Comments of the Slovak Rectors' Conference on the EDPB Guidelines on the processing of personal data for scientific research purposes (srk@srk.sk, www.srk.sk/en)

1. Comments of the Slovak Medical University in Bratislava on the EDPB (European Data Protection Board) Guidelines on the processing of personal data for scientific research purposes

1. Lack of cross-border harmonisation for clinical trials

Area of concern:

The document repeatedly relies on Member State legislation to determine specific conditions and exemptions applicable to the processing of genetic, biometric and health data.

Potential impact:

For medical universities and medical faculties participating in international research consortia, this lack of centralised harmonisation represents a significant challenge. The Guidelines do not provide a unified standard for multicentre clinical trials across the EU, placing Slovak researchers in a complex position where national legislation governing health data may conflict with the data retention requirements or consent procedures applied by partner institutions in countries such as Austria or Germany.

2. Operational ambiguity regarding the interface with the EHDS

Area of concern:

Although the Guidelines acknowledge the European Health Data Space (EHDS) Regulation and the use of secure processing environments, they do not clarify how academic medical registries should practically transition into this framework.

Potential impact:

University hospitals manage extensive historical patient registries and biobanks. The text lacks practical guidance on how to bridge the gap between internal university data structures and the requirements for secondary use of data established by the EHDS. This exposes institutions to potential bureaucratic barriers when sharing data for broader European research and development (R&D) projects.

3. Missing technical thresholds for medical AI and rare diseases

Area of concern:

The EDPB acknowledges that advances in artificial intelligence are driving significant medical breakthroughs and refers to "synthetic data" as a privacy-enhancing technology (PET). However, it does not provide detailed scientific criteria or technical parameters for the use of these tools.

Potential impact:

In medical research and development—particularly in the training of AI models for rare diseases—the distinction between pseudonymised and identifiable data is extremely narrow due

to unique genetic profiles or clinical markers. The Guidelines miss an important opportunity to define clear security thresholds for the use of patient-derived data in machine learning. As a result, developers of medical AI systems are left uncertain as to the point at which a clinical dataset may legally be considered "fully anonymised".

4. Legal barriers to university technology transfer and the creation of spin-off companies

Area of concern:

The document outlines the allocation of responsibilities within public–private partnerships and notes that research activities may transition from a legal basis of public interest to one based on legitimate interest for commercial purposes. However, it does not adequately define the compliance boundaries during the phase of clinical translation.

Potential impact:

When university researchers develop a patentable medical device or a novel pharmaceutical product, the project moves from academic research into commercial exploitation. The Guidelines do not provide a clear regulatory transition pathway or protocol for university technology transfer offices managing the transfer of data-related responsibilities and ownership from a public university (public interest basis) to a commercial spin-off company (legitimate interest basis). This creates substantial legal uncertainty and compliance risks during the commercialisation process.

2. Comments of the University of Veterinary Medicine and Pharmacy in Košice on the EDPB Guidelines on the processing of personal data for scientific research purposes

Within the clinical departments of the University of Veterinary Medicine and Pharmacy in Košice, research primarily focuses on veterinary medicine, experimental models and the processing of biological material of animal origin. In many cases, the processed data concern animals, which are not subject to the scope of application of the GDPR.

However, in certain situations, personal data relating to natural persons may also be processed directly or indirectly, particularly data concerning animal owners. This may occur, for example, where identification or contact details of owners are recorded as part of clinical studies or retrospective analyses of veterinary patients, or where animal health data are linked to a specific identifiable individual. Similarly, personal data may be processed in questionnaire-based studies, informed consent procedures, or through cooperation with external entities.

Cases where the GDPR applies:

1. Clinical studies involving client-owned animals, where the following data are collected:
owner's name and contact details,
address,
signature on the informed consent form.
2. Questionnaire-based studies:
owner satisfaction surveys,
epidemiological surveys,
data concerning the lifestyle of animals and their owners.
Such activities constitute the processing of personal data.

In these cases, compliance with GDPR requirements must be ensured, including transparency towards data subjects, data minimisation, and the implementation of appropriate technical and organisational measures to protect personal data.

Comments on the EDPB Guidelines on the processing of personal data for scientific research purposes

We consider EDPB Guidelines 1/2026 to be beneficial, as they provide a more detailed interpretation of the processing of personal data in scientific research and clarify the conditions for applying GDPR exemptions. In particular, we consider the definition of criteria for scientific research to be highly valuable.

From the perspective of veterinary research, it would be appropriate to include more practical examples concerning the processing of data relating to animals and their owners, as well as situations arising from cooperation between universities, veterinary clinics, private companies and research organisations.

