25th of June, 2026

BBMRI-ERIC's response to the European Data Protection Board's Public Consultation on draft Guidelines 1/2026 on processing of personal data for scientific research purposes.

Introduction

BBMRI-ERIC (Biobanking and Biomolecular resources Research Infrastructure – European Research Infrastructure Consortium) is the European research infrastructure (RI) for biobanking and biomolecular resources, one of the largest RIs in the health and life sciences. Set up in 2013, it includes around 500 biobanks within 26 Nodes from 25 Member/Observer countries plus the global organization IARC/WHO. A distributed research infrastructure, BBMRI-ERIC enables the development of innovative technology and processes as a cross-domain network that facilitates responsible access to high-quality samples, data and biomolecular resources. We achieve this through multidisciplinary expertise and service provision, scientific excellence, knowledge exchange, and partnerships in health and life sciences. BBMRI-ERIC's vision is simplified as: "Biobanking for a Healthier World".

In the guidelines, we note that biobanks are mentioned once and provided as an example of a research infrastructure. We also note that section 2.2 is dedicated to research data infrastructures that have the purpose of making the data available for future research projects within a specific area of research. We also note that footnote 25 within section 2.2 refers to Article 2(a) Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 8.8.2009, pp. 1). On this point, we wish to note that BBMRI-ERIC, established under the ERIC Regulation, operates as a distributed, three-layered digital and physical ecosystem. The infrastructure is structured into interconnected tiers to facilitate access to biological samples and data for biomedical research.
The three layers are organized as follows:

- **Biobanks:** The foundational physical layer. These are the local repositories (such as the Medical University of Graz or the Medical University of Innsbruck) where biological materials (tissues, blood, DNA) and clinical data are physically stored, managed, and annotated.
- **National Nodes:** The national management layer. Entities like **BBMRI.at** coordinate the activities of individual biobanks within a specific member country, linking them to the pan-European infrastructure and ensuring harmonization of procedures.
- **Central BBMRI-ERIC:** The pan-European headquarter. Based in Graz, Austria, it oversees the overarching infrastructure, facilitating cross-border access to samples and data, ethical/legal frameworks, and digital tools such as the BBMRI-ERIC Directory and Negotiator.

For ease of understanding, within this document, we refer to "research infrastructures" and these can include each of the layers specified above.

BBMRI-ERIC welcomes the publication of these draft Guidelines and appreciates the opportunity to provide comments during the public consultation. The Guidelines represent an important step towards promoting a more consistent interpretation and application of the GDPR across scientific research in Europe, particularly for biobanks and biomolecular resources that facilitate responsible, cross-border research using health and genetic data. As biobanks also operate in the sensitive health data domain, we particularly appreciate the focus of the Guidelines on this area. We thank the EDPB for its commitment to engaging with stakeholders and for recognising the value of consultation in developing practical and effective guidance.

This document is a joint effort between BBMRI-ERIC's central executive management office (Headquarters) and some of its National Nodes' ELSI experts[1]. BBMRI-ERIC is enabling the development of innovative technology and processes through facilitation of responsible access to high-quality samples, data and biomolecular resources, and our comments to the Guidelines reflect this.

To ensure clarity and ease of review, the comments below follow the same structure, section titles, and numbering as the EDPB Guidelines. This approach enables readers to identify immediately the specific provision to which each comment relates. Some of the comments relate to the use of personal data in research generally, while others are specific to biobanks, national nodes, and/or BBMRI-ERIC. Moreover, where a specific amendment to the text of the Guidelines is proposed, the comment is identified as "PROPOSED ADDITION" and the suggested wording is provided in quotation marks and italics. Where observations are intended to invite further consideration by the EDPB without proposing specific drafting changes, the comment is identified as "SUGGESTIONS".

