# AIRC Policy on Biological Samples and Data Sharing

## 1. Purpose and Scope

Fondazione AIRC per la ricerca sul cancro ETS (AIRC) recognizes that the responsible management and sharing of biological samples and research data are key components of good research practice and an ethical obligation toward patients and donors. Biological samples and associated data generated through AIRC funding shall be managed and shared as strategic research assets to accelerate scientific discovery, ensure scientific quality, reproducibility and transparency, reduce resource fragmentation, and promote sustainability. This Policy aims to foster collaboration within and beyond the AIRC-funded research community, maximize public benefit, and improve patient outcomes.

The **AIRC Policy on Biological Samples and Data Sharing** sets out AIRC's principles and expectations regarding the management and governance of biological samples and related research data generated through AIRC-funded projects, and their sharing with the scientific community. The Policy applies to all researchers and institutions receiving AIRC funding and complements existing national, European and institutional regulations. AIRC does not seek ownership, custody, or direct control over biological samples or research data generated through its funding. Responsibility for the storage, governance and access to such resources remains with the institutions and researchers in accordance with applicable legal and ethical frameworks.
AIRC does not intend to establish or operate a centralised biobank or repository for the storage of biological samples. Rather, it promotes the use of qualified national and international infrastructures and encourages progressive alignment with recognised standards.
Within this framework, AIRC acts as a driver of quality, interoperability and responsible sharing, encouraging researchers to make their resources accessible through trusted infrastructures and governed access mechanisms.

## 2. Biological Samples

### 2.1 Storage and Management

Biological samples generated within AIRC-funded projects shall be stored and managed in biobanks that comply with applicable quality management systems and ethical, legal and societal requirements, and that facilitate responsible access to samples for scientifically and ethically approved research projects. Where available, biobanks should operate in accordance with BBMRI-ERIC standards or equivalent advanced national or international standards. The same principles apply to biospecimen collections where access to a fully developed biobanking infrastructure is not immediately available.

Affiliation with the BBMRI-ERIC Infrastructure shall progressively be pursued to grant optimal data and biospecimen visibility and sharing. AIRC recognises that access to fully compliant infrastructures may not be immediately achievable in all contexts and therefore promotes progressive alignment over time, provided

that equivalent safeguards and commitments to quality and interoperability are demonstrated.

## 2.2 Access and Governance

Access to biological samples must be governed by transparent, fair and accountable procedures that preserve traceability, scientific integrity and respect for donor consent. Access decisions should be documented and managed through appropriate governance arrangements, including, where relevant, an institutional access committee or equivalent oversight mechanism and the use of appropriate agreements governing transfer and use.

# 3. Research Data and Metadata

AIRC supports the principle that research data generated through its funding should be **findable, accessible, interoperable and reusable (FAIR)**, while ensuring compliance with legal and ethical standards.

- Data generated shall remain under the responsibility and custodianship of the institutions that generate them. Nothing in this Policy transfers ownership or control to AIRC.
- Data sharing shall be open or subject to controlled access, as appropriate, based on data sensitivity, consent conditions, and applicable legal requirements, including those relating to personal data concerning health or genetic data. Adequate technical and organizational measures should be in place to ensure data security, confidentiality and integrity throughout the data life cycle.

Metadata should, wherever possible, remain discoverable even where full data access must be restricted.
AIRC is developing a strategy to facilitate the visibility and **sharing of the metadata** describing the data generated from the analysis of biological samples, including, but not limited to, molecular, genomic, transcriptomic, proteomic, imaging and clinical annotations. Once the AIRC platform and its relative regulations will become available, Principal Investigators of funded projects **shall be prepared to share** the metadata through the platform.

# 4. Ethical and Legal Framework

Data sharing shall be carried out on the basis of an appropriate legal basis under Regulation (EU) 2016/679 (GDPR) and applicable national law, and shall be subject to appropriate technical and organizational measures designed to ensure the security, confidentiality and integrity of personal data and to protect the privacy and rights of data subjects, in accordance with Articles 25, 32 and 89 of the GDPR.
Access shall be aligned with the FAIR "Accessible" principle ("as open as possible, as closed as necessary"), taking into account the sensitivity of the data (e.g., clinical or genomic data) and any applicable legal, ethical or contractual constraints. Any restrictions shall be justified and documented.
Where the legal basis for processing is informed consent, such consent must be formulated in a manner that allows participants to be informed about and to decide on the potential secondary use of their data for

future cancer research within the AIRC network, including data sharing and reuse under governed research frameworks.

Applicants must ensure that participant information and consent procedures, where applicable, are compatible with future data reuse and sharing for research purposes, and that existing protocols or consent frameworks are amended where required.

Researchers and institutions must ensure an appropriate level of transparency towards participants, including where data are reused for research purposes, in accordance with applicable law.

## 5. Responsibilities and Oversight

Researchers funded by AIRC are required to:

- plan from the outset of their projects the appropriate management and sharing of biological samples and data;
- ensure that informed consent and ethical approvals adequately cover current and potential future uses, in accordance with applicable law;
- provide evidence of affiliation to BBMRI-ERIC or proof of adherence to equivalent advanced national or international standards;
- deposit samples and metadata in accordance with this Policy;
- cooperate with AIRC monitoring and reporting requirements related to data and sample sharing
- ensure that any processing of personal data for research purposes is appropriately assessed and managed in accordance with applicable law.

Projects involving data and/or sample collection must include a Data and Sample Management Plan. Where it is not required at the application stage, it must be submitted with in each renewal request. The Data and Sample Management Plan must describe:

- the types of samples and/or data to be generated;
- quality control, standardization and documentation;
- how data will be made available within and outside the AIRC community;
- data governance: roles and responsibilities for sample and data stewardship, access decisions, compliance, and long-term preservation shall be clearly defined and assigned within funded projects.
- access control and oversight mechanisms, including the role of an institutional Data/Biobank Access Committee (or equivalent), documentation of decisions and justifications, and the use of appropriate agreements (e.g., DUA/MTA) for controlled access and for defining mechanisms of collaboration, citation and co-authorship.
- data protection and security measures; breach and security incident procedures;
- long-term curation and accessibility beyond the funding period, including defined retention periods and end-of-life procedures (anonymisation/secure destruction) where applicable.

Projects involving biospecimens collections shall provide evidence of affiliation to BBMRI-ERIC or proof of

adherence to equivalent advanced national or international standards by the time of "renewal with progress" submission.

AIRC will not routinely intervene in access decisions, which remain under the responsibility of the relevant project or program governance structures. AIRC retains the right to undertake appropriate measures in case of proven non adherence to this Policy, applied gradually and proportionately to the nature and severity of the non-compliance. These may include, in the most serious cases, the termination of the grant, the obligation to return grant money to AIRC, the ineligibility to apply to AIRC calls for proposals, and the exclusion from AIRC review panels and other bodies.

## 6. Entry into Force and Transitional Provisions

This Policy enters into force on January 1, 2027 and applies to all new grants not yet awarded as of that date. Grants already awarded at the date of entry into force are strongly encouraged to align with this Policy and shall be subject to its requirements from the first renewal request submitted after the entry into force of this Policy. Obligations relating to metadata sharing through the AIRC platform shall become effective only once AIRC has formally communicated that the platform and its implementing rules are operational; AIRC may provide a reasonable adaptation period for compliance.