Tampere University Response to EDPB Guidelines 1/2026 on the Processing of Personal Data for Scientific Research Purposes

Public consultation submission, 25 June 2026

To the European Data Protection Board

Tampere University submits the following observations on the EDPB Guidelines 1/2026 on the Processing of Personal Data for Scientific Research Purposes (version for public consultation, adopted 15 April 2026).

Tampere University Foundation sr, operating as Tampere University, is a multidisciplinary research university in Finland under the Universities Act 558/2009 (Section 2), with a statutory mission to promote free research and academic education. We submit this response on our own behalf; it has not been coordinated with other Finnish universities or with Universities Finland (Unifi).

Our General comments raise four points.

The first is the legislative interim. We ask the EDPB to clarify how the Guidelines relate to the proposed Digital Omnibus (COM(2025) 837 final), and to confirm that controllers may continue to apply the GDPR as currently in force (General comment 1.1).

The second is the legal basis for university research. The final Guidelines should reflect that Articles 6(1)(e) and 6(1)(f) are both available in parallel for scientific research, without categorical precedence, anchored in Member State law where it so provides. In Finland, Section 4(1)(3) of the Data Protection Act 1050/2018 supplies the Article 6(1)(e) basis on which our research mission rests (General comment 1.2).

The third is the architecture of national research law. Member State law under Article 89 GDPR usually takes the form of a coordinated legislative package rather than a single derogation. In Finland it spans several sector-specific statutes, including the Medical Research Act 488/1999, the Biobank Act 688/2012 and the Act on the Secondary Use of Health and Social Data 552/2019, and is now complemented at EU level by the European Health Data Space Regulation (EU) 2025/327 (General comment 1.3).

The fourth is AI-related research, which we address within the EDPB's mandate under Article 70(1) GDPR (General comment 1.4).

Yours faithfully,

Tampere University

1. General comments

1.1 Interplay between the Guidelines and the proposed Digital Omnibus

The Digital Omnibus proposal (COM(2025) 837 final, 19 November 2025) would change several provisions central to these Guidelines: an Article 3(1)(b) definition of “scientific research”; a Recital 29 reiteration of the compatibility presumption for further processing for scientific purposes (without amending Article 5(1)(b) itself); a new Article 13(5) information derogation; and a recharacterisation of scientific research as a “legitimate interest” in proposed Recital 32. We take no position on the desirability of the proposal as such.

Three points would benefit from clarification in the final Guidelines.

First, operability under the GDPR as currently in force. We ask the EDPB to confirm that, until the Omnibus is adopted, the Guidelines continue to apply on the basis of the GDPR as currently in force, including the six key-indicative factors, the Article 5(1)(b) presumption as currently formulated, and Articles 13 and 14.

Second, the update process. We ask the EDPB to indicate whether and how it intends to update the Guidelines once the Omnibus is adopted.

Third, the transitional period. Unless and until the Omnibus is adopted, controllers must apply the GDPR as currently in force while also assessing the foreseeable effects of the Omnibus on existing research programmes. Transitional guidance would assist that work.

These points are developed at paragraph level in Specific comments 2.1, 2.4, 2.5, 2.7, 2.9 and 2.12.

1.2 Parallel application of Articles 6(1)(e) and 6(1)(f) for scientific research

We strongly welcome that the Guidelines cite the Finnish Data Protection Act 1050/2018 as a Member State example on three points: a legal basis for scientific research (Section 4(1)(3)), a derogation for special-category data (Section 6(1)(7)), and a framework of safeguards for research (Section 31).

We ask the EDPB to confirm in section 4.3 that Articles 6(1)(e) and 6(1)(f) remain parallel legal bases for scientific research, and that neither enjoys categorical precedence where Member State law provides for both. We recognise the limit in Article 6(1), second subparagraph: a

public authority may not rely on Article 6(1)(f) in the performance of its tasks, so the parallel operates where each basis is applicable.

In Finland, universities rely on Article 6(1)(e) virtually without exception. Section 2 of the Universities Act 558/2009 sets the statutory research mission, and Section 4(1)(3) of the Data Protection Act 1050/2018 provides the corresponding legal basis. Article 6(1)(f) remains available in parallel for processing outside the public-task mission, such as certain commercial research collaborations. National guidance in France (CNIL) likewise allocates public-sector research bodies to the public-task ground rather than to legitimate interest; we note this as comparative national practice, not as a determinant of the EU position.