2. The scope of the concept 'processing of personal data for scientific research purposes'

2.1 Key-indicative factors for determining whether processing of personal data is motivated by scientific research purposes

Comment 1:
We welcome the EDPB's effort to clarify the meaning of "scientific research purposes" under the GDPR. However, the Guidelines would benefit from greater alignment with the definition in the European Health Data Space Regulation (EHDS). While the six indicative factors are useful, they do not map neatly onto the definition in the EHDS. The definition in the EHDS includes development and innovation activities,

[1] Particular recognition should be given to the experts from BBMRI.it, BBMRI.at, BBMRI.cz, and the BBMRI-ERIC Headquarters ELSI team for their valuable contributions to this public consultation.

and the training, testing and evaluation of algorithms, including in medical devices, in vitro diagnostics, AI systems and digital health applications. This reflects a deliberately broad and sector-specific understanding of research and innovation in health data governance. We suggest taking the opportunity to clarify if criteria will apply to both "scientific research" as defined in the GDPR and in the EHDS Regulation. Without clarification, there is a risk that Health Data Access Bodies (HDABs), data holders, controllers and researchers will apply two different thresholds: one under the EHDS for access to electronic health data, and another under the GDPR for assessing whether the processing qualifies as scientific research. This could create legal uncertainty, inconsistent access decisions across Member States, and unnecessary barriers to socially valuable research.

Proposed addition:

"*Where the processing concerns electronic health data within the scope of the European Health Data Space Regulation, the assessment of whether processing is carried out for scientific research purposes should take account of the permitted purposes for secondary use under the EHDS. In particular, health-related research, development and innovation activities, and the training, testing and evaluation of algorithms in medical devices, in vitro diagnostics, AI systems and digital health applications may fall within the scope of scientific research purposes where they are conducted in accordance with applicable methodological, ethical, governance and data protection safeguards. The EHDS does not displace the GDPR, but it provides a relevant Union law framework for interpreting and applying GDPR research provisions coherently in the health data context.*"

Comment 2:

There are many stages of the life-cycle of samples/data (e.g. collection, processing, storage, sharing, use, and eventual disposal or long-term preservation of biological samples and associated data) and different individuals and entities involved in the processing of personal data for scientific research at different stages of the life-cycle. The Guidelines do not address whether the six-factor assessment should be taken once or whether it must be re-assessed each time data or samples are subsequently accessed or reused for a new research project. This distinction is important because the biobank itself may clearly satisfy the characteristics of scientific research, while individual downstream projects may differ in their objectives, methodologies, or governance arrangements. Clarification on this point would reflect the realities of biobanks' operations and how they are governed, reduce unnecessary duplication in assessment, and promote a consistent application of the GDPR across biobanks.

Suggestions:

We recommend that the Guidelines distinguish between:

- The assessment of a biobank that operates for scientific research purposes as part of its core functions; and
- The assessment of individual downstream research projects making use of the data from the biobank.

We recommend that where a biobank has been established with an appropriate governance framework and oversight mechanisms, and having as one of its stated purposes the provision of samples and data for scientific research, and satisfies the characteristics identified in the Guidelines, this assessment

should not need to be repeated each time samples or data are accessed for a new research project. Rather, subsequent assessments should focus on whether the proposed processing falls within the biobank's scientific research mandate, complies with its applicable governance framework, and meets any additional ethical and data protection requirements relevant to the specific research project.

Comment 3:
Generally, the non-exhaustive nature of the proposed criteria risks creating legal uncertainty and inconsistent application. While flexibility is desirable, the absence of minimum criteria risks leaving excessive discretion to data controllers, especially in borderline cases (e.g. development or AI training).

Suggestions:
To promote legal certainty and a consistent application of the GDPR, the EDPB should consider providing a clearer framework for applying the criteria such as mandatory criteria for an activity to qualify as "scientific research." We also would welcome some examples of how the criteria should apply in more contemporary research settings, including foundation models, federated learning, medical AI, synthetic data, and real-world evidence studies.

2.2 Research data infrastructures

Comment 4:
The Guidelines are project-centric and framed around specific research projects, whereas the reality of modern scientific research is that researchers use research infrastructures established for long-term use, such as biobanks that collect, curate, store, and make available data for use in research. These biobanks are not passive in the research process as they provide critical functions e.g., quality assurance, and data harmonization.

We welcome the inclusion of a specific section on research infrastructures as BBMRI-ERIC and its biobanks are research infrastructure, as defined by the EDPB, but greater clarification would be welcome on the relationship between a research infrastructure and downstream uses. Specifically, it is unclear whether downstream uses of the data from a research infrastructure, such as a biobank, can rely on the assessment of criteria performed by the research infrastructure.

Suggestions:
We suggest that the EDPB could take the initiative to clarify whether downstream uses of data can rely on the assessment of the six criteria by the research infrastructure using biobanks as an example.

