

# ISoOR-AB Accreditation Policy

**International Society of Organoid Research Accreditation Body (ISoOR-AB)**

**Effective Date:** June 25, 2025

## 1. Purpose

This policy establishes the framework and guiding principles under which the International Society of Organoid Research Accreditation Body (ISoOR-AB) operates its accreditation program. ISoOR-AB provides impartial assessment and accreditation of Conformity Assessment Bodies (CABs) that perform organoid biobank-related evaluations.

The policy ensures that ISoOR-AB activities are consistent with **ISO/IEC 17011**, promote international harmonization, and uphold scientific and ethical excellence in organoid biobanking accreditation.

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## 2. Scope

ISoOR-AB accredits CABs that assess organoid biobanks against the **ISoOR-ISOB standard**.

Accreditation applies to CABs globally that are involved in auditing, assessing, or certifying organoid biobanks and associated activities. This policy governs all ISoOR-AB applicants, accredited CABs, and assessment operations.

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## 3. Guiding Principles

ISoOR-AB upholds the following core principles:

- **Impartiality:** Accreditation decisions are objective, independent, and free from conflicts of interest.
  - **Transparency:** Procedures, criteria, and outcomes are open and clearly communicated.
  - **Scientific and Ethical Excellence:** Assessments are based on recognized scientific standards and ethical practices.
  - **Confidentiality:** Information about applicants, CABs, and assessments is strictly protected.
  - **International Alignment:** Activities conform with ISO/IEC 17011 and recognized global accreditation practices.
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## 4. Legal Status and Authority

ISoOR-AB is an independent, non-profit accreditation body established by ISoOR.

- **ISoOR:** Standard-setting organization (ISoOR-ISOB), develops organoid biobanking standards.
- **ISoOR-AB:** Independent entity, accredits CABs and maintains impartiality.

ISoOR-AB has the authority to **grant, renew, suspend, or withdraw CAB accreditation** in accordance with established criteria.

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## 5. Governance Structure

The ISoOR-AB accreditation program is managed through:

- **Board of Directors:** Provides strategic oversight and ensures independence from ISoOR standard-setting activities.
- **Accreditation Committee:** Makes final decisions on CAB accreditation.
- **Technical Expert Panels:** Conduct on-site or remote assessments of CABs.
- **ISoOR-AB Secretariat:** Coordinates operations, documentation, and communication.

Separation of roles is maintained to protect impartiality and prevent conflicts of interest.

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## 6. Accreditation Process

ISoOR-AB accreditation follows a defined, consistent process:

1. Submission of CAB application
  2. Review of documentation and procedures
  3. On-site or remote assessment of CAB capabilities
  4. Evaluation of compliance with ISoOR-ISOB standard and ISO/IEC 17011
  5. Decision by the Accreditation Committee
  6. Issuance of accreditation certificate to successful CABs
  7. Surveillance, monitoring, and re-accreditation at defined intervals
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## 7. Impartiality and Independence

ISoOR-AB ensures impartiality through:

- **Conflict of interest screening** for all assessors, reviewers, and decision-makers
  - **Independent peer review** of assessment reports
  - **Separation of standard-setting and accreditation functions**
  - **Transparent decision-making processes**
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## 8. Confidentiality and Data Protection

All information obtained during applications, assessments, and surveillance is treated confidentially. ISoOR-AB manages data in accordance with applicable laws and regulations — including, where relevant, **GDPR, PDPA, CCPA, and APPI** — and implements measures to prevent unauthorized access, use, or disclosure.

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## 9. Complaints and Appeals

ISoOR-AB maintains mechanisms for CABs or stakeholders to:

- Submit complaints regarding accredited CABs or ISoOR-AB processes
- Appeal accreditation decisions
- Receive independent review of complaints and appeals by designated panels

Decisions on complaints and appeals are documented and communicated transparently.

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## 10. Recognition and International Alignment

ISoOR-AB seeks international recognition by:

- Aligning its program with **ISO/IEC 17011**
- Engaging with **APAC, ILAC**, and other global accreditation organizations
- Promoting mutual recognition and harmonization in organoid biobank accreditation

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## 11. Use of Accreditation Symbol

Accredited CABs may use the ISoOR-AB accreditation mark to indicate compliance.

- **Conditions for use:** Must follow guidelines provided by ISoOR-AB
- **Unauthorized use:** Will result in corrective action, including possible withdrawal of accreditation

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## 12. Policy Review and Revision

This policy is reviewed every **three years** or when regulatory or standard changes occur.

- Revisions are approved by the **ISoOR-AB Accreditation Committee**
- Updates ensure continued alignment with ISO/IEC 17011 and best practices.