Concerns about the Digital Omnibus proposed Recital 32 are developed in Specific comment 2.7.

1.3 The role of national supplementary legislation under Article 89 GDPR, including EHDS

We ask the EDPB to recognise, in the introduction to the Guidelines, that Member State research law typically takes the form of a coordinated legislative package rather than a single derogation.

In Finland the package comprises the Data Protection Act 1050/2018 (Sections 4, 6 and 31), the Medical Research Act 488/1999, the Biobank Act 688/2012, the Act on the Secondary Use of Health and Social Data 552/2019, the Act on the Openness of Government Activities 621/1999 and the Universities Act 558/2009. Together these instruments define what counts as scientific research, allocate legal bases, frame the Article 89(1) safeguards and set the conditions for register-based research.

At EU level, the package is now complemented by the European Health Data Space Regulation (EU) 2025/327, which is phasing into application.

The EHDS Regulation matters here because, for the secondary use of health data, it defines scientific research more broadly than these Guidelines: under Article 53(1)(e), secondary use covers the training, testing and evaluation of artificial intelligence systems where this contributes to scientific research. Where such secondary use is itself scientific research, the compatibility presumption in Article 5(1)(b) (paragraph 19) means that no separate Article 6(4) test is required; the controller must nonetheless assess lawfulness and apply the Article 89(1) safeguards. We invite the EDPB to clarify how the EHDS authorisation framework (the Health Data Access Bodies, and Findata in Finland) relates to that analysis.

The Court of Justice has confirmed[1] that national special legislation does not exempt controllers from Articles 5, 6(1) and 9 of the GDPR. The same logic applies to the Finnish framework: the Data Protection Act, the Medical Research Act and the Biobank Act provide legal bases and procedural conditions but do not override the GDPR's general requirements, including the Article 89(1) safeguards.

1.4 AI-related research within the scope of the EDPB's Article 70(1) mandate

AI-related research raises GDPR-interpretive questions that the present Guidelines do not yet address. We invite the EDPB to add a short dedicated treatment within the scope of its mandate under Article 70(1) GDPR. We recognise that this mandate is GDPR interpretation, not a political assessment of the AI Act or the proposed Digital Omnibus.

Three questions in particular would benefit from clarification.

When does AI-related processing qualify as scientific research under Article 89(1), and when does it fall outside it? The proposed Article 88c, if adopted as proposed, would draw a line that controllers must then identify in practice.

Can a single research project contain both Article 89(1) scientific-research processing and AI-development processing at different stages? If so, how should the legal bases and safeguards be allocated across those stages?

Which of the safeguards listed in paragraph 170 are particularly relevant to AI-research risk profiles such as black-box opacity, biased training data and the use of personal data for generalisation beyond the original research cohort?

The EHDS Regulation offers a useful reference point. Article 53(1)(e) expressly includes AI training, testing and evaluation in the secondary use of health data for scientific research, and Articles 73 and 87 set the secure-processing-environment infrastructure and role-allocation rules under which such processing may occur.

[1] Case C-65/23, *K GmbH*, judgment of 19 December 2024.

2. Specific comments

2.1 Scope of “scientific research”, the six key-indicative factors (paragraphs 11-12)

We ask the EDPB to clarify how the Guidelines reconcile with the proposed Article 3(1)(b) definition of scientific research in the Digital Omnibus, and in particular whether they will be updated after Omnibus adoption or applied to the GDPR as currently in force. We take no position on the desirability of the change, but an explicit transitional indication would assist controllers preparing long-term research programmes during the legislative interim.

The six key-indicative factors align with the constitutive features of scientific research identified by the Supreme Administrative Court of Finland in KHO:2013:181: *criticality, autonomy, advancement, generalisability and openness*. This convergence anchors the test in a European judicial continuum and reduces the interpretive burden on controllers.

We invite the EDPB to clarify two points in paragraph 12: how the presumption interacts with the controller’s accountability under Articles 5(2) and 24, in particular what the controller must demonstrate where not all six factors are met; and whether any factor, in particular autonomy and adherence to ethical standards, operates as a necessary condition. In KHO:2013:181, the Supreme Administrative Court treated autonomy and openness as decisive even where a research plan and qualifications were otherwise sound.

