ISoOR-AB Accreditation Checklist for Organoid Biobanks

Step 1: Eligibility Check

☐ Biobank legally registered in China (valid business license)

☐ Complies with national biosafety regulations

☐ Institutional Review Board (IRB) approval in place for human-derived organoids

☐ Data governance protocols ensure donor privacy and sample information security

☐ Processes align with ISoOR-ISOB

☐ Any gaps in documentation, facilities, or staff training have been addressed

Step 2: Application Submission

☐ Filled out the ISoOR-ISOB Pre-Assessment Questionnaire, covering:

- Institutional info (name, registration, structure, contacts)

- Organoid workflows (acquisition, processing, expansion, QC, storage, distribution, data management)

- Facility layout, environmental monitoring, and equipment lists

- Personnel qualifications, roles, and training records

- SOPs for all organoid-related procedures and data handling

- Ethical approvals, consent frameworks (IRB, consent types)

- Data traceability: LIMS, audit trails, backup/security systems

☐ Quality Manual detailing QC, risk management, and internal audit processes

☐ Submitted all documents via info@isoor-ab.org

☐ Application fee paid and scope of activities clearly specified

☐ All submissions made within six months of eligibility confirmation

Step 3: Documentation Review

☐ SOPs meet ISoOR-ISOB / ISO 20387/international standards for biobanking

☐ Staff training records are complete and current

☐ IRB, consent forms, and ethics documentation compliant with Chinese and international regulations

☐ Biosafety documentation demonstrates compliance with national standards

☐ Data management systems validated for security, traceability, and privacy

☐ If a Corrective Action Request (CAR) is issued, responses and revisions submitted within 3 months

Step 4: On-Site Audit

☐ Organoid workflows inspected and validated on site

☐ Sample traceability (barcoding, LIMS) verified

☐ Biosafety protocols, facilities, and PPE observed

☐ Staff interviews and qualification verification conducted

☐ Equipment calibration and maintenance confirmed (e.g. freezers, incubators)

☐ Data systems audited for security and privacy compliance

☐ Non-conformities (major/minor) documented and corrective action plans in place with 30–90 day remediation

Step 5: Accreditation Decision

☐ All major issues closed within 30 days for full accreditation (3-year validity)

☐ Minor issues resolved in 3–6 months for conditional accreditation

☐ Corrective action evidence submitted via portal

☐ Await official ISoOR-ISOB certificate

Step 6: Post-Accreditation Monitoring

☐ Annual self-assessment report submitted (SOP updates, internal audits, staff training, key QC metrics)

☐ Surveillance audits conducted yearly (onsite or remote), possibly unannounced

☐ Quality management team assigned to oversee ongoing compliance

☐ Full re-accreditation every 3 years (repeat Steps 2–5)

Step 7: Global Recognition

☐ Certificate received with unique accreditation number

☐ Listed in the ISoOR International Registry of organoid biobanks

☐ Accreditation promoted via publications, grant proposals, and communications

☐ Network and collaboration opportunities leveraged (ISoOR events, partnerships, funding programs)

Additional Compliance Aspects

☐ Meets China's Human Genetic Resources Management Regulations (2019)

☐ Adheres to pathogens-related biosafety regulations (e.g. Biosafety Law, pathogen lab regulations)

☐ Follows ethical governance and waste disposal norms (e.g. 2003 biomedical waste rules)

☐ Aligns with global interoperability via ISO 20387, IAF/ILAC MRAs, and APAC recognition

Recommendations

☐ Kick off with a self-assessment using this checklist to identify critical gaps.

☐ Map out SOPs, Quality Manual, and IRB/consent documentation well in advance.

☐ Train staff systematically and calibrate equipment pre-audit.

☐ Engage with ISoOR community events and stay updated on international best practices.

☐ Use ISoOR's templates and guidance, and reach out to the Accreditation Committee for support.