

## INSTITUTIONAL POLICY

### FOR MANAGEMENT AND SHARING OF RESEARCH DATA

#### 1. Preamble and Scope

- a) AIBILI - Association for Innovation and Biomedical Research on Light and Image is a Research Technology Organisation in the health area dedicated to development and clinical research of new products for medical therapy and diagnostic imaging. In this context, AIBILI, as a Research Performing Organization (RPO), commits to the advancement of science and the wide dissemination of knowledge to the benefit of society by adopting practices on open, reproducible and responsible research.
- b) AIBILI recognizes “openness” as one of its guiding principles and commits to promoting it by - among others - encouraging and supporting research processes and tools that encourage collaboration, enabling new working models and new social relationships, stimulating the dissemination of knowledge and the accessibility and re-usability of research outputs, encouraging **open access to Publications and Research Data from Publicly funded monocentric national studies sponsored by AIBILI performed at AIBILI Clinical Trial Centre and supported by an Electronic Data Capture (EDC) system**. Research Data is defined as the data (such as clinical and demographic data and images) used to validate the results presented in scientific publications or other data described in the Data Management Plan. **Genetic data, due to its highly sensitive nature, requires stringent protection measures, and therefore is not included in the Research Data definition.**
- c) Open access to Publications and Research Data will also be applied if requested by public funding bodies financing the clinical study.

#### 2. Jurisdiction and Effect of Policy

The Policy applies to all researchers active at **AIBILI**. In cases where research is funded by a third party, any agreement with that party concerning access rights, deposit and storage takes precedence over this Policy.

The Policy has been approved by the **Management Committee** and takes effect from **06/10/2025**

#### 3. Rights, Responsibilities, and Duties

##### 3.1 AIBILI is responsible for:

- a) Supporting and empowering the transition of **Publicly funded monocentric national studies sponsored by AIBILI, performed at AIBILI Clinical Trial Centre and supported by an EDC system**, to Open Access/ Open Science through education, training and awareness-raising actions targeting researchers and other employees, along with the provision of the necessary infrastructure and funding to support this transition.
- b) Establishing the **AIBILI Dataverse Repository** as the Institutional Open Access Repository according to international standards, containing digital content and providing advanced tools for search, navigation and Open Access to its content.

- c) Mandating the use of persistent identifiers (like DOIs, ORCID or others) for both policy and researchers to support the overall FAIRness of data outputs.
- d) Releasing a Data Management Plan (DMP) for each research study before the beginning of data collection. The DMP is updated as necessary over the research lifecycle. Updated DMPs are version-controlled.
- e) Personal Data Privacy Committee is responsible for promoting compliance and awareness of applicable personal data protection laws, in particular Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April (GDPR), Portuguese Law nº58/2019 of 8th August and AIBILI Data Protection and Privacy Policy (<https://www.aibili.pt/privacy-policy/>), advising on the implementation and monitoring compliance of data protection standards data curation and stewardship.
- f) Developing and providing mechanisms and services for storage, safekeeping, registration, deposition and sharing of data and other records, according to the FAIR principles, as well as their long-term preservation, and providing appropriate guidance to researchers.
- g) Embedding Open Science practices in **Publicly funded monocentric national studies sponsored by AIBILI, performed at AIBILI Clinical Trial Centre and supported by an EDC system**, namely in recruitment, research assessment and evaluation criteria beyond the provision of open access to publications and data.
- h) Monitoring policy compliance by comparing the content of the repository with information gathered from indexing services and through data on the use (access and downloads) per publication/department/unit/institute etc.
- i) Ensure support for the justified costs related to Research Data Management (RDM) and the implementation of practices that make data FAIR (Findable, Accessible, Interoperable, and Reusable).
- j) Foster a collaborative approach among researchers and support staff to identify relevant costs for grant applications, emphasizing the importance of including these costs through the creation of a comprehensive data management plan.
- k) Ensuring the compliance of the AIBILI Dataverse Repository in relation to FAIR (Findable, Accessible, Interoperable and Reusable) data principles.
- l) Having Intellectual Property Rights (IPR) and data protection policies in place to support Open Science.
- m) Having an Open Licensing policy mandating a coherent and comprehensive set of licenses for releasing content and data.
- n) Promoting Open Science practices and related skills.

### 3.2 Researchers are responsible for:

- a) Managing publications, data and educational resources in adherence with the principles and requirements expressed in this Policy.
- b) Registering new research projects at the proposal stage according to AIBILI's internal procedures (SOP) in order to ensure that they are provided with the appropriate institutional support.
- c) Complying with the organizational, regulatory, institutional, and other contractual and legal requirements related to the production, curation, deposit, management, and

distribution of publications and data in case there is no other agreement with third parties taking precedence.

- d) Ensuring that the principles governing the handling of data (in adherence with the present Policy and funders' mandates) are included in a Data Management Plan (DMP).
- e) Approving a DMP for every research activity they are coordinating.
- f) Choosing the appropriate type of licensing for their research outputs.
- g) Use of existing generic and/or domain specific standards or protocols whenever possible.

