

ISoOR-Accreditation Procedures Manual for Organoid Biobanks

International Society of Organoid Research (ISoOR)

July 30, 2025

Contents

1	Introduction	4
2	Purpose and Scope	4
2.1	Purpose	4
2.2	Objectives	4
2.3	Scope	4
3	Definitions and Abbreviations	5
4	Accreditation Program Overview	6
4.1	Objectives of the Accreditation Program	6
4.2	Structure of the Accreditation Process	6
4.3	Principles of Accreditation	6
4.4	Responsibilities of Participants	6
4.5	Alignment with International Frameworks	7
5	Application for Accreditation	7
5.1	Eligibility Requirements	7
5.2	Application Package	7
5.3	Submission and Initial Processing	7
5.4	Application Fees and Financial Agreement	8
5.5	Application Validity and Expiration	8
5.6	Confidentiality and Data Handling	8
6	Documentation Review	8
6.1	Objective	8
6.2	Required Documentation	8
6.3	Review Process	8
6.4	Outcomes	9
7	Assessment Process	9
7.1	Objectives	9
7.2	Planning and Preparation	9

7.3	Onsite Assessment	9
7.4	Post-Assessment Actions	9
7.5	Special Considerations	9
8	Decision-Making Process	9
8.1	Governance	9
8.2	Inputs to Decision	10
8.3	Decision Categories	10
8.4	Notification	10
8.5	Appeals Process	10
9	Granting of Accreditation	10
9.1	Conditions for Granting	10
9.2	Accreditation Certificate	10
9.3	Renewal Process	11
9.4	Changes to Scope	11
10	Surveillance and Reassessment	11
10.1	Objectives	11
10.2	Surveillance	11
10.3	Reassessment	11
10.4	Reporting and Follow-Up	11
10.5	Extraordinary Assessments	11
11	Handling of Complaints and Appeals	12
11.1	Purpose	12
11.2	Complaint Procedure	12
11.3	Appeals Procedure	12
11.4	Confidentiality	12
11.5	Records	12
12	Suspension, Withdrawal, and Reduction	12
12.1	Grounds for Action	12
12.2	Process	12
12.3	Suspension	13
12.4	Withdrawal	13
12.5	Reduction of Scope	13
13	Confidentiality and Data Protection	13
13.1	Obligations	13
13.2	Measures	13
13.3	Disclosure	13
13.4	Breach Response	13
14	Use of Accreditation Symbols and Statements	14
14.1	Usage Guidelines	14
14.2	Prohibited Uses	14
14.3	Enforcement	14
15	Record Keeping	14

15.1	Types of Records	14
15.2	Retention Period	14
15.3	Access and Security	14
15.4	Disposal	15
16	Staff Competence and Training	15
16.1	Requirements	15
16.2	Training Program	15
16.3	Monitoring and Evaluation	15
16.4	Assessor Certification	15
17	Fees and Payments	15
17.1	Fee Structure	15
17.2	Payment Terms	16
17.3	Consequences of Non-Payment	16
17.4	Refunds	16
18	Communication and Transparency	16
18.1	Principles	16
18.2	Channels	16
18.3	Public Information	16
19	Continuous Improvement	17
19.1	Approach	17
19.2	Activities	17
19.3	Review Cycle	17
20	References and Related Documents	17
20.1	Standards	17
20.2	Policies	17
20.3	Supporting Documents	17
20.4	Availability	18

1 Introduction

The International Society of Organoid Research (ISoOR), through its Accreditation Body (ISoOR-AB), provides accreditation to Organoid Biobanks that demonstrate compliance with ISO/IEC 17011 and the ISoOR International Standard for Organoid Biobanks (ISoOR-ISOB). This manual outlines the comprehensive procedures, ensuring:

- Transparent, consistent, and impartial decision-making.
- Rigorous compliance with international quality and competence standards.
- Structured support for Organoid Biobanks seeking accredited status.

ISoOR aligns with regional and international frameworks, including:

- Asia Pacific Accreditation Cooperation (APAC).
- International Laboratory Accreditation Cooperation (ILAC).
- International Accreditation Forum (IAF).

This alignment facilitates mutual recognition of accreditations worldwide, enhancing the credibility of accredited Organoid Biobanks.

