ISoOR-AB Accreditation Checklist for Organoid Biobanks

Version 2.0

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Prepared by:

ISoOR Accreditation Body (ISoOR-AB)

International Society of Organoid Research (ISoOR)

Step 1: Eligibility Check

☐ Organoid Biobank is legally established and authorized to operate in its jurisdiction.

☐ Applicable biosafety regulations and requirements have been identified and implemented.

☐ Appropriate ethical approvals are in place for human-derived organoids.

☐ Data governance procedures protect donor privacy, confidentiality, and sample information.

☐ Operations are aligned with the requirements of the ISoOR-ISOB Standard and internationally recognized best practices, including ISO 20387, WHO, ISBER, and OECD guidance.

☐ Internal self-assessment has been completed using the ISoOR-AB Accreditation Checklist.

☐ Deficiencies in documentation, facilities, personnel, or training have been addressed.

Step 2: Application Submission

☐ ISoOR-AB Pre-Assessment Questionnaire completed.

☐ Institutional information and organizational structure documented.

☐ Tissue acquisition and donor management procedures documented.

☐ Organoid initiation and processing procedures documented.

☐ Organoid expansion and passaging procedures documented.

☐ Characterization and quality control procedures documented.

☐ Cryopreservation and storage systems documented.

☐ Distribution and sharing procedures documented.

☐ Data management and traceability systems documented.

☐ Facility information and environmental monitoring procedures documented.

☐ Personnel qualifications and training records available.

☐ Standard Operating Procedures (SOPs) available and controlled.

☐ Ethical approvals and consent framework documented.

☐ Quality Manual describing quality control, risk management, internal audits, and corrective actions available.

☐ Scope of activities clearly defined.

☐ Application documents submitted through the ISoOR-AB portal or by email.

☐ Application fees paid.

☐ Submission completed within six months following eligibility confirmation.

Step 3: Documentation Review

☐ SOPs are consistent with the ISoOR-ISOB Standard and internationally recognized biobanking practices.

☐ Personnel training records are current and complete.

☐ Ethics approvals and consent procedures comply with applicable regulations.

☐ Biosafety documentation demonstrates regulatory compliance.

☐ Data management systems provide traceability, integrity, security, and confidentiality.

☐ Corrective Action Requests (CARs), if issued, have been addressed within the required timeframe.

☐ Documentation review requirements satisfied.

Step 4: On-Site Assessment

☐ Organoid workflows evaluated by ISoOR-AB assessors.

☐ Sample traceability systems verified.

☐ Biosafety procedures and laboratory practices observed.

☐ Personnel competency and qualifications evaluated.

☐ Equipment maintenance and calibration records reviewed.

☐ Data management systems assessed for security and traceability.

☐ Major and minor nonconformities documented.

☐ Corrective action plans established and implemented.

☐ Assessment report issued.

Step 5: Accreditation Decision

☐ Major nonconformities resolved.

☐ Minor nonconformities addressed according to agreed timelines.

☐ Evidence supporting corrective actions submitted.

☐ Accreditation decision issued by ISoOR-AB.

☐ ISoOR-AB Accreditation Certificate received.

☐ Unique accreditation number assigned.

☐ Biobank entered into the ISoOR International Registry of Accredited Organoid Biobanks.

Step 6: Post-Accreditation Monitoring

☐ Annual self-assessment reports submitted.

☐ SOP revisions documented.

☐ Internal audit results reviewed.

☐ Personnel training records updated.

☐ Quality indicators monitored.

☐ Surveillance assessments completed remotely and/or on site.

☐ Significant organizational or operational changes reported to ISoOR-AB.

☐ Reassessment completed every three years.

Step 7: Recognition and Collaboration

☐ Accreditation status appropriately communicated in scientific publications and professional activities.

☐ Participation in scientific collaborations and networking opportunities encouraged.

☐ Continuous improvement activities maintained.

☐ International best practices monitored and implemented when appropriate.

Additional Compliance Considerations

☐ Applicable national regulations governing human biological materials implemented.

☐ Biosafety and pathogen-related regulations followed.

☐ Ethical governance procedures established.

☐ Biomedical waste management procedures established.

☐ Traceability and quality systems maintained in accordance with the ISoOR-ISOB Standard and internationally recognized best practices.

☐ External information generated by qualified laboratories, technical experts, or Conformity Assessment Bodies (CABs), when available, may be considered by ISoOR-AB to reinforce confidence in assessment outcomes, without replacing ISoOR-AB's own assessment activities.

Recommendations

☐ Conduct periodic self-assessments to identify opportunities for improvement.

☐ Maintain current SOPs, Quality Manuals, and ethics documentation.

☐ Provide continual training and competency development for personnel.

☐ Maintain equipment calibration and environmental monitoring programs.

☐ Participate in ISoOR scientific activities and remain informed of evolving international best practices.

☐ Use ISoOR-AB guidance documents and consult the Accreditation Committee whenever clarification is required.