We also invite the EDPB to clarify whether the six-factor test will remain operational under a possible Article 3(1)(b) Omnibus definition. The Omnibus draft does not give autonomy or independence, and verifiability or transparency, the same prominence as the Guidelines. EDPB-EDPS Joint Opinion 2/2026, paragraph 29(ii) and footnote 38, holds that product research and development may support innovation but does not necessarily constitute scientific research. That is a stricter line than the Omnibus text, and it supports retaining the six-factor test as currently drafted.

Factor (iv) carries particular weight in Finnish constitutional and administrative case-law. In KHO:2013:181, the Supreme Administrative Court treated even a funder’s contractual right to comment on publications as enough to undermine autonomy, and the decision turned on this point. We invite the EDPB to retain factor (iv), alongside the other five factors, as a full part of the six-factor test in the final Guidelines.

Finally, we welcome the recognition in paragraph 11(iv) that research may be conducted under the supervision of qualified researchers, which addresses the autonomy factor for supervised

research. National practice on whether doctoral and supervised early-career research falls within scientific research as a whole nonetheless varies. We invite the EDPB to confirm that such research qualifies where the remaining factors are met, and to address the allocation of controllership in that setting (see Specific comment 2.11). National practice in France (CNIL) has expressly included *thèses de doctorat ou mémoires de recherche* within research scope.

2.2 Research data infrastructures (paragraph 13)

We welcome the explicit recognition that research data infrastructures may themselves constitute scientific research processing under the GDPR. This is operationally important for both institutional research registries and national-level structures, such as Findata under the Act on the Secondary Use of Health and Social Data 552/2019, the Finnish biobank network under the Biobank Act 688/2012, and the future EHDS Health Data Access Bodies.

Example 4 describes a public-authority pupil-data infrastructure based on a statutory task. We invite the EDPB to clarify whether the analysis in section 2.2 also covers infrastructures that universities and other research bodies operate under Article 6(1)(e) or 6(1)(f), without an explicit statutory mandate, where the six-factor test is satisfied.

2.3 Ancillary processing operations (paragraphs 14-15)

We welcome the explicit recognition of ancillary processing operations as part of scientific research. This eliminates a long-standing uncertainty over preparatory processing, including contact-data collection, sampling and pseudonymisation, which has often preceded substantive research processing in practice.

Paragraph 15 requires each ancillary operation to have a clear scientific-research objective, assessed case by case against the six factors. We ask the EDPB to confirm that this case-by-case assessment may be carried out and documented at project level, by recording in the research plan, the data management plan and the privacy notice how each ancillary operation (contact-data collection, sampling, pseudonymisation) serves the scientific-research purpose, rather than through separate standalone assessments. Project-level documentation prepared before processing begins should then be recognised as sufficient for accountability under Article 5(2).

2.4 Data protection principles, purpose compatibility and storage limitation (paragraphs 16-31)

Paragraph 21 already distinguishes the compatibility assessment under Article 5(1)(b) from the lawfulness assessment under Article 6(1), recalling that compatibility of purposes should not be

confused with the principle of lawfulness (Joint Opinion 2/2026 paragraph 32). We invite the EDPB to make that distinction more operational, for example through a short decision sequence, because the paragraph 19 presumption can easily be misread as automatic permission to process further, which it is not.

Recital 29 of the Digital Omnibus states that further processing for archiving, scientific or statistical purposes is compatible without the Article 6(4) test. We ask the EDPB to address that clarification and to issue transitional guidance separating the position under the GDPR as currently in force from the position that would follow if the Omnibus were adopted as proposed (see General comment 1.1). Without it, controllers cannot design research programmes that outlast the legislative interim.

A reference to the EHDS Regulation (EU) 2025/327 in section 3.1.1, or its footnotes, would also help, as a parallel framework for the secondary use of health data. Where the EHDS authorisation framework itself defines and authorises the secondary use, we invite the EDPB to clarify how that framework relates to Articles 5(1)(b), 6 and 6(4), rather than requiring controllers to duplicate the EHDS assessment with a separate compatibility analysis.

We invite the EDPB to confirm that retaining research data for verification purposes is compatible further processing under Article 5(1)(b) read with Article 89(1), provided the Article 89(1) safeguards apply throughout. Verification here covers both *ethical verification* (research-integrity review and investigation of scientific misconduct under national procedures) and *verification of the research data itself* (peer review, replication studies and audit of the underlying data).