2 Purpose and Scope

2.1 Purpose

This manual serves as the authoritative procedural reference for all parties involved in the accreditation of Organoid Biobanks under ISoOR. It provides:

- A clear explanation of ISoOR's accreditation criteria, steps, and decision points.
- Defined responsibilities for applicants, assessors, and internal staff.
- Mechanisms for quality control, continuous improvement, and stakeholder communication.

2.2 Objectives

- To ensure standardized and fair evaluation of Organoid Biobanks.
- To promote transparency in the accreditation process.
- To support international harmonization of Organoid Biobank quality standards.

2.3 Scope

This manual applies to:

- All Organoid Biobanks seeking ISoOR accreditation.
- ISoOR staff and assigned third-party assessors.
- Review committees responsible for interpreting results and granting accreditation.

- Ongoing surveillance and reassessment processes.
- Stakeholders requiring clarity on ISoOR's operational procedures.

It covers the full lifecycle of accreditation:

1. Application
2. Documentation and eligibility review
3. Onsite assessment
4. Nonconformity resolution
5. Final decision
6. Surveillance, complaints, appeals
7. Suspension, withdrawal, or reduction

3 Definitions and Abbreviations

- **Accreditation:** Formal recognition that an Organoid Biobank is compliant with ISoOR-ISOB and relevant standards.
- **Applicant:** An organization that has formally submitted an application for accreditation.
- **Assessment:** A systematic, independent, and documented process for evaluating the Organoid Biobank's compliance with defined standards.
- **Assessor:** A qualified individual authorized by ISoOR-AB to conduct audits and evaluations.
- **Corrective Action:** A documented procedure implemented to address identified nonconformities and prevent recurrence.
- **Nonconformity:** A deviation from a specific requirement stated in ISoOR-ISOB or other relevant standards.
- **Surveillance:** Ongoing monitoring of an accredited Organoid Biobank to ensure continued conformity.
- **ISoOR:** The International Society of Organoid Research.
- **ISoOR-AB:** ISoOR-Accreditation Body.
- **APAC:** Asia Pacific Accreditation Cooperation.
- **ILAC:** International Laboratory Accreditation Cooperation.
- **ISO/IEC 17011:** International standard defining requirements for accreditation bodies operating certification/inspection programs.

4 Accreditation Program Overview

4.1 Objectives of the Accreditation Program

The ISoOR Accreditation Program is designed to:

- Verify the technical competence and compliance of Organoid Biobanks.
- Ensure compliance with ISO/IEC 17011 and ISoOR-ISOB.
- Facilitate international recognition through alignment with global frameworks.
- Promote ethical, transparent, and robust biobanking practices.

Accreditation is a continuous compliance process involving documentation reviews, onsite assessments, corrective actions, surveillance, and re-evaluations.

4.2 Structure of the Accreditation Process

The ISoOR Accreditation Program consists of five main phases:

1. **Application and Eligibility Verification:** Submission of application forms and core documentation; review of eligibility criteria.
2. **Document Review:** Evaluation of QMS documents, SOPs, risk management plans, and staff qualifications.
3. **Onsite Assessment:** In-person evaluation of facilities, staff competence, biobanking processes, and impartiality safeguards.
4. **Corrective Action and Decision:** Organoid Biobank response to nonconformities; Accreditation Committee decision.
5. **Post-Accreditation Monitoring:** Includes surveillance audits, reassessments, and response to changes or complaints.

4.3 Principles of Accreditation

The ISoOR accreditation process is governed by:

- **Impartiality:** Decisions are made independently, free from conflicts of interest.
- **Transparency:** Processes, timelines, and expectations are clearly communicated.
- **Competence:** Assessors are trained and monitored to maintain technical expertise.
- **Confidentiality:** Proprietary and sensitive information is handled under strict protocols.
- **Accountability:** All assessments, decisions, appeals, and complaints are documented and auditable.

4.4 Responsibilities of Participants

- **ISoOR-AB:** Manages the program, maintains integrity, trains assessors, and ensures ISO/IEC 17011 compliance.

- **Accredited Organoid Biobanks:** Maintain QMS, report changes, cooperate with surveillance, and use accreditation marks appropriately.
- **Assessors:** Conduct objective and thorough evaluations based on ISO/IEC 17011.

