also make it impossible or seriously impair the achievement of the scientific research purposes if the controller researches developments or trends **over a predefined and objectively justified period of time necessary for the completion of the specific research project** and the request is received while the research is still in progress".

21. Chapter 7.1 / Paragraph 137 (de facto)

21.1. "This means that individual researchers, such as researching healthcare staff, laboratory technicians or other persons involved in scientific research are generally not considered controllers, but rather acting under the authority of a controller."

21.2. Although this is indeed the rule, we consider that for the completeness of the analysis it is necessary to refer to the concept of de facto controller. The construction of the de facto controller has long been introduced by the group of Article 29 of the previous Directive 95/46/EC, according to which "If a natural person working within a company or public body uses data for his or her own purposes, outside the activities of the company, this person shall be considered as a de facto controller and will be liable as such" (group of Article 29, Opinion 1/2010, p. 17).

21.3. Proposal: we propose to add the following **"Nevertheless, it should be acknowledged that where an individual researcher or other person involved in scientific research uses personal data for their own purposes and outside the activities, mandate, or authority of the controller, that person may be regarded as a de facto controller and may be held liable as such."**

22. Finally, we would like to make a more general comment. Many examples simply sterilely repeat the wording of the law without really shedding light on its interpretation. In other words, it would be more useful instead of mentioning "the controller who received the necessary safeguards" to mention a more practical example where the theoretical controller had taken safeguard measures a, b and c.

23. In conclusion, we believe that the guidelines should simplify the application of a law, and not introduce concepts that will complicate things, so in general we recommend that the terminology of the regulation should be used as much as possible and unnecessary neologisms should be avoided.

We thank the Board for the opportunity to share comments on the Draft Guidelines.

Best Regards,

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