ISoOR Accreditation Pathway for Organoid Biobanks (ISoOR-ISOB)

Introduction

The ISoOR Accreditation Pathway for Organoid Biobanks (ISoOR-ISOB) provides a structured process for organoid biobanks to achieve accreditation. The ISoOR Accreditation Body (ISoOR-AB) oversees the process, engaging Conformity Assessment Bodies (CABs) for assessments. Follow these seven steps to achieve accreditation.

Accreditation Pathway

1. Eligibility Check

Confirm your biobank meets the foundational requirements for accreditation:

- **Legal Status**: Ensure your biobank is legally registered in your country with a valid business license.
- **Compliance**: Verify adherence to national and international standards:
    - *Biosafety*: Follow regulations* for safe handling of biological materials, including organoids, in laboratory facilities.
    - *Ethics*: Secure approvals from an Institutional Review Board (IRB) for human-derived organoids, ensuring compliance with biomedical research ethics.
    - *Data Governance*: Implement secure systems for data storage and handling, protecting donor privacy and sample information.
- **Biobanking Standards**: Align operations with global biobanking best practices, including protocols for organoid collection, storage, quality control, and traceability.
- **Action**: Conduct a self-assessment using ISoOR-ISOB checklists (available at the ISoOR-AB website) to confirm readiness. Address gaps in documentation, facilities, or training before applying.

2. Application Submission

Submit a formal application to ISoOR-AB:

- **Required Documents**:
    - Completed ISoOR-ISOB Pre-Assessment Questionnaire, covering:

        - General institutional information (e.g., institution name, legal registration, mission, organizational structure, key contact person, current scope of organoid research, collaborations, funding sources).
        - Organoid workflows, including:
            - *Tissue Acquisition and Donor Management* (source of tissues, ethical protocols, consent process, donor metadata, sample handling).
            - *Tissue Processing and Organoid Initiation* (dissociation methods, embedding, culture conditions, medium components, incubation parameters).
            - *Organoid Expansion and Passaging* (culture monitoring, passaging methods, batch tracking, contamination controls).
            - *Characterization and Quality Control* (phenotypic, genotypic, functional assays, inclusion criteria).
            - *Cryopreservation and Storage* (freezing protocols, storage format, alarm and monitoring).
            - *Distribution and Use* (approval process, packaging, data sharing policy, post-distribution follow-up).
            - *Data Management* (LIMS, linkage of samples and metadata, backup, data security).
        - Facility and equipment details, such as laboratory layout, climate control, essential equipment, and environmental monitoring procedures.
        - Personnel structure and qualifications, including roles, responsibilities, education, training, and ongoing education programs.
        - Standard Operating Procedures (SOPs) for derivation, expansion, cryopreservation, quality control, and data management, and procedures for periodic review and compliance.
        - Ethical approvals and consent framework, covering ethics committee approval, consent procedures, types of consent, and compliance with international guidelines.
        - Data management and traceability systems, addressing data categories, chain of custody, backup protocols, data security, and audit trails.

    - Quality Manual outlining quality control, risk management, and internal audit processes.

- **Submission Process**:

    - Submit documents electronically via the ISoOR-AB online portal or by email and provide hard copies if requested.
    - Specify the scope of your biobank's activities (e.g., organoid testing, storage, sharing).

- **Action**: Register on the ISoOR-AB website, pay the application fee, and submit within 6 months of eligibility confirmation. Ensure SOPs are clear and detailed.

3. Documentation Review

ISoOR-AB will evaluate your submitted materials to ensure compliance:

- **Focus Areas**:
    - *SOPs*: Verify procedures for organoid handling meet international biobanking standards (e.g., quality control, sample integrity).
    - *Training Records*: Confirm staff are qualified for organoid workflows and biosafety.
    - *Ethics*: Check IRB approvals and consent forms for compliance with national regulations.
    - *Biosafety*: Ensure facilities meet safety standards for biological materials.
    - *Data Systems*: Validate secure, traceable data management for organoids and donor information.

- **Outcome**:
    - If compliant, proceed to the on-site audit.
    - If deficiencies are found, ISoOR-AB will issue a Corrective Action Request (CAR) with a 3-month deadline to resolve issues.

- **Action**: Respond promptly to CARs, updating SOPs or records as needed, and submit revisions via the ISoOR-AB portal or email.

4. On-Site Audit

ISoOR-AB will assign a Conformity Assessment Body (CAB) to visit your biobank to verify operations:

- **Audit Scope**:
    - Observe organoid workflows (e.g., derivation, culture, storage, distribution).
    - Check sample traceability (e.g., barcoding, laboratory information management systems).
    - Inspect biosafety measures (e.g., lab cleanliness, protective equipment).
    - Verify staff qualifications through interviews and training records.
    - Confirm equipment calibration and maintenance (e.g., freezers, incubators).
    - Audit data systems for security and compliance with privacy regulations.

- **Process**:
    - Includes opening/closing meetings, document sampling, and facility tours.
    - Non-conformities are classified as major (systemic issues) or minor (isolated), with resolution timelines of 30–90 days.