This is the interpretation Tampere University currently relies on: the extended retention period recognised in paragraph 27 is treated as compatible further processing of the original dataset, for which the original legal basis ordinarily remains available. Consistently with paragraph 21 of the Guidelines and the distinction recalled in Joint Opinion 2/2026 paragraph 32, we recognise that the suitability of that legal basis for the further processing must still be assessed, and that prolonged retention is subject to a regular review of its continued necessity under paragraph 31. We ask the EDPB to confirm this approach in the final Guidelines.

The duty to fix the storage period before processing begins must also be reconciled with the acknowledged uncertainty of longitudinal studies. We ask the EDPB to confirm that criterion-based retention periods (for example, “until the cohort reaches age 80” or “until last publication plus five years”) satisfy Article 25(1).

This sits within the constraint set by paragraph 29: where the purpose of a future project cannot yet be specified, storage may be justified under Article 5(1)(e) only by reference to a defined

area of research, not to generic “scientific research”, and the future activities must be reasonably foreseeable in relation to that field. A criterion-based retention period is compatible with that constraint, because it fixes the endpoint of retention by reference to the defined research field and design rather than to an open-ended label.

2.5 Consent as a legal basis, Article 6(1)(a) and Article 9(2)(a) (paragraphs 35-55)

We support the EDPB’s recognition that imbalance of power may invalidate consent. In *Meta v Bundeskartellamt*, the Grand Chamber held that where there is “clear imbalance” between the data subject and the controller, consent presumptively does not meet the freely-given requirement.[2] EDPB-EDPS Joint Opinion 3/2026 paragraph 46 confirms the same approach in research contexts. The explicit list of vulnerable groups (prisoners, pupils, the unemployed, marginalised persons) is operationally useful.

We ask the EDPB to confirm in section 4.3 that the proposed Recital 32 of the Digital Omnibus does not displace Article 6(1)(e) where Union or Member State law provides for the latter. Recital 32 states that scientific research pursues a legitimate interest within Article 6(1)(f), provided its other conditions are met. Articles 6(1)(e) and (f) should both be available as legal bases for scientific research, without categorical precedence (see General comment 1.2).

We welcome the explicit distinction between ethical consent for participation in research (for example under the Clinical Trials Regulation (EU) 536/2014 or the Medical Research Act 488/1999) and GDPR consent as a legal basis. This is consistent with the EDPB Document on health research (2 February 2021) paragraph 5 and EDPB-EDPS Joint Opinion 3/2026 paragraph 46.

2.6 Public interest task, Article 6(1)(e) (paragraphs 56-59)

We strongly welcome the recognition, in paragraph 56, that Article 6(1)(e) is a legal basis of particular importance for scientific research, and the Guidelines’ explicit recognition of Section 4(1)(3) of the Finnish Data Protection Act 1050/2018 as a Member State example. For Finnish universities this is the principal legal basis: Section 2 of the Universities Act 558/2009 sets the statutory research mission, and Section 4(1)(3) of the Data Protection Act provides the corresponding Article 6(1)(e) basis. We rely on it virtually without exception.

This reliance is deliberate. Many university research settings involve a structural imbalance of power (researcher and student, clinician and patient, employer and employee) that can prevent

[2] Case C-252/21, *Meta Platforms and Others v Bundeskartellamt*, judgment of 4 July 2023, paragraph 149.

consent from being freely given. Article 6(1)(e), anchored in the statutory research mission, avoids that difficulty, and we ask the EDPB to keep the recognition in paragraph 56 prominent in the final Guidelines.

Two clarifications are particularly helpful, and we ask the EDPB to retain them. Paragraph 57 distinguishes Article 6(1)(e), which authorises processing, from Article 6(1)(c), which mandates it, and confirms that the law need not prescribe the precise manner of the research. Paragraph 58 confirms that Article 6(1)(e) is available not only to public bodies but also to private actors where Union or Member State law covers their activity. Both points matter in Finland, where research is conducted by universities, university hospitals, and private and foundation-based research institutes alike.

The Guidelines note that the list of Member State examples is not exhaustive. In the Finnish health-research context, Section 4(1)(3) is concretised by sectoral statutes, in particular Section 11a of the Biobank Act 688/2012 (Article 6(1)(e) read with Article 9(2)(i)) and the Act on the Secondary Use of Health and Social Data 552/2019; these operate as part of the same Article 6(1)(e) framework. As recalled in General comment 1.3, such national legislation provides a legal basis but does not exempt controllers from the general requirements of Articles 5, 6(1) and 9 of the GDPR.[3]

Because Article 6(1)(e) is the operative basis for Finnish university research, we ask the EDPB to preserve the balance between sections 4.2 and 4.3 in the final Guidelines: Articles 6(1)(e) and 6(1)(f) are parallel bases, and the proposed Recital 32 of the Digital Omnibus should not be read as giving Article 6(1)(f) precedence where Member State law provides an Article 6(1)(e) basis (see General comment 1.2). Processing under Article 6(1)(e) remains subject to the necessity and proportionality requirements recalled in paragraph 59.