#### 4. Open Access to Publications

##### AIBILI:

- a) Requires researchers to deposit in the AIBILI Dataverse Repository a machine-readable electronic copy of the full text (published article or final peer-reviewed manuscript), as well as the related metadata after publication. Researchers are held responsible for the timely deposit of their publications in the institutional repository. This step also applies in the case of open access publishing ("Gold Open Access").
- b) In the case of "Green Open Access", the AIBILI requires the full text of all publications referred to above to be made immediately and publicly available<sup>1</sup> under a standard open license (CC BY, CC-BY-NC, CC BY-ND or CC BY-NC-ND) or equivalent. For monographs, deposit remains mandatory, but access could be closed.
- c) Requires the metadata of the publication to be made openly accessible in the case of 'closed' publications with the aim to increase their visibility.
- d) Retain ownership of copyright and license to publishers only those rights necessary for publication. Authors (or their organizations) must ensure Open Access to the Author Accepted Manuscripts (AAMs) or the Version of Record (VoR) of research articles, at the time of publication. All research articles must be made available under appropriate licenses - CC BY, CC BY-NC, CC BY-ND or CC BY-NC-ND, or equivalent.
- e) Requires researchers to deposit in the AIBILI Dataverse Repository publications that resulted from **Publicly funded monocentric national studies sponsored by AIBILI, performed at AIBILI Clinical Trial Centre and supported by an EDC system**, authored prior to the date of effect of the current policy and make them openly accessible whenever possible.
- f) Data Availability Statements are provided in publications indicating how to access the underlying data or how to request legitimate access to closed data.
- g) Clear guidance on how to cite a broader range of research outputs including data and software, as well as actors and enablers such as data managers, data stewards, funding bodies, research infrastructures and organizations.

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<sup>1</sup> If immediate deposit is not possible, a 6-month embargo in Science, Technology, Engineering and Mathematics (STEM) or 12 for publications in the social sciences and humanities is allowed.

## 5. Open Access to Research Data

### AIBILI:

- a) Encourages researchers to deposit the data of **Publicly funded monocentric national studies sponsored by AIBILI, performed at AIBILI Clinical Trial Centre and supported by an EDC system**, needed to validate the results presented in scientific publications in the **AIBILI Dataverse Repository**. Data should be provided with persistent identifiers and must be linked with publications where possible.
- b) Encourages that data and services are handled according to FAIR principles (i.e. Findable, Accessible, Interoperable and Re-usable). Data should also be traceable and available whenever possible for subsequent use.
- c) AIBILI follows the principle “as open as possible as closed as necessary”. If data cannot be open due to legal, privacy or other concerns (for example sensitive data or personal data) this should be clearly explained. Metadata ensuring that data are findable should be provided in all instances.
- d) Requires researchers to approve a DMP for every **Publicly funded monocentric national studies sponsored by AIBILI, performed at AIBILI Clinical Trial Centre** and supported by an EDC system, research activity they are involved in.
- e) Requires researchers to define usage rights through the assignment of appropriate licenses - CC BY, CC BY-NC, CC BY-ND or CC BY-NC-ND, or equivalent.
- f) Requires that data are stored for a certain period (e.g. as defined by the respective protocols and/or AIBILI retention policies). In the event that these records need to be deleted or destroyed after the expiration of the required archived duration or for legal and ethical reasons, such actions need to consider all legal and ethical perspectives.
- g) Requires users to submit a data access request directly on the AIBILI Dataverse Repository that will be either granted or denied by the AIBILI Data Access Committee (DAC). This data access request submission is implemented due to the sensitive type of data that will be stored in the AIBILI Dataverse Repository.

## 6. Open Science and Citizen Science

AIBILI actively encourages the uptake of Open Science practices (beyond open access to publications and data) the release of **Publicly funded monocentric national studies sponsored by AIBILI and run by AIBILI Clinical Trial Centre** data and content under open and standard open licenses. AIBILI supports citizen science projects as long as they adhere to all applicable Ethical, Clinical and personal data protection national and European legislation, and where possible connects students' curricula and degrees to citizen science projects as a means to rethink the knowledge production and circulation models inside and outside the university.

## 7. Infrastructure

- a) Ensures that the **AIBILI Dataverse Repository** meets trusted quality standards (OpenAIRE compatible, meeting FAIR principles, has a transparent repository policy).
- b) Ensuring that the **AIBILI Dataverse Repository** is registered in appropriate registries and is interoperable through the OpenAIRE Guidelines.

## 8. Research Assessment and Evaluation

### AIBILI commits to:

- a) Developing in cooperation with funding agencies, institutional departments and other appropriate units a framework for research assessment and evaluation that incentivizes research quality and Open Science behaviors and practices.
- b) Adopt open science metrics.

## 9. Training

- a) AIBILI commits to ensuring adequate and continual training of personnel to maintain and improve their competence on open science, including open access publishing, FAIR, open data, data management, research integrity, reproducibility, and transparency.
- b) Appropriate funding for these activities should be ensured and to that end synergies with Research Funding Organizations (RFOs) and other stakeholders should be sought.

## 10. Monitoring Policy Compliance and Validity of the Policy

This Policy is intended to support the organization's open access to **Publicly funded monocentric national studies sponsored by AIBILI, performed at AIBILI Clinical Trial Centre and supported by an EDC system**, and is reviewed annually by the Management Committee to ensure its effectiveness and compliance and published on the AIBILI website.

All employees must comply with this Policy and any associated guidelines or procedures.

The Management Committee is responsible for ensuring that this Policy is communicated to all employees, and for monitoring compliance and enforcing disciplinary action where necessary.

Directors and supervisors are responsible for ensuring that their employees are aware of this policy and for enforcing compliance.

Non-compliance with this Policy and any associated guidelines or procedures, may lead to disciplinary action.

References: <https://www.openaire.eu/model-policy-on-open-science-for-research-performing-organisations>

“Quadro de referência para Políticas e Estratégias de Ciência Aberta e Gestão de Dados de Investigação”, (13/06/2025)