- **Duration**: 2–5 days, depending on biobank size and complexity.
- **Action**: Prepare staff for interviews, ensure equipment is calibrated, and organize records for easy access during the audit.

5. Accreditation Decision

ISoOR-AB will review audit findings and issue a decision:

- **Outcomes**:
    - *Full Accreditation*: Valid for 3 years, awarded if no major issues or all are resolved within 30 days. You receive an ISoOR-ISOB certificate.
    - *Conditional Accreditation*: Granted with minor issues, requiring corrective actions within 3–6 months, verified by follow-up review.
    - *Rejection*: Issued for unresolved major issues, with feedback for reapplication after 6 months.
- **Process**: ISoOR-AB evaluates audit reports and corrective actions, ensuring alignment with global biobanking standards.
- **Action**: Address any non-conformities quickly, submit evidence via the ISoOR-AB portal, and await certificate issuance (1–2 months post-audit).

6. Post-Accreditation Monitoring

Maintain accreditation through ongoing compliance:

- **Annual Self-Assessment**:
    - Submit a report to ISoOR-AB, including updates to SOPs, internal audit results, staff training, and quality metrics (e.g., organoid viability, contamination rates).
- **Surveillance Audits**:
    - ISoOR-AB conducts annual checks (on-site or remote) to verify compliance.
    - Unannounced audits may occur to ensure consistent standards.
- **Re-Accreditation**:
    - Undergo a full reassessment every 3 years, repeating steps 2–5.
- **Non-Compliance**: Failure to meet standards may lead to suspension or withdrawal, with corrective actions required to restore status.
- **Action**: Assign a quality management team to track compliance, submit annual reports by ISoOR-AB deadlines, and prepare for re-accreditation.

7. Global Recognition

Accredited biobanks gain enhanced credibility and collaboration opportunities:

- **Certificates and Listings**:
    - Receive an official ISoOR-ISOB Certificate with a unique registration number.
    - Be listed in the ISoOR International Registry for organoid biobanks.

- **Benefits**:
    - *Higher Visibility and Trust Within China*: ISoOR-ISOB accreditation signals to regulators, funding agencies, hospitals, and industry in China that your biobank meets recognized international standards of quality and reliability.
    - *Preferred Access to National Funding*: Some Chinese funding programs (e.g., National Natural Science Foundation of China, Ministry of Science and Technology, provincial initiatives) may prioritize or require standardized, accredited biobanks as collaborators or recipients.
    - *Strengthening Collaborative Opportunities*: ISoOR-ISOB accreditation makes your biobank a preferred and trustworthy candidate for partnerships with Chinese hospitals, biotechnology companies, and research institutes, fostering collaborations on drug testing, disease modeling, personalized medicine, and biotechnology innovation.
    - *Enhanced Competitive Edge*: Displaying the ISoOR-ISOB logo signals to stakeholders across China (regulators, industry, academia) that your operations follow rigorous, standardized procedures, adding credibility and prestige.

- **Action**: Promote your accreditation in publications, apply for research grants, and network with global biobanks through ISoOR-AB events.

Additional Notes

- **Timeline**: Expect 6–12 months from application to accreditation, with annual reports and 3-year reassessments.
- **Costs**: ISoOR-AB fees cover application, audit, and surveillance (contact ISoOR-AB for specifics). Budget for documentation and facility upgrades.
- **Resources**: Access ISoOR-AB checklists and templates via the ISoOR-AB website.

Recommendations

1. **Self-Assessment**: Use ISoOR-AB checklists to identify gaps in SOPs, ethics, or facilities. Update data systems to meet privacy laws.
2. **Documentation**: Prepare a clear Quality Manual and detailed SOPs for organoid workflows. Secure IRB approvals early.
3. **Audit Prep**: Train staff on biobanking standards, calibrate equipment, and test traceability systems before the audit.
4. **Networking**: Engage with ISoOR-AB events to connect with other biobanks and promote your accredited status.
5. **Contact ISoOR-AB**: Visit the ISoOR-AB website for application forms and submission details. Email the Accreditation Committee for guidance.

ISoOR-ISOB Accreditation Required Documents

- ISoOR-ISOB Pre-Assessment Questionnaire (Download)
- Scope of your biobank's activities (PDF format)
- ISoOR-AB checklist (Download)

Actions

- Proceed with the application fee: [Click here]
- Submit documents: [Click Here]

Additional notes for China Mainland:

Organoid biobanks in China must comply with the Biosafety Law (2020), Regulations on the Management of Human Genetic Resources (2019), and Regulations on the Management of Pathogenic Microorganisms Laboratories Biosafety (2004), alongside technical standards like GB19489-2008 and WS233-2002. Ethical oversight is critical for human-derived organoids, and waste disposal must follow 2003 regulations. Internationally, WHO, ISBER, and OECD guidelines inform practices, ensuring global compatibility. Compliance is verified through accreditations, audits, and approvals, with a focus on biosafety, ethical governance, and HGR management.