2.7 Legitimate interest, Article 6(1)(f) (paragraphs 60-63)

We note that the Guidelines recognise scientific research as capable of constituting a legitimate interest under Article 6(1)(f). For Finnish university research, however, Article 6(1)(e) is the operative basis (see General comment 1.2 and Specific comment 2.6); we rely on Article 6(1)(f) only for processing outside the public-task mission, such as certain commercial research collaborations. We therefore ask the EDPB to confirm that the proposed Recital 32 of the Digital Omnibus does not give Article 6(1)(f) precedence over an available Article 6(1)(e) basis.

[3] Case C-65/23, *K GmbH*, judgment of 19 December 2024.

2.8 Processing of special categories, Article 9 GDPR (paragraphs 64-75)

We welcome the EDPB's confirmation that Article 9(1) also covers data from which special-category information can be inferred. The Court of Justice has held that inference-based special-category data attracts the same protections as directly collected data.[4] That position relieves a recurring interpretive uncertainty for register-linked research.

We strongly welcome the Guidelines' explicit reference to Section 6(1)(7) of the Finnish Data Protection Act 1050/2018 as an Article 9(2)(j) derogation. Section 6(2) of the Data Protection Act lists eleven specific safeguards (including logging, access controls, pseudonymisation, encryption and a data protection impact assessment) that operationalise Article 89(1) in conjunction with the Article 9(2)(j) derogation.

Paragraph 75 currently confines to *medical research* the rule that reliance on Article 6(1)(f) for special-category processing also requires an Article 9(2) derogation. We acknowledge that explicit limitation, but the underlying rule is general: under paragraph 64, a controller processing special categories for scientific research must identify an applicable Article 9(2) derogation, so the combined operation of Articles 6 and 9 applies to all special-category processing, not only to clinical trials. We invite the EDPB to confirm that the same requirement applies to all scientific research with special-category data, and to consider relocating the clarification outside the medical-research-specific framing of paragraph 75.

2.9 Information obligations, Articles 12-14 GDPR (paragraphs 76-110)

We invite the EDPB to clarify how the proposed new Article 13(5) GDPR (introduced by the Digital Omnibus) relates to the existing Article 14(5)(b). Three points would assist controllers: whether the impossibility or disproportionate-effort threshold is intended to be identical; whether the indicative situations in paragraph 100 apply to the new Article 13(5) in parallel; and how the Article 89(1) safeguards link to the proposed Article 13(5) derogation (see General comment 1.1). We take no position on the desirability of the Omnibus change.

Explicit guidance on the three thresholds in Article 14(5)(b) (*impossible*, *disproportionate effort*, and *render impossible or seriously impair*) would also help. Indicative criteria or example situations would let controllers identify the applicable threshold without case-by-case improvisation.

[4] Case C-184/20, *OT*, paragraphs 120-127; Case C-21/23, *ND v DR Lindenapotheke*, paragraphs 79-83.

We welcome the EDPB's reference to *Másdi*: Member State law may exempt a controller from Article 14 only where the law itself ensures information at least as broad as Articles 14(1) to (4).[5] A general research statute without a concrete information mechanism does not satisfy this equivalence requirement.

Paragraphs 87 to 89 give welcome practical guidance on contact details. A controller should not delete contact details where it anticipates further processing for scientific research; where it holds none, it should seek them from public registries unless this would require disproportionate effort; and failing that, it should inform data subjects indirectly, for example through a published notice. This is the operational counterpart to the foreseeability of further processing addressed in Specific comment 2.4: a controller that anticipates further research must preserve the means to inform data subjects when it occurs.

We also invite the EDPB to add a reference, in section 5.4.2.5, to EHDS Article 58 as a Union-level example of an Article 14(5)(c) information mechanism. The Health Data Access Body must publish centrally accessible information on legal basis, safeguards, rights, granted data permits and research outcomes, which complements Article 14 of the GDPR in a structurally distinct way.