3. Data protection Principles (Article 5 GDPR)

3.1.1 Presumption of purpose compatibility

Comment 5 :
Paragraphs 22 and 23 would benefit from clearer drafting by distinguishing between the different legal bases for processing under Articles 6 and 9 GDPR and explicitly referring to the relevant provisions. This would improve legal certainty, avoid conflating the general lawful basis for processing with the conditions for processing special categories of personal data, and assist controllers in assessing lawfulness of further processing.

Comment 6 :
Greater clarity on the relationship between the presumption of compatibility under Article 5(1)(b) and the requirement to identify and appropriate legal basis for processing is needed. We are concerned that the current text leaves uncertainty as to:

- When the presumption of compatibility applies automatically;
- When a new legal basis for processing is required; and
- How the compatibility assessment interacts with purpose specification, proportionality, and the safeguards required by Article 89.

Proposed addition:
"*The presumption of compatibility for scientific research under Article 5(1)(b) GDPR facilitates the further processing of personal data for scientific research purposes but does not remove the requirement to identify an appropriate legal basis under Article 6 GDPR and, where applicable, a condition under Article 9 GDPR. Controllers should therefore assess the lawfulness of the further processing, taking into account the purpose specification, the principle of proportionality, and the implementation of the appropriate safeguards required by Article 89 GDPR. Where the original processing was based on Article 6(1)(e) or (f), the same legal basis may, where appropriate, support the further scientific research processing. Where the original legal basis was Article 6(1)(a) or (c), controllers should assess whether that legal basis continues to apply or whether an alternative lawful basis is required*".

4. Lawfulness (Articles 5(1)(a), 6(1) and 9 of the GDPR)

4.1.2 Specificity

Comment 7 :
We would welcome more clarity on the term "relevant to the particular field of research". This is particularly important where research is cross disciplinary and cross borders.

Suggestions:
The Guidelines could clarify an assessment to be followed by considering whether an ethical guideline is "relevant to the particular field of research" and/or provide suggestions e.g., Declaration of Helsinki and Declaration of Taipei.

Comment 8:
Paragraphs 46 and 47 would benefit from greater clarity as to when a data controller can rely on the scope of the original consent, in accordance with Recital 33, for subsequent research projects. While the Guidelines recognise that broad consent may be appropriate in certain research contexts, they do not explain how controllers should assess whether a new research project remains within the scope of the original consent or whether additional consent or another legal basis should be considered. This is of particular importance for research infrastructures such as biobanks that provide data over a long period of time to multiple research projects.

Suggestions:
The Guidelines could provide examples to enable data controllers to make an assessment as to whether the research falls within the original consent.

Comment 9:
We welcome the suggestion to consult organisations representing patient views as it recognises the importance of stakeholder engagement in research. This would be particularly welcome as, while such organisations can provide important insights into data subjects' views, they do not have the authority to interpret the GDPR and at the end might even risk to be disregarded completely. Therefore, data controllers would welcome clarification as to the extent to which they need to involve these views in the assessment of "reasonable expectations".

Suggestions:
The Guidelines could clarify that consultation with representative organisations should be regarded as one relevant factor in assessing reasonable expectations, alongside other objective considerations such as the information provided to data subjects, the context in which the data were collected, the nature of the relationship between the data subjects and the controller, established governance arrangements, and applicable ethical and legal frameworks. Such clarification would provide greater legal certainty while continuing to encourage meaningful stakeholder engagement.

Comment 10 (biobanks):
The requirement that broad consent relate to a "certain area of scientific research" would benefit from further clarification. As currently drafted, it is unclear how narrowly that area should be defined and whether it encompasses the operational models of general-purpose biobanks, population biobanks, national genomic initiatives, and other research infrastructures that support a wide range of future health research.
The examples provided in the Guidelines may suggest that the relevant area of research should be disease-specific (e.g. neurodegenerative disease research). However, many biobanks are established to facilitate future research across multiple diseases, conditions, or biomedical disciplines. It would therefore be helpful for the Guidelines to clarify that the concept of a "certain area of scientific research" should be interpreted in a manner that reflects the realities of contemporary research infrastructures, such as biobanks, and is not limited to narrowly defined disease areas.

Suggestions:
The Guidelines could explain that, depending on the nature and purpose of the research data infrastructure, a "certain area of scientific research" may encompass broader domains such as human health research, biomedical research, or genomics research, provided that the scope of the consent is sufficiently transparent, the reasonable expectations of participants are respected, and appropriate

governance, access controls, transparency measures, oversight mechanisms, and withdrawal procedures are in place. Practical examples illustrating acceptable formulations of broad consent for different types of research infrastructures would significantly improve legal certainty and promote harmonised implementation across Member States.

