AIRC Position on EDPB Guidelines 1/2026 on the processing of personal data for scientific research purposes
With the scientific contribution of IFOM-ETS

Introduction

AIRC Foundation for cancer research - *We face cancer. Together.*

Since 1965, the AIRC Foundation has consistently supported independent cancer research, with the aim of translating scientific discoveries into new treatments. Over the past sixty years, it has invested more than €2.7 billion, contributing to major advances in cancer prevention, diagnosis, and treatment that have significantly increased survival rates while also reshaping the public narrative around cancer. AIRC is the leading non-profit funder of cancer research in Italy. It supports the work of approximately 5,000 scientists based in nearly 100 institutions nationwide, selecting projects through a rigorous peer-review process that guarantees scientific quality, merit, and independence. A network of 17 regional committees and offices, together with a community of 20,000 volunteers and the trust of 4.5 million supporters, makes AIRC a truly "national foundation," capable of mobilizing civil society, the scientific community, businesses, and institutions. The Foundation also includes IFOM – the Institute of Molecular Oncology – an international center of excellence that attracts researchers from around the world. In addition, AIRC promotes a culture of health by disseminating scientific knowledge, prevention guidelines, and research outcomes through schools, universities, companies, and the media.

IFOM-ETS, the Institute of Molecular Oncology of AIRC, contributes scientific expertise in molecular oncology, biomedical research, genomics, data-driven research and advanced research infrastructures.

AIRC's perspective is that of a major non-profit funder and enabler of cancer research. IFOM-ETS brings direct experience as a research institute operating in biomedical and molecular oncology research.

For AIRC, this consultation represents an important opportunity to contribute to a European framework that protects individuals, strengthens trust and enables research to deliver tangible benefits for patients and society.

This position does not question the overall direction of the Guidelines. Rather, it identifies selected areas where further clarification, practical examples and operational guidance could improve their

effectiveness and applicability, particularly for cancer research, non-profit research organisations, academic institutions, research infrastructures and biobanks.
The comments below relate in particular to the sections of the Guidelines concerning purpose compatibility, storage limitation, consent, transparency, data subjects' rights, allocation of responsibility and appropriate safeguards.

Summary of key recommendations

AIRC recommends that the EDPB:

1. ensure a flexible, proportionate and research-sensitive implementation of the Guidelines, especially for non-profit, academic and philanthropically funded research;
2. facilitate responsible secondary use of personal data, biological samples and research datasets, while maintaining appropriate safeguards;
3. preserve broad consent as a legitimate and workable model for long-term biomedical research, while recognising dynamic consent as a valuable but context-specific and non-mandatory tool;
4. clarify how transparency obligations, long-term retention and the exercise of data subject rights, including erasure and objection, should apply in long-term research contexts;
5. strengthen patient and participant engagement through proportionate governance models that support trust, transparency and collective value for society;
6. reduce fragmentation across Member States and provide practical examples for safeguards, biobanks, genomic research, AI-driven research and cross-border collaboration.

Why this matters for cancer research

Cancer research increasingly depends on the responsible use, reuse and integration of data and biological samples over time. Progress in oncology often requires longitudinal studies, long-term follow-up, reuse of existing datasets and biospecimens, integration of clinical, genomic, molecular and biological information, collaboration across institutions and countries, secure data-sharing mechanisms and the responsible use of advanced computational methods.
A clear, proportionate and harmonized regulatory framework is therefore essential. Overly restrictive or fragmented interpretations could slow down research, reduce the value of public and philanthropic investments, and ultimately delay benefits for patients.
Scientific progress and strong data protection should not be seen as opposing objectives. Responsible data governance, transparency, patient engagement and robust safeguards are essential conditions for trustworthy research.

1. Promote proportionate and research-sensitive implementation

AIRC supports a pragmatic, risk-based and proportionate implementation of the Guidelines.

The GDPR already provides a framework that recognises the societal value of scientific research while requiring appropriate safeguards for data subjects. The Guidelines should ensure that this balance is preserved in practice and that their application does not lead to overly restrictive interpretations that could hinder public-interest research, philanthropic research, academic research and long-term biomedical studies.