2.10 Data subjects' rights, Articles 15-21 and Article 89(2) (paragraphs 111-128)

We strongly welcome the Guidelines' explicit reference to Section 31 of the Finnish Data Protection Act 1050/2018 as a Member State implementation of Article 89(2).

We draw the EDPB's attention to footnote 164: the combination "Version 2.1, 28 March 2023" does not match the EDPB's own version table for Guidelines 01/2022 (Version 2.0 = 28 March 2023; Version 2.1 = 30 May 2024). The footnote should be corrected to one of those two combinations.

The Court of Justice in *GC and Others* held that an erasure request cannot be rejected in abstract reliance on a "research" label.[6] The controller must assess all circumstances, including the severity of interference and whether continued access is strictly necessary. This case-by-case approach should anchor the EDPB's treatment of the Article 17(3)(d) research exception, particularly where special-category or criminal-conviction data are processed.

[5] Case C-169/23, *Nemzeti Adatvédelmi v UC Másdi*, judgment of 28 November 2024, paragraphs 44 and 54.

[6] Case C-136/17, *GC and Others*, judgment of 24 September 2019.

We welcome the high threshold for the Article 17(3)(d) research exception (*render impossible or seriously impair*), consistent with the strict-interpretation principle reaffirmed by the Court of Justice in *Agentsia po vpisvaniyata v OL*.[7] Paragraph 120 of the Guidelines proposes indicative criteria (the small versus large data-subject group, the importance of an individual record to the result, and the existence of an ongoing longitudinal study), which are useful for small-cohort research such as rare-disease studies and small ethnographic samples. We ask the EDPB to confirm that those factors are illustrative rather than exhaustive.

We also draw the EDPB's attention to footnote 174, which cites C-200/23 paragraph 124 for the strict-necessity principle. Paragraph 124 in fact concerns Article 17(3)(b) (legal obligation) in the context of public registers (the *Manni* balancing) and does not address the research exception. We invite the EDPB to consider *Másdi* paragraphs 44 and 54 as a more accurate anchor for the requirement that derogations from data subjects' rights provide equivalent protection.

We welcome the recognition that Article 21(6) provides a basis for declining objections where the processing is necessary for a public-interest task. In Finland, Section 2 of the Universities Act 558/2009 combined with Section 4(1)(3) of the Data Protection Act provides that legal foundation.

Paragraph 125 takes this further: a controller relying on Article 6(1)(f) may also decline an objection under Article 21(6) where it can show that the research processing is a legitimate interest coinciding with a public interest. This confirms that Articles 6(1)(e) and 6(1)(f) operate in parallel at the stage of the right to object, which supports the parallel-basis reading set out in General comment 1.2.

2.11 Controller, processor and joint controllers, including EHDS role allocation (paragraphs 129-145)

We strongly welcome the EDPB's confirmation that role allocation is functional and rests on the parties' actual conduct rather than on the contractual label. This reflects EDPB Guidelines 07/2020 paragraphs 11-12 and the settled case-law on functional controllership.[8]

Paragraph 144 uses two different terms for the instrument that allocates responsibilities between joint controllers. The first sentence states that the allocation "must be laid down in an agreement", whereas the following sentence refers to an "arrangement", and the paragraph then ties the requirement to Article 26(2) GDPR. Article 26(1) deliberately uses the broader term "arrangement", which need not take the form of a formal contract: Article 26(1) expressly allows

[7] Case C-200/23, *Agentsia po vpisvaniyata v OL*, judgment of 4 October 2024.

[8] Case C-25/17, *Jehovan todistajat*; Case C-210/16, *Wirtschaftsakademie*; Case C-604/22, *IAB Europe*.

the respective responsibilities of joint controllers to be determined by Union or Member State law, and Article 26(2) requires only that the essence of the arrangement be made available to data subjects. We invite the EDPB to use "arrangement" consistently in paragraph 144, in line with Article 26, and to clarify that joint controllers may allocate their responsibilities through an arrangement that is not necessarily a formal contract, provided that its essential content is made available to data subjects.

We take note of the EDPB's reference to *Tiroler Landesregierung*, which recognises that a Union or Member State law conferring a role, task and powers may implicitly designate the controller.[9] We invite the EDPB to confirm that this implicit-designation framework coexists with, rather than displaces, a functional, project-level assessment under Article 4(7), so that controllers may continue to assess controllership case-by-case, by reference to who determines the purposes and essential means of processing. In Finland, Section 2 of the Universities Act 558/2009 sets the statutory research mission, but we allocate controllership in any individual research project on functional grounds.