Comment 11 (biobanks):
The section on broad consent would benefit from recognising the relationship between broad consent and governance, as reflected in the research ethics literature on biobanking and long-term research infrastructures. In these contexts, the ethical acceptability of broad consent does not derive solely from the breadth of the research purpose, but from the combination of purpose specification with robust governance arrangements that regulate future access to and use of data and samples.
Accordingly, participant protection is achieved not only through the description of the research area, but also through ongoing governance and oversight mechanisms, including transparent access procedures, independent review, accountability measures, participant information, withdrawal mechanisms, and compliance with applicable ethical and legal standards. Recognising this relationship would better reflect the operation of contemporary data infrastructures such as biobanks and help explain why broad consent may remain compatible with the GDPR despite the impossibility of specifying every future research project at the time consent is obtained.

Proposed addition:
"*In assessing whether broad consent is sufficiently specific in accordance with Recital 33 GDPR, the data controller should take into account not only the description of the area of scientific research, but also the governance framework within which the research is conducted*".

Comment 12:
We have concerns that the requirement of "reasonable expectations" could be interpreted as data controllers needing to be satisfied that the data subject would have anticipated each use of their data. Such an interpretation would be at odds with Recital 33 which specifically states that it is often not possible to identify all future use of data at the time of data collection. Related to this, it should be clear that reasonable expectations should inform the interpretation of the scope of consent, but they cannot replace the legal requirements for valid consent or expand its scope beyond what was originally communicated to data subjects.

Suggestions:
The Guidelines could clarify that the reasonable expectations of data subjects are one factor in assessing whether a subsequent scientific research project remains within the scope of the original broad consent, taking into account the information provided to participants, the stated area of scientific research, and the governance framework of the research.

4.1.2.2 Dynamic consent

Comment 13:
The Guidelines seem to define dynamic consent as repeated consent, which is not how it is known in the literature and in practice. Dynamic consent is generally known as the use of a digital interface and/or information technology to enable the ongoing communication and interaction with participants, that can

include the provision of information related to the use of a participant's data and contact to enable consent for purposes that the participant has not consented to.

Suggestions:
The Guidelines could clarify that dynamic consent is generally understood as a digital communication and participant engagement model that enables ongoing interaction between participants and researchers throughout the research life cycle. It typically makes use of information technology to facilitate communication, provide participants with information about the use of their data and samples, manage participant preferences, and, where appropriate, obtain consent for new research purposes or activities that fall outside the scope of the original consent. Accordingly, obtaining renewed consent is one possible function of dynamic consent, rather than its defining characteristic.

Comment 14:
The Guidelines suggest that there are circumstances when dynamic consent is the most appropriate form of consent. The Guidelines should clarify that dynamic consent is one governance model among several that may be appropriate depending on the nature of the research and the relationship between researchers and participants. Broad consent supported by appropriate governance, transparency and Article 89 safeguards remains a legitimate model recognised by Recital 33 GDPR. The Guidelines present dynamic consent in a positive light without recognising any of its limitations. Dynamic consent is not feasible, proportionate, or possible in some contexts, including for legacy cohorts and archived pathology collections. Dynamic consent relies upon digital literacy, access to digital tools, internet connection, and ongoing communication. We currently have an issue with lack of representation in the data sets. The need for access to digital tools and digital literacy may limit the involvement of underrepresented populations in datasets. The Guidelines should acknowledge that dynamic consent may have implications for representativeness and inclusiveness. Furthermore, not all participants want to continue to have engagement. For those who do not want to have this ongoing engagement, they may be excluded. Finally, with the exception of studies such as the CHRIS study and the RUDY study, the use of dynamic consent is not tested in large scale studies. This should be recognised in the guidance.