4.5 Alignment with International Frameworks

ISoOR models its processes on:

- ISO/IEC 17011: Requirements for accreditation bodies.
- ISoOR-ISOB: Standard for Organoid Biobanks.
- ILAC/IAF/APAC Guidance: Supporting harmonization and mutual recognition.

5 Application for Accreditation

5.1 Eligibility Requirements

Organoid Biobanks must meet:

- Legal entity status authorized to operate as an Organoid Biobank in their jurisdiction.
- Documented QMS aligned with ISO/IEC 17011 and ISoOR-ISOB.
- Qualified personnel, facilities, and processes for biobanking activities.
- Operational history or readiness demonstrating compliance capability.

Pre-application consultations are available via www.isoor.org/standards or secretary@isoor.org.

5.2 Application Package

The application package includes:

1. ISoOR Accreditation Application Form.
2. Organizational chart and governance structure.
3. Quality Manual or QMS overview.
4. SOPs for biobanking processes, impartiality, and data management.
5. Facility layout showing biobanking and administrative areas.
6. Personnel qualifications and training records.
7. Scope of Accreditation Sought, detailing biobanking types and standards.

Documents must be in English or accompanied by certified translations.

5.3 Submission and Initial Processing

1. Acknowledgment: ISoOR-AB confirms receipt within 5 business days.
2. Administrative Review: Verifies completeness within 15 calendar days.

3. Eligibility Confirmation: Confirms eligibility for documentation review.

5.4 Application Fees and Financial Agreement

- Non-refundable application fee, published on www.isoor.org.
- Invoice issued upon eligibility confirmation, due within 30 days.
- Financial Agreement outlines costs for assessments and surveillance.

5.5 Application Validity and Expiration

Applications are valid for 12 months; delays may require reapplication.

5.6 Confidentiality and Data Handling

Information is treated confidentially per ISoOR's Data Protection Policy, except as required by law or frameworks (e.g., ILAC, APAC).

6 Documentation Review

6.1 Objective

Ensuring that submitted documentation aligns with ISoOR-ISOB and ISO/IEC 17011 requirements, this phase verifies the Organoid Biobank's Quality Management System (QMS) and technical competence.

6.2 Required Documentation

Applicants must provide:

- Quality Manual detailing QMS structure, policies, and objectives.
- Standard Operating Procedures (SOPs) for all biobanking activities.
- Compliance documentation, including risk management plans.
- Training records and personnel qualification certificates.
- Evidence of internal audits and management reviews.

6.3 Review Process

1. Assigned to a team of at least two assessors with relevant expertise.
2. Review conducted within 30 calendar days of eligibility confirmation.
3. Assessment includes conformity checks, identification of gaps, and preliminary non-conformities.
4. Report generated and shared with the applicant for response.

6.4 Outcomes

- Approval to proceed to onsite assessment if documentation is compliant.
- Request for corrective actions if minor nonconformities are identified.
- Deferral or rejection if major nonconformities persist after review.

7 Assessment Process

7.1 Objectives

Confirming operational conformity, staff competence, and facility readiness through an onsite evaluation.

7.2 Planning and Preparation

- Assessor team assigned based on scope and expertise.
- Pre-assessment meeting scheduled with the applicant.
- Logistics coordinated, including travel and access arrangements.

7.3 Onsite Assessment

- Duration: 1-3 days, depending on scope and complexity.
- Activities include facility tours, staff interviews, process observations, and record reviews.
- Nonconformities categorized as major, minor, or observations.

7.4 Post-Assessment Actions

- Preliminary findings shared with the applicant at the exit meeting.
- Formal report submitted within 15 days, detailing nonconformities and recommendations.
- Applicant given 30 days to submit corrective action plans.

7.5 Special Considerations

- Remote assessments allowed with justification and ISoOR-AB approval.
- Confidentiality maintained throughout the process.

8 Decision-Making Process

8.1 Governance

Managed by the independent ISoOR Accreditation Committee, comprising experts in biobanking and accreditation.

8.2 Inputs to Decision

- Assessment reports from documentation and onsite reviews.
- Applicant's corrective action responses and evidence.
- Committee deliberations and consensus.