As a soft-law instrument, the Guidelines will significantly influence how research institutions, ethics committees, biobanks, research infrastructures and supervisory authorities interpret and apply the GDPR. For this reason, additional practical examples and model scenarios would be highly beneficial, particularly in relation to broad consent, secondary use of data and biological samples, transparency over time, access governance, allocation of roles and responsibilities, long-term retention and proportionate safeguards.

A proportionate approach is particularly important for non-profit organizations and publicly or philanthropically funded research. Disproportionate compliance burdens may divert resources away from research activities and reduce the societal impact of philanthropic and public investments.

Proportionate implementation is also essential to ensure that philanthropic resources entrusted by citizens and donors are used primarily to advance research and generate public benefit, while maintaining robust protection for research participants.

AIRC recommends that the EDPB include practical examples showing how proportionate compliance can be achieved by non-profit research funders, academic institutions, biobanks and research infrastructures without lowering the level of protection for data subjects.

2. Facilitate responsible secondary use of data and biological samples

AIRC strongly supports the presumption of compatibility for further processing of personal data for scientific research purposes.

The possibility to reuse existing datasets is essential to biomedical research. It enables longitudinal studies, avoids unnecessary duplication of data collection, reduces the burden on patients and participants, and maximises the value of public and philanthropic investments in research.

In cancer research, secondary use is particularly important because scientific progress often depends on connecting data and samples collected at different times, in different settings and for different but related research purposes.

The reuse of data and biospecimens should therefore be actively facilitated through research infrastructures, biobanks, secure data-sharing mechanisms, harmonised governance frameworks, transparent and accountable access procedures, and appropriate technical and organisational safeguards.

Further guidance should also recognise that biological samples are not static materials. They may represent continuing sources of information, as new data can be generated over time through evolving technologies and scientific methods. This is particularly relevant for genomic, molecular and multi-omics research.

AIRC recommends that the EDPB clarify how the presumption of compatibility applies in practice to the secondary use of data and biospecimens in biobanks, longitudinal cohorts, cancer research infrastructures and cross-border biomedical research.

3. Preserve broad consent while recognizing dynamic consent where appropriate

AIRC supports the recognition of flexible consent models, including broad consent and dynamic consent, in line with the evolving and iterative nature of biomedical research.

Broad consent should remain a legitimate, purpose-based and workable model for long-term biomedical research, provided that the scientific purpose or research area is sufficiently defined and that appropriate safeguards and governance mechanisms are in place.

Uncertainty regarding future technologies, analytical methods, computational approaches, omics platforms, sample size or experimental models should not invalidate broad consent, provided that future use remains within the scope of the defined research area.

Dynamic consent and digital engagement tools may represent valuable complementary mechanisms in specific contexts. They can support transparency, trust and continuous engagement with participants, particularly in long-term and multi-phase research projects.

However, dynamic consent should not become a mandatory benchmark or an implicit requirement for all research infrastructures. Digital platforms, dashboards or project-by-project consent management tools may be useful in some settings, but they should not be treated as the default standard for all forms of biomedical research.

AIRC recommends that the EDPB clarify that broad consent remains a fully legitimate model for long-term biomedical research, and that dynamic consent be adopted whenever best suited. AIRC acknowledges that a combination of both approaches to consent is also possible.

4. Clarify transparency, long-term retention and data subject rights

Transparency is essential to maintaining trust and accountability in scientific research. AIRC supports clear, accessible and meaningful information for patients and research participants.

However, in large-scale and long-term biomedical research, transparency obligations must remain proportionate and operationally feasible. This is especially relevant where research continues over many years, where data and samples are reused in successive projects, where participants may no longer be contactable, or where research infrastructures support multiple studies over time.

The Guidelines should provide further operational guidance on how transparency can be ensured in a proportionate way through layered information, public notices, participant portals, periodic updates, governance reports, communication of research outcomes and other suitable mechanisms.

AIRC also supports the possibility to retain personal data for extended periods when necessary for verification, reproducibility, future research and long-term follow-up. In longitudinal biomedical research, mandatory anonymisation at the conclusion of each individual study may limit scientific value, impair reproducibility, prevent future data integration and reduce the possibility of long-term follow-up.