3. Comments of Comenius University Bratislava on the EDPB Guidelines on the processing of personal data for scientific research purposes:

We welcome the initiative of the European Data Protection Board (EDPB) to bring greater clarity to the issue of personal data processing for scientific research purposes. However, as legal experts and representatives of the biomedical research sector (biobanks), we must note that the proposed Guidelines 1/2026, in many respects, paralyze long-term research and ignore the evolving European legislative reality. Below, we present key comments that we request be implemented:

I. Summary of Comments

- Elimination of broad consent: The EDPB is artificially pushing the concept of "dynamic consent," thereby negating the intent of Recital 33 of the GDPR and imposing an unbearable logistical and financial burden on biobanks.

- Threat to statistical validity: A restrictive interpretation of exceptions to the right to erasure for large datasets ignores the cumulative effect of erasures and the threat of introducing bias into research.

- Failure to account for the specificities of retention and purpose limitations in relation to biobanks

- Lack of basis and justification for key research factors: The EDPB creates its own 6 key research points, which, however, have no basis in the GDPR and are arbitrarily compiled from multiple sources, none of which have the nature of international agreements, The EDPB is thus usurping the authority to define research beyond the scope of its competencies and without taking into account the forthcoming definition of research under the Digital Omnibus.

- Technical requirements: Supervisory authorities will view examples of technological safeguards (homomorphic encryption, synthetic data) as a minimum standard, which is economically devastating for the public research institutions with which the biobank collaborates.

- Prematurity and lack of conceptual framework: The guidelines completely ignore the upcoming Digital Omnibus and the European Biotech Act, which fundamentally change the paradigm of scientific research (they introduce a legal definition of research, exemptions from Article 13 of the GDPR, and equate pseudonymized data with anonymized data).

II. Specific Comments and Legal Analysis

1. The risk of undermining the validity of ongoing research through a restrictive interpretation of the right to erasure (Section 6.2.2, paragraph 120, p. 48)

In paragraph 120, the EDPB asserts that if a controller processes data from a large number of data subjects, the erasure of one person's data is unlikely to "seriously jeopardize" the research, and therefore the exception under Article 17(3)(d) should not apply. This interpretation completely ignores the cumulative effect of erasure rights in long-term projects, as well as the financial costs that biobanks may incur in collecting and storing samples they

will not be able to use. If a biobank is forced to delete data simply because it has "a lot of other data," this will devalue the dataset and introduce systematic bias into the research.

Biobanks cannot yet rely on the legal exception to erasure (Article 17(3)(c) of the GDPR) because a law on biobanks does not yet exist; therefore, the interpretation of Article 17(3)(d) of the GDPR is of critical importance to biobanks. We are of the opinion that if the data is already being used for research and the controller has already invested significant financial resources in the preparation, storage, or selection of the data, then the withdrawal of consent should not affect the lawfulness of further processing. Furthermore, in the context of a biobank, it is expected that the biobank will process a large number of samples, which stems from its nature and the fulfillment of its objectives; the biobank is therefore of the opinion that it should be presumed by default to be processing data for research purposes, and the exception under Article 17(3)(d) should not be interpreted restrictively; to this end, more specific conditions for the application of this exception should be established, or an example should be provided demonstrating that a refusal to delete data from the biobank's database may be legitimate.

Comment: We request that exceptions to erasure be assessed primarily based on scientific methodology and the preservation of statistical validity, not on the arithmetic number of subjects in the database.

2. Replacing broad consent with dynamic consent (Sections 3.2 and 4.1.2.1, paragraphs 46–48)

The EDPB's requirement to ensure "adequate predictability" for long-term research goes far beyond the very scope and purpose of Recital 33 of the GDPR; in the field of biobanking and genetic research, it is by its very nature impossible to predict ex ante, with a 10- to 20-year outlook, technological advances, the discovery of new biomarkers, or previously unknown correlations between genetic mutations and diseases. The strict requirement to specify future research projects (e.g., as in Example 8 of the guidelines) negates the very purpose of the concept of "broad consent," which was incorporated into the GDPR precisely to reflect the specificities and unpredictability of scientific research. Equally categorical is the EDPB's conclusion in paragraph 46 of the guidelines, according to which a research institution is required to switch to a model of so-called dynamic consent and to recontact data subjects if a new research project deviates from the originally anticipated parameters imposes a crippling

administrative and financial burden on academic institutions. In the specific context of Slovak science and research, this requirement is logistically unfeasible, as domestic institutions, unlike Western European infrastructure, do not have dedicated mobile applications or portals for research participants, and local biobanks primarily operate with historical paper-based consent forms. Updating contact information e.g., a change of permanent residence or inactive email addresses after decades, is practically impossible to implement systematically, and in long-term projects, situations arise where the data subjects have died in the interim or are unreachable for objective reasons. Enforcing the requirement to recontact data subjects for the purpose of further specifying the purpose and obtaining a legal basis would thus lead to the de facto paralysis and blocking of ongoing research projects, which is in direct conflict with Article 89(1) of the GDPR, according to which Member States and supervisory authorities are to create conditions to support scientific research,

rather than creating disproportionate barriers that lead to the devaluation of legitimately collected biological samples and data.