8.3 Decision Categories

- **Grant:** Full accreditation awarded with no unresolved issues.
- **Conditional Grant:** Accreditation with specific conditions to be met within 90 days.
- **Defer:** Decision postponed pending further information or corrective actions.
- **Deny:** Accreditation not granted due to unresolved major nonconformities.

8.4 Notification

- Written decision communicated within 15 days of committee meeting.
- Includes rationale, conditions (if any), and appeal rights.

8.5 Appeals Process

- Handled by an independent Appeals Panel.
- Applicant must submit appeal within 30 days of notification.
- Review completed within 60 days, with a binding decision.

9 Granting of Accreditation

9.1 Conditions for Granting

Accreditation is granted when:

- All major and minor nonconformities are resolved.
- The Organoid Biobank meets ISoOR-ISOB and ISO/IEC 17011 requirements.

9.2 Accreditation Certificate

- Valid for 3 years from the date of issue.
- Includes the Organoid Biobank's name, accreditation scope, and unique certificate number.
- Signed by the ISoOR-AB Chair.

9.3 Renewal Process

- Requires successful completion of triennial reassessment.
- Annual surveillance audits maintain validity.
- Application for renewal must be submitted 6 months prior to expiration.

9.4 Changes to Scope

- Must be notified to ISoOR-AB within 30 days of change.
- May require additional assessment.

10 Surveillance and Reassessment

10.1 Objectives

Ensuring ongoing compliance and addressing changes in operations or standards.

10.2 Surveillance

- Conducted annually, either onsite or remotely.
- Focuses on previously identified issues and new activities.
- Duration: 1 day, adjustable based on scope.

10.3 Reassessment

- Full evaluation every 3 years, mirroring initial assessment.
- Includes updated documentation and onsite review.
- Outcome determines renewal or revocation.

10.4 Reporting and Follow-Up

- Surveillance/reassessment reports issued within 15 days.
- Corrective actions required within 30 days for nonconformities.

10.5 Extraordinary Assessments

- Triggered by complaints, significant changes, or regulatory updates.
- Conducted at ISoOR-AB discretion.

11 Handling of Complaints and Appeals

11.1 Purpose

Establishing an impartial mechanism for resolving disputes related to accreditation decisions or processes.

11.2 Complaint Procedure

- Submitted in writing to ISoOR-AB within 30 days of the incident.
- Includes details of the issue, evidence, and desired outcome.
- Acknowledged within 5 business days; resolved within 30 days.

11.3 Appeals Procedure

- Filed within 30 days of a decision notification.
- Reviewed by an independent Appeals Panel, excluding original assessors.
- Decision communicated within 60 days, considered final and binding.

11.4 Confidentiality

All complaint and appeal details are handled confidentially, with access limited to authorized personnel.

11.5 Records

Maintained for 10 years, documenting submission, review, and resolution.

12 Suspension, Withdrawal, and Reduction

12.1 Grounds for Action

Actions may be taken for:

- Noncompliance with ISoOR-ISOB or ISO/IEC 17011.
- Ethical or legal breaches (e.g., data misuse).
- Failure to resolve nonconformities within stipulated timelines.
- Non-payment of fees.

12.2 Process

- Notification issued with details and a 30-day response period.
- ISoOR-AB evaluates response; decision made by the Accreditation Committee.
- Status updated on the ISoOR public registry.

12.3 Suspension

- Temporary halt of accreditation, lasting up to 6 months.
- Requires corrective action and reassessment to lift.

12.4 Withdrawal

- Voluntary by the Organoid Biobank with 60 days' notice.
- Involuntary due to unresolved issues, effective immediately.

12.5 Reduction of Scope

- Applied when specific activities fail to meet standards.
- Requires reassessment to restore full scope.

13 Confidentiality and Data Protection

13.1 Obligations

ISoOR-AB and assessors must protect:

- Proprietary information of Organoid Biobanks.
- Personal data of staff and donors, compliant with GDPR and HIPAA.

13.2 Measures

- Data encryption and secure storage.
- Access restricted to authorized personnel.
- Regular audits of data handling practices.

13.3 Disclosure

Information shared only:

- With applicant consent.
- As required by law or ILAC/APAC agreements.

13.4 Breach Response

- Immediate notification to affected parties.
- Investigation and corrective actions within 15 days.