Where scientifically justified and accompanied by appropriate safeguards, long-term retention in pseudonymised form may be appropriate. Practical examples would be useful in relation to immediate anonymisation, long-term pseudonymisation, separate retention of re-identification keys, controlled re-identification mechanisms where scientifically justified, and retention policies for biobanks and longitudinal cohorts.

AIRC recognises the importance of data subjects' rights under the GDPR, including the rights to erasure and objection. At the same time, the GDPR provides specific limitations where the exercise of these rights would render impossible or seriously impair the achievement of scientific research objectives, provided that appropriate safeguards are in place.

This issue is particularly important in cancer research. In some contexts, deletion or interruption of processing may compromise the validity of longitudinal studies, undermine reproducibility, affect the integrity of datasets, or prevent long-term follow-up.

AIRC recommends that the EDPB provide practical examples illustrating how transparency, retention, erasure and objection should be assessed and documented in scientific research, especially in relation to pseudonymised datasets, biobanks, longitudinal cohorts, registries and multi-centre studies.

5. Strengthen patient participation, trust and collective value

Patients and research participants should not only be regarded as data subjects requiring protection, but also as essential partners in the research ecosystem.

Patients are the primary contributors of data and biological samples. Their trust is a critical asset for cancer research and should be supported through transparent, understandable and participant-centred governance models.

This is particularly relevant for broad consent, secondary use, continuous transparency, governed sharing and longitudinal research infrastructures.

AIRC recommends that the Guidelines further recognise and encourage proportionate mechanisms for patient and participant engagement, including accessible communication of research outcomes, periodic updates on the use of data and samples, involvement of patient representatives in advisory bodies or access governance mechanisms where appropriate, support for patient advocacy initiatives, prevention and public education programmes, and communication of the collective value generated by research.

This should not necessarily imply an individual return of results in all cases, which may be scientifically, ethically or operationally complex. Rather, the Guidelines should encourage models that strengthen trust, accountability and a visible return of research value to patients, participants and society.

High standards of data protection, strong patient engagement and responsible data reuse should be seen as mutually reinforcing objectives.

6. Clarify safeguards, emerging research needs and harmonisation

AIRC supports the adoption of robust safeguards for the rights and freedoms of data subjects. At the same time, the Guidelines should provide clearer guidance on which safeguards are proportionate to different levels of risk, particularly for non-profit and academic research organisations.

Appropriate safeguards may include, depending on context and risk, pseudonymisation, anonymisation where compatible with the research purpose, secure processing environments, access controls, confidentiality obligations, ethical oversight, independent governance committees, data access agreements, privacy-enhancing technologies, restrictions on onward use, and safeguards for publication and dissemination of research results.

Further guidance would also be useful in areas of emerging importance for biomedical research, including genomic and multi-omics research, biological samples and derivatives, AI-driven research and privacy-enhancing or distributed methodologies such as federated learning.

Artificial intelligence and machine learning may generate derived outputs such as biomarkers, predictive scores, classification systems, trained models and other research artefacts. While such outputs may not always be directly identifiable, they can retain biological, clinical or predictive relevance and may originate from sensitive personal data. Additional clarification would therefore be helpful on their legal qualification and governance throughout the research lifecycle.

Finally, AIRC underlines the importance of greater harmonisation in the interpretation of rules applicable to health, genetic and research data. Fragmentation across Member States can hinder cross-border research, reduce the effectiveness of European research infrastructures and create uncertainty for collaborative scientific projects.

AIRC recommends that the EDPB provide practical examples of proportionate safeguards for different research scenarios and use the Guidelines to support a more coherent European framework for biomedical research.

Conclusion

AIRC welcomes the EDPB Guidelines 1/2026 as an important step towards a more research-sensitive interpretation of the GDPR.

A balanced, flexible and harmonised approach is essential to accelerate cancer research and deliver tangible benefits to patients and society.

AIRC remains fully committed to high standards of data protection, ethical research, patient trust and responsible data governance. At the same time, the European framework should continue to enable scientific progress, secondary use of data and samples, long-term research, cross-border collaboration and the responsible use of emerging technologies.

AIRC therefore encourages the EDPB to ensure that the final Guidelines provide not only legal clarity, but also practical conditions for responsible, patient-centred and high-impact biomedical research in Europe.