Comment: We request that the EDPB explicitly acknowledge that, in the case of biobanking infrastructures, the field of research or the purpose itself (e.g., "biomedical and genetic research") may be defined more broadly, i.e., without the need to constantly re-contact data subjects and switch from general consent to dynamic consent.

3. The Enormous Burden of Partner Changes and the Duty to Inform (Section 5.5 and Paragraph 96)

The EDPB requires (Section 5.5) that data subjects be proactively informed of any new research partner or of the data that such a partner generates and derives from the original data with which the biobank shares data. Although there is an exception for "disproportionate effort" (Article 14(5)(b)), the EDPB states in point 96 that this exception must not be used routinely.

Comment: We request that the EDPB explicitly state in the guidelines that, in the case of long-term international biobank consortia, the application of the disproportionate effort exception in the context of routine changes to or additions of research partners is a standard and legitimate practice (e.g., through website updates).

4. Overburdening patients with bureaucracy, separation of interfaces (Section 4.1.3, point 55, p. 27)

In point 55, the EDPB states that in the case of complex or sensitive processing, the controller should provide a separate interface or form that addresses solely GDPR consent, distinct from ethical consent to participate in research (e.g., under the CTR). The phrase "it may be necessary for the controller to provide a separate interface or form" without precise criteria opens the door to overly strict supervisory authorities. We therefore believe that there is no precise boundary for when consents must be requested separately and when together. Supervisory authorities could mechanically require separate documents from biobanks, which would again create unnecessary bureaucracy. This pressure to separate rather than integrate will lead in practice to the so-called "over-consent effect" (consent fatigue) and to absolute confusion for the patient.

Comment: We ask the EDPB to prioritize support for integrated, layered forms where both ethical and legislative aspects are in one place, clearly distinguished graphically. It should

specify when exactly consents must be granted separately or when exactly they may be granted together.

5. The practical significance of the presumption of compatibility is nullified (Section 3.1.1, points 21–22)

Although Article 5(1)(b) of the GDPR states that further processing for scientific purposes is compatible, the EDPB argues in points 21 and 22 that this does not imply automatic lawfulness, and the controller must seek a new, separate legal basis for secondary processing each time, which is nearly impossible when the original basis is "consent."

This interpretation renders the entire Article 5(1)(b) meaningless and devoid of purpose, particularly in cases where a biobank may collect data from volunteers for research purposes but without an identified project i.e., for an archive, whereby this data may subsequently be used for multiple research projects. No biobank in the world operates in such a way that it has a specific grant and scientific project approved from the outset for every single test tube. The infrastructure is always built first. If the original legal basis was the consent of the data subject (which is standard practice), the EDPB considers relying on the original basis to be nearly impossible without obtaining new consent. If a biobank were required to seek a new legal basis for every single sub-project or to recontact thousands of volunteers (who, years later, may no longer be alive or may have changed their contact information), the operation of biobanks would become logistically unfeasible.

Comment: We request that Section 3.1.1 be reworded to respect the intent of Recital 50 of the GDPR, namely that where the compatibility of purposes is demonstrable, it is not necessary to construct an entirely new, separate legal basis, at least for the area of biobanks.

6. Disproportionate technological requirements for appropriate safeguards (Sections 8.4 and 8.5)

In the text (Sections 8.4 and 8.5), the EDPB explicitly mentions advanced technologies such as federated storage, homomorphic encryption, synthetic data, and independent data trustees (data trustees). Although these are listed as examples, supervisory authorities will immediately begin requiring them as a mandatory minimum during inspections pursuant to Article 89(1). While the biobank maintains high security standards, these technologies may be financially and personnel-wise unattainable for Slovak public universities.

Comment: We request the addition of a clear provision stating that the implementation of these advanced technologies must take into account the operator's economic capabilities and the state of the art, while standard pseudonymization and strict access rights remain a fully sufficient safeguard.

7. The impracticability of the principle of storage limitation and purpose limitation of long-term scientific archives (Section 3.2, points 27–31, pp. 18–20)

Although Article 5(1)(e) of the GDPR explicitly allows for an exception under which personal data may be retained for scientific purposes for longer than is necessary to fulfill the original purposes, the EDPB imposes such restrictive conditions on this exception in Section 3.2 that it renders it impractical in practice. Given the nature of the biobank's function, it is not desirable to impose restrictions on the retention or disposal of samples, even if no specific purpose for

their use (such as a specific research project) has yet been established, or even in cases where these data have already been used in some research but may still be useful in the future.