A further configuration would benefit from explicit treatment: the allocation of controllership where a natural person conducts research without an employment relationship with the institution, such as a doctoral candidate, a grant-funded researcher or a master's thesis author. An employed researcher acts under the authority of the institution as controller; a non-employed researcher does not. In our reading, such a researcher is ordinarily the controller of their own research, determining its purposes and essential means, consistent with the natural-person controllership that paragraph 137 recognises.

Where the institution subsequently processes the same personal data to discharge its own statutory duties, for example in examining a thesis and ensuring good scientific practice, it does so for a distinct purpose of its own, rather than jointly with the researcher; in Finland that processing rests on a statutory obligation of the institution within the meaning of Article 6(1)(c). This mirrors the analysis in Example 25, where a body that processes the same data for its own statutory task, outside the scope of the research, is a separate controller, and it is consistent with paragraph 134, under which supervising or commenting on a research protocol does not by itself make the institution a controller of the researcher's processing. We invite the EDPB to clarify how controllership should be allocated in this situation; confirmation that an institution processing such data to meet its own statutory duties acts as a separate controller, on its own legal basis, would assist universities. This question connects to the scope of doctoral research addressed in Specific comment 2.1.

[9] Case C-638/23, *Tiroler Landesregierung*, judgment of 27 February 2025.

We welcome Example 25 (a non-interventional observational study with a pharmaceutical sponsor, university hospitals and a private research institute as joint controllers, a federated database, and sub-projects in changing constellations). The multi-layered allocation (federated joint controllership, sub-project constellations, and independent subsequent processing) is operationally important for university research consortia.

We invite the EDPB to add a dedicated treatment of EHDS roles in section 7. EHDS Article 2(1)(t) defines a "health data holder" as a controller or joint controller under the GDPR. EHDS Article 87 then allocates roles so that a Health Data Access Body may be controller of its own activities (data collection, secure-processing-environment operation, permit issuance) but processor when it transfers data to a data user under a permit. This dual-role processing is a structural feature of EHDS that the Guidelines should address.

2.12 Appropriate safeguards under Article 89(1), including AI-research safeguards (paragraphs 146-171)

We invite the EDPB to clarify how Article 89(1) safeguards interact with stricter Member State safeguards. In Finland, Section 6(2) of the Data Protection Act 1050/2018 prescribes eleven safeguards for special-category processing, and Section 31 permits derogations from certain data subjects' rights (Articles 15, 16, 18 and 21) for research; where such a derogation is combined with the processing of special categories of data, the controller must carry out a data protection impact assessment and submit it in writing to the Data Protection Ombudsman before processing begins. The Guidelines should confirm that Member State law may supplement but not lower the Article 89(1) threshold.

We draw the EDPB's attention to footnote 240, which cites *EDPS v SRB* "para. 82" for the phrase "means reasonably likely to be used to identify the data subject". Paragraph 82 contains a reformulation of the *Breyer* doctrine ("does not, in itself, mean…"); paragraph 84 elaborates the standard ("means reasonably likely to be used", citing *Gesamtverband Autoteile Handel*); and paragraph 87 contains the verbatim phrase ("means reasonably likely to be used for the purposes of identifying the data subject").[10] We invite the EDPB to amend the citation to "para. 87" alone or to "paras. 84 and 87".

We also ask the EDPB to indicate the version status of the cited pseudonymisation guidance. EDPB Guidelines 01/2025 on Pseudonymisation are still in their public-consultation version (adopted 16 January 2025; consultation closed 14 March 2025; final version not yet published as of June 2026). The footnotes should reflect that status, and we invite the EDPB to coordinate

[10] Case C-413/23 P, *EDPS v Single Resolution Board*, judgment of 4 September 2025.

the publication of the final pseudonymisation guidelines with the final version of the present Guidelines.