14 Use of Accreditation Symbols and Statements

14.1 Usage Guidelines

- Limited to the accredited scope, as specified on the certificate.
- Requires prior approval from ISoOR-AB for marketing materials.
- Must include the accreditation number and validity period.

14.2 Prohibited Uses

- Misrepresentation of accreditation status.
- Use after suspension, withdrawal, or expiration.

14.3 Enforcement

- ISoOR-AB monitors usage via public reports and audits.
- Misuse may lead to suspension or legal action.

15 Record Keeping

15.1 Types of Records

Includes:

- Application forms and supporting documents.
- Assessment reports, nonconformity logs, and corrective actions.
- Accreditation decisions, certificates, and surveillance outcomes.
- Complaints, appeals, and resolutions.

15.2 Retention Period

- Minimum of 10 years from the end of the accreditation cycle.
- Electronic and physical records stored securely.

15.3 Access and Security

- Access granted only to authorized ISoOR-AB staff.
- Backups maintained offsite with encryption.
- Regular audits ensure compliance with data protection standards.

15.4 Disposal

- Records destroyed securely after retention period.
- Documentation of destruction maintained.

16 Staff Competence and Training

16.1 Requirements

ISoOR-AB staff and assessors must demonstrate:

- Expertise in biobanking, quality management, and ISO/IEC 17011.
- Relevant academic or professional qualifications.
- Experience in accreditation or related fields.

16.2 Training Program

Includes:

- Induction training on ISoOR policies and procedures.
- Ongoing professional development, including workshops and webinars.
- Assessments to verify competence, conducted annually.

16.3 Monitoring and Evaluation

- Performance reviews based on assessment outcomes.
- Feedback from Organoid Biobanks and internal audits.
- Remedial training provided as needed.

16.4 Assessor Certification

- Initial certification after training and evaluation.
- Recertification required every 3 years.

17 Fees and Payments

17.1 Fee Structure

Includes:

- Non-refundable application fee.
- Assessment fees based on scope and duration.
- Annual surveillance fees.
- Additional charges for extraordinary assessments or appeals.

Fee schedules are published on www.isoor.org/fees.

17.2 Payment Terms

- Invoices issued upon eligibility confirmation or assessment scheduling.
- Payment due within 30 days.
- Late payments incur a 5% penalty per month.

17.3 Consequences of Non-Payment

- Suspension of accreditation after 60 days of non-payment.
- Withdrawal if unpaid after 90 days.

17.4 Refunds

- No refunds for application or assessment fees.
- Partial refunds possible for canceled surveillance, at ISoOR-AB discretion.

18 Communication and Transparency

18.1 Principles

Communication is guided by:

- Clarity in all interactions with stakeholders.
- Timeliness in responding to inquiries (within 5 business days).
- Impartiality in sharing information.

18.2 Channels

Includes:

- Email: accreditation@isoor.org.
- Website: www.isoor.org (public registry of accredited Biobanks).
- Annual reports and newsletters.

18.3 Public Information

- List of accredited Organoid Biobanks and their scopes.
- Summary of accreditation policies and procedures.
- Contact details for inquiries and complaints.

19 Continuous Improvement

19.1 Approach

Based on:

- Analysis of assessment and surveillance data.
- Feedback from Organoid Biobanks, assessors, and stakeholders.
- Benchmarking against ILAC and APAC best practices.

19.2 Activities

Includes:

- Internal audits of ISoOR-AB processes, conducted biannually.
- Training updates to reflect new standards or technologies.
- Process optimization based on identified inefficiencies.

19.3 Review Cycle

- Comprehensive review of the manual every 2 years.
- Updates published with stakeholder consultation.

20 References and Related Documents

20.1 Standards

- ISO/IEC 17011:2017 - Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies.
- ISoOR-ISOB: International Standard for Organoid Biobanks (latest version).

20.2 Policies

Includes:

- ISoOR Conflict of Interest Policy.
- ISoOR Confidentiality and Data Protection Policy.
- ISoOR Impartiality Policy.

20.3 Supporting Documents

- Accreditation Application Form.
- Assessment Report Template.
- Corrective Action Plan Template.

- Surveillance Audit Checklist.

20.4 Availability

All documents are accessible via www.isoor.org/standards or upon request to secretary@isoor.org.