Suggestions:
1. Clarify that dynamic consent is one possible governance model, rather than the preferred or default approach. The Guidelines should make clear that the GDPR does not require dynamic consent and that broad consent, supported by appropriate governance, transparency and the safeguards required by Article 89 GDPR, remains a legitimate model for scientific research recognised by Recital 33 GDPR.
2. Revise the wording suggesting that dynamic consent is the most appropriate model of consent in certain circumstances. Instead, the Guidelines should state that controllers may consider dynamic consent where it is appropriate, feasible and proportionate in light of the nature of the research, the relationship with participants, and the characteristics of the research data infrastructure.
3. Recognise the practical limitations of dynamic consent. The Guidelines should acknowledge that dynamic consent is not appropriate or feasible in all research settings, including legacy collections, archived pathology samples, historical cohorts, and research data infrastructures where ongoing participant interaction is not possible or would be disproportionate.
4. Acknowledge the potential implications for equity and representativeness. The Guidelines should recognise that digital consent platforms may present barriers for individuals with limited digital access or digital literacy and may therefore affect the inclusion of populations that are

already underrepresented in research. Data controllers should consider these factors when selecting an appropriate consent model.

5. Recognise participant preferences. The Guidelines should acknowledge that some participants value ongoing engagement, while others prefer to provide consent without repeated interaction. Accordingly, no single consent model is appropriate for all research contexts.

4.1.3 Consent to participate in scientific research pursuant to ethical or legal requirements not stemming from the GDPR

Comment 15:
The distinction drawn between consent to participate in research and consent as a legal basis for processing personal data under the GDPR is welcome. However, the Guidelines would benefit from clarifying that compliance with the GDPR does not remove the need to comply with separate legal and ethical requirements governing the collection, storage and use of human biological materials.
This is particularly relevant in the biobanking context, where biological samples and associated data are frequently subject to national legislation and ethical requirements that exist independently of the GDPR. The legal basis for processing the personal data associated with a biological sample and associated data should therefore not be conflated with the legal or ethical requirements applicable to the collection and use of the biological sample itself.

4.4.3 Derogations laid down in Union or MS law (Article 9(2)(g) and (j) GDPR)

Comment 16:
Research infrastructures such as BBMRI-ERIC facilitate access to samples and data across multiple Member States. The practical value of these Guidelines will therefore depend upon their ability to promote a harmonised interpretation of the GDPR while acknowledging that additional requirements may arise under national laws governing ethics, human biological materials, and health research. The Guidelines would benefit from distinguishing between matters governed by the GDPR, where harmonisation is sought, and matters left to Member State law, where controllers must undertake an additional national law assessment.

Suggestions:
The Guidelines could expressly acknowledge that the application of the GDPR in scientific research must be read together with applicable Union and Member State legislation. Where national laws impose additional requirements, controllers must comply with those requirements.

Comment 17:
The EDPB further emphasises that the secondary use of electronic health data under the EHDS relies on its own legal basis, capable of satisfying the requirements of Article 9(2) GDPR, does not relieve actors involved from taking into account the choices expressed by the data subject when consenting to participation in a biobank, where the data originate from a biobank acting as a health data holder under the EHDS. Broad consent for biobanking, as described in section 4.1.2.1, is frequently accompanied by specific participant choices regarding, for example, the scope of research, commercial use, sharing with third parties, international transfers, recontact, the return of individual findings, and withdrawal. Although these choices do not constitute the legal basis for processing under the EHDS, they remain an important component of the governance framework governing the collection and subsequent use of

data and biological samples. They contribute to the safeguards implemented pursuant to Article 89(1) GDPR and help define the reasonable expectations of data subjects regarding the further processing of their personal data. Accordingly, where relevant to the conditions under which the data may be reused, biobanks acting as health data holders should ensure that these participant choices are capable of being communicated through appropriate governance arrangements and accompanying metadata so that they can be respected throughout the secondary-use process. The right to opt out provided for under the EHDS remains unaffected and operates in addition to, rather than as a substitute for, the choices expressed by participants through the biobanking consent process.

Comment 18 (third layer):
Footnote 115 names in a demonstrative way national laws providing derogations for processing personal data for scientific research purposes, pursuant to Article 9(2)(j) GDPR.

Suggestions:
We suggest adding to the list section 16 of *Czech Data Processing Act*[2] as an example of a law providing derogations for processing personal data for scientific research purposes. Even though footnote 115 is an example, it can help national states when determining which provisions of their national law can be considered as derogations pursuant to Article 9(2)(j) of the GDPR as this is not always clear.
Section 16 of the *Czech Data Processing Act* should be considered a derogation pursuant to Article 9(2)(j) of the GDPR as long as safeguards mentioned in this provision are implemented by data controllers. Section 16 could also be considered an example of a provision aiming to provide legal basis for data processing for research pursuant Article 6(1)(e) of the GDPR.