Under point 3.2, the Committee acknowledges that it may be problematic to determine an exact retention period, which we agree with, as well as the recognition that it is sufficient to specify a certain area of research within the scope of the purpose. However, the second sentence in point 29 is problematic, as it states that data retention for "generic scientific purposes without any specification of purpose cannot be justified by reference to Article

5(1)(e) of the GDPR." The EDPB requires that future scientific activities be "reasonably foreseeable" at the time of data storage, and the controller must substantiate how it plans to use the data in future projects. To complete this restriction, the Board, in paragraph 31, imposes an obligation on controllers to regularly reassess the necessity of retention and mandates the transformation of data into an anonymized format if it is demonstrated that anonymous data is sufficient for a specific purpose.

Comment: This approach demonstrates a fundamental misunderstanding of the methodology of long-term scientific research and ignores the purpose of research infrastructures (registers and biobanks), which the GDPR explicitly protects and supports in Recital 157. We propose including biobanks at least as an exception.

8. Lack of coherence and disregard for Legislative Developments

The proposed guidance is premature and out of touch with European reality. The document fails to reflect the Digital Omnibus package currently under consideration, which introduces groundbreaking amendments directly into the GDPR:

- New Article 13(5), which will allow for a waiver of the information obligation even in the case of direct data collection for scientific purposes due to disproportionate effort.

- New Article 41a or changes to the definition of personal data, under which pseudonymized data will, under certain conditions, be considered directly anonymized, as it may not be possible for some participants in the research chain to link it to a specific individual.

- The introduction of a definition of scientific research into the GDPR that has nothing to do with the aforementioned 6 key conditions established by the EDPB.

Comment: We request that the EDPB suspend the final approval of the guidelines until the legislative process for the Digital Omnibus is completed; otherwise, the guidelines will lose their legal basis upon the entry into force of the new legislation.

9. Artificial and restrictive narrowing of the concept of "scientific research" (Section 2, points 11–12, pp. 8–10)

Recital 159 of the General Data Protection Regulation explicitly requires that the processing of personal data for scientific research purposes be interpreted broadly (including technological development, applied research, and privately funded research). However, in point 11 of the proposed draft, the EDPB introduces a restrictive, exhaustive list of 6 key indicative factors (methodological approach, hypothesis, autonomy, academic qualifications, etc.), while in point 12 it disproportionately places the burden of proof on the controller. According to the EDPB, if a research activity does not meet all 6 factors simultaneously, the controller must actively defend and demonstrate why it should be considered research.

We believe that the EDPB is clearly exceeding its authority with this interpretation. In constructing these six factors, the Board refers to the European Code of Conduct for Research Integrity (ALLEA / ECCRI) and the European Charter for Researchers. However, these documents are non-binding "soft law." Without any basis in the text of the GDPR itself, non-

binding academic recommendations are thus being transformed into strict and enforceable legal conditions intended to serve as a test of the lawfulness of processing.

Furthermore, the EDPB's selection of these specific six factors is arbitrary and unsystematic. The guidelines provide no justification for why the Board selected these specific characteristics and omitted other key principles defined in the ECCRI Code, such as the sustainability of research.

By the very nature of its existence and its legal purpose, a biobank necessarily serves scientific and research purposes. However, it participates in projects in different ways at various stages of its life cycle.

- During the initial collection, processing, and long-term storage of samples and data in a biobank infrastructure, there is logically no specific scientific hypothesis (one is formulated only months or years later in the context of a specific project).

- Strict application of point 12 would mean that the initial (infrastructural) phase of biobanking would lose its presumption of scientific research, thereby placing the sector in a state of extreme legal uncertainty.

- Although biobanks, by their very nature, always rigorously adhere to ethical standards, transparency, verifiability, and a methodological approach, they cannot be penalized for not having a final peer-reviewed project or a defined hypothesis in the initial stages of biological material collection. Establishing rigid requirements would thus paralyze long-term biobanking.

Comment: We request that the EDPB revise points 11 and 12 (as well as the 15th ancillary processing operation) so that the proposed indicative factors serve solely as illustrative examples. The absence of any of the factors (e.g., the lack of an explicit hypothesis during the data infrastructure development phase) must not give rise to the presumption that the activity is not scientific research or that biobanks are identified within the guidelines as a sui generis entity that always processes data for research purposes (provided that ethical standards are adhered to).

We propose that, in the context of biomedical research, the EDPB explicitly take into account the fact that research projects are subject to approval by an independent ethics committee, which in itself constitutes a significant guarantee of the scientific legitimacy, ethicality, and public interest of the research.

We propose that the concept of scientific research be interpreted consistently and broadly in the sense of Recital 159 of the GDPR, in direct connection with legislative developments and the legal definition of research being prepared within the Digital Omnibus, and that no requirements be included that do not follow from these definitions. This will prevent the artificial creation of bureaucratic obstacles that would disproportionately hinder public institutions (biobanks) as well as private researchers from achieving their scientific goals.