An institutional illustration of Article 25 in practice. Tampere University operates a five-tier information-classification model (Secret 1R, Strictly Confidential 2A, Confidential 3Y, Internal 4G, Open 5W). It aligns closely with a shared data-classification approach developed within the Finnish higher-education sector under Universities Finland (Unifi) and the Rectors' Conference of Finnish Universities of Applied Sciences (Arene), although sector-wide adoption to date remains limited. Technical controls escalate with the classification tier and are enforced at system level. Anonymous sharing links are blocked at every tier except Open (5W). Internal (4G) and Secret (1R) data cannot be shared outside the organisation. At the two most-protected tiers (Strictly Confidential 2A and Secret 1R), AI tools such as Copilot are blocked and email and attachments are encrypted; at the Secret tier (1R), access is further restricted to authorised users and forwarding, printing and copying are disabled. This is one institutional model of how Article 89(1) can be operationalised; we offer it as illustration rather than as an EU-wide recommendation. We invite the EDPB to recognise, among the section 8.5 safeguards, that information-classification models of this kind (data classification combined with system-level technical controls, including restrictions on AI tools for the most sensitive tiers) are a practical means of operationalising Article 89(1), and to address how those safeguards relate to AI tools increasingly embedded in research environments.

We welcome the explicit cross-reference to EHDS Article 73 and Recital 77 (secure processing environment) and to Data Governance Act Article 2(20). EHDS Article 73 sets a structured minimum standard (state-of-the-art access controls, unique identifiers, one-year minimum logging, and regular third-party audits), and Recital 77 designates the secure processing environment as an "essential safeguard".

Finally, we invite the EDPB to add a subsection on AI-related research safeguards, within the scope of its Article 70(1) GDPR mandate (see General comment 1.4). Four points would benefit from clarification. First, when AI-related processing qualifies as scientific research under Article 89(1), and when it falls under the proposed Article 88c GDPR. Second, whether a single research project can contain both Article 89(1) research processing and Article 88c AI development at different stages. Third, how the proposed Article 9(5) interacts with the section 8.4 safeguards for genetic and biometric data. Article 9(5) permits incidental residual special-category data in AI training, subject to controller measures to avoid collecting it, to remove it once detected, and to protect it where removal would require disproportionate effort. Fourth, which section 8.5 safeguards are particularly relevant to AI research, given its specific risk profile. As elsewhere, we recognise that the EDPB's mandate is GDPR interpretation, not a

political assessment of the Omnibus or the AI Act.

Annex, sources cited

Union law
Regulation (EU) 2016/679 (General Data Protection Regulation), in particular Articles 4, 5, 6, 9, 13, 14, 17, 21, 24, 25, 35, 70 and 89.
Regulation (EU) 536/2014 (Clinical Trials Regulation).
Regulation (EU) 2022/868 (Data Governance Act), Article 2(20).
Regulation (EU) 2025/327 (European Health Data Space Regulation), Articles 2(1)(t), 53(1)(e), 58, 73 and 87, and Recital 77.
COM(2025) 837 final, Digital Omnibus proposal of 19 November 2025.
Court of Justice of the European Union
C-582/14, *Breyer* (19 October 2016).
C-25/17, *Jehovan todistajat*.
C-136/17, *GC and Others* (24 September 2019).
C-210/16, *Wirtschaftsakademie*.
C-184/20, *OT*.
C-252/21, *Meta Platforms and Others v Bundeskartellamt* (4 July 2023).
C-319/22, *Gesamtverband Autoteile-Handel* (9 November 2023).
C-21/23, *ND v DR Lindenapotheke*.
C-65/23, *K GmbH* (19 December 2024).
C-169/23, *Nemzeti Adatvédelmi v UC Másdi* (28 November 2024).
C-200/23, *Agentsia po vpisvaniyata v OL* (4 October 2024).
C-413/23 P, *EDPS v Single Resolution Board* (4 September 2025).
C-604/22, *IAB Europe*.
C-638/23, *Tiroler Landesregierung* (27 February 2025).
EDPB documents and Joint Opinions
EDPB Guidelines 07/2020 on the concepts of controller and processor.
EDPB Guidelines 01/2022 on the right of access.
EDPB Guidelines 01/2025 on Pseudonymisation (public consultation version, adopted 16 January 2025).
EDPB Document on health research (2 February 2021).
EDPB-EDPS Joint Opinion 2/2026.
EDPB-EDPS Joint Opinion 3/2026.
National DPA guidance
CNIL guidance on research outside the health sector; CNIL public-task / legitimate-interest allocation guidance.
Finnish law
Universities Act 558/2009, Section 2.
Data Protection Act 1050/2018, Sections 4, 6 and 31.
Medical Research Act 488/1999.
Biobank Act 688/2012, Section 11a.
Act on the Secondary Use of Health and Social Data 552/2019.
Act on the Openness of Government Activities 621/1999.
Finnish case-law
Supreme Administrative Court of Finland, KHO 2013:181.