

ISoOR-ISOB Accreditation Checklist for Organoid Biobanks

Step 1: Eligibility Check

- Biobank legally registered in China (valid business license)
- Complies with national biosafety regulations (e.g. Biosafety Law, WS233-2002, GB19489-2008)
- Institutional Review Board (IRB) approval in place for human-derived organoids
- Data governance protocols ensure donor privacy and sample information security
- Processes align with ISO 20387 and international biobanking best practices (WHO, ISBER, OECD)
- Self-assessment completed using the ISoOR-ISOB checklist
- 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 ISoOR portal (plus hard copies, if requested)
- Application fee paid and scope of activities clearly specified
- All submissions made within six months of eligibility confirmation

Step 3: Documentation Review

- SOPs meet 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.