5. Obligations to inform (Articles 12-14 GDPR)

5.1. General

Comment 19 (second layer):
Paragraph 79 is concerned with digital platforms/portals developed for this effect considering accessibility, but it does not tackle overcoming potential lack of digital literacy. An analogue alternative should also be provided, especially for provision of consent and exercise of other GDPR rights. Analogue alternatives (including those catered to children) are also suggested in the EDPB's Transparency Guidelines[3]. Analogue alternatives (including those catered to children) are also suggested in the EDPB's Transparency Guidelines.

Suggestions:
In paragraph 81, it is better to state "*digital and analogue*" because digital portals should not replace human interaction.

5.4.2.3 Disproportionate effort (Article 14 (5)(c) GDPR)

Comment 20 (biobanks):
The Guidelines on this point would benefit from greater practical detail. This issue is particularly relevant to legacy biobanks, pathology archives, and historical collections, where personal data may have been

[2] https://uoou.gov.cz/media/act-no-110-2019-coll.pdf
[3] EDPB's Transparency Guidelines

collected many years or decades earlier and maintaining contact with participants is often not feasible. The Guidelines should give more concrete indicators/ criteria for disproportionate effort. Otherwise, without clearer thresholds, supervisory authorities may diverge on whether biobanks must attempt individual recontact, especially where records are old, participants are deceased, or contact details are unreliable.

Suggestions:
We recommend inserting some criteria for data controllers to take into account when assessing disproportionate effort. Some examples:

- *"The age of the collection and the time elapsed since data collection;*
- *Whether participants are deceased or cannot reasonably be contacted;*
- *The reliability and completeness of available contact details;*
- *The number of data subjects concerned;*
- *The costs and organisational burden of recontact relative to the privacy risk;*
- *Whether alternative transparency measures, such as publicly available privacy notices, websites, or participant portals, are available"*

Providing practical examples illustrating circumstances in which the disproportionate effort exception is likely to apply would significantly improve legal certainty and promote a more harmonised application of Article 14(5)(b) GDPR across Member States.

7. Attribution of responsibility (controller and processor)

7.1 Controller

Comment 21:
We would welcome the guidelines clarifying how accountability under the GDPR is to be allocated across the research data lifecycle when personal data is shared between two independent data controllers. This is particularly important in the context of federated research infrastructures.

Suggestions:
The Guidelines should clarify how accountability is allocated across the research data lifecycle where personal data are shared between independent controllers. In distributed or federated research infrastructures, the biobank collecting the data and the organisation subsequently accessing and processing the data for research purposes may be established in different Member States and subject to differing national interpretations of the GDPR. While each controller remains accountable for compliance with respect to its own processing activities, the Guidelines should clarify which controller is expected to demonstrate compliance with the relevant factors discussed throughout the Guidelines (e.g. compatibility of further processing, implementation of safeguards, transparency obligations, and necessity and proportionality assessments). Greater clarity would promote consistent application of the accountability principle and reduce legal uncertainty in cross-border research collaborations. In the case of biobanks, the Guidelines do not clarify who bears the burden of demonstrating compliance with the factors at each stage of the data lifecycle — the original biobank, the accessing researcher, or both. For distributed infrastructures, like BBMRI-ERIC, the node collecting data and the node/ researcher that processes data may be in different Member States with divergent interpretations.

8. Appropriate safeguards (Article 89(1) of the GDPR)

8.3 Anonymization and pseudonymization of personal data

Comment 22:
The Guidelines state that anonymized data, or alternatively pseudonymised data, should be used as long as research purposes can be fulfilled; directly identifiable data should be processed only where strictly necessary and proportionate. In genomics and biobanking, anonymisation is often difficult or unstable because genetic data may remain uniquely identifying, especially when linked with phenotypic or registry data. The Guidelines should avoid presenting anonymisation as the default benchmark for genomic biobanks and should recognise robust pseudonymisation plus governance as often the more realistic and scientifically necessary model.

Suggestions:
In determining whether anonymisation or pseudonymisation is appropriate, data controllers should take into account the nature of the data and the scientific objectives of the research. In fields such as genomics and biobanking, where anonymisation may not be technically feasible or may undermine the scientific value of the research, robust pseudonymisation supported by the safeguards required under Article 89 GDPR, together with appropriate governance, access controls and security measures, may constitute the most appropriate and proportionate approach.