"ISoOR-ISOB Pre-Assessment Questionnaire"

1) General institutional information

1.1. Institution Name

Full legal name of the institution, including any acronyms or abbreviations.

1.2. Institution Type

(e.g., Public University, Private Research Institute, Hospital-Affiliated Laboratory, Biotechnology Company)

1.3. Country and Region

Specify the country, region, and city where the institution is headquartered.

1.4. Institutional Address

Provide the full mailing address of the main campus or laboratory site.

1.5. Website

Official website URL.

1.6. Year of Establishment

The year the institution was officially founded.

1.7. Legal Registration Number / License

Include any national or international registration/license numbers relevant to the institution's operation.

1.8. Institutional Mission Statement

A concise summary of the institution's mission and long-term vision, especially in relation to biomedical research and organoid technologies.

1.9. Organizational Structure

Brief description of the institutional hierarchy, including major departments or divisions involved in organoid research and biobanking.

1.10. Key Contact Person for ISoOR-ISOB Accreditation

i. Name
ii. Title/Position
iii. Email
iv. Phone number
v. Department/Division

1.11. Current Scope of Organoid Research/Biobanking Activities

A short summary (2–3 paragraphs) of the institution's ongoing work in organoid research, development, or biobanking. Mention key areas such as disease modeling, drug screening, regenerative medicine, or personalized therapy.

1.12. Affiliations and Collaborations

List major partnerships with academic institutions, hospitals, biotech companies, or consortia related to organoid science and biobanking.

1.13. Funding Sources

General overview of main sources of funding (government, private, international grants, etc.)

2) Description of organoid workflows

organoid workflows refers to a **comprehensive, step-by-step outline** of how the institution handles the entire lifecycle of organoid samples—from tissue acquisition to final use or distribution. This helps assess whether your processes meet the standards for reproducibility, quality, ethics, and biosafety required by **ISoOR-ISOB accreditation**.

a) Tissue Acquisition and Donor Management

i. Source of tissues (e.g., surgical resection, biopsy, fetal tissue, iPSC-derived, etc.)
ii. Ethical protocols in place (IRB approvals, informed consent process)
iii. Donor metadata collection (age, sex, diagnosis, treatment status, etc.)
iv. Sample transportation and handling conditions (e.g., temperature control, timing)

b) Tissue Processing and Organoid Initiation

i. Dissociation methods (enzymatic, mechanical, or combined)

ii. Isolation of stem/progenitor cells (if applicable)
iii. Embedding and matrix used (e.g., Matrigel, collagen, synthetic hydrogels)
iv. Culture medium composition (growth factors, supplements, inhibitors)
v. Incubation parameters (temperature, oxygen levels, CO_2 %, humidity)

c) Organoid Expansion and Passaging

i. Culture monitoring procedures (morphological criteria, growth curves)
ii. Passaging frequency and method (mechanical shearing, enzymatic digestion)
iii. Batch tracking (lot numbers, passage number, operator identity)
iv. Contamination controls (mycoplasma testing, sterility checks)

d) Characterization and Quality Control

i. Phenotypic characterization (histology, immunofluorescence, microscopy)
ii. Genotypic verification (karyotyping, STR profiling, sequencing)
iii. Functional assays (drug testing, differentiation potential, electrophysiology)
iv. Inclusion/exclusion criteria for biobank acceptance

e) Cryopreservation and Storage

i. Freezing protocol (cooling rate, cryoprotectant used, freezing medium)
ii. Storage format (vials, plates, cryobags)
iii. Storage systems (LN_2 tanks, -80°C freezers, automated systems)
iv. Temperature monitoring and alarm systems

f) Distribution and Use

i. Request approval process (scientific and ethical review)
ii. Packaging and shipping conditions (cold chain maintenance, dry shippers)
iii. Data sharing policies with recipients
iv. Post-distribution tracking (feedback, usage reporting)

g) Data Management

i. Database system used (LIMS, REDCap, custom software)
ii. Linkage between samples and metadata
iii. Backup protocols
iv. Access control and data security measures

3) Facility and equipment specifications

Objective:

To establish an environment that supports the high-quality production, maintenance, and storage of organoids, ensuring contamination-free conditions and compliance with regulatory standards.

Key Elements:

a) **Facility Layout and Design:**

i. The facility should be designed to minimize contamination risks and ensure optimal conditions for cell culture, storage, and processing. This includes:

- ✓ Separate clean rooms for different phases (e.g., organoid generation, expansion, cryopreservation).
- ✓ HEPA-filtered air systems (class II or III biosafety cabinets) to maintain a sterile environment.
- ✓ Positive pressure rooms for cell culture areas, with negative pressure for areas housing biohazardous materials.

b) **Climate Control:**

i. Temperature and humidity control systems with alarms to maintain stable conditions for cell culture (typically 37°C and 5% CO_2).

ii. A backup power system to ensure that refrigeration, freezers, and incubators remain operational during power failures.

c) **Laboratory Equipment:**

i. Essential equipment for organoid biobanks includes:

- ✓ CO_2 incubators
- ✓ Cryopreservation systems (vapor-phase liquid nitrogen tanks, controlled-rate freezers)
- ✓ Centrifuges (low-speed and microcentrifuges)
- ✓ Automated cell counters and microscopes for quality control

- ✓ Sterilization equipment (autoclaves)

All equipment must be regularly calibrated and validated according to the manufacturer's specifications and regulatory guidelines.

d) **Environmental Monitoring:**

i. Airflow, temperature, and humidity are continuously monitored. For critical equipment like incubators and freezers, redundant monitoring systems should be in place.
ii. Surface contamination checks, microbial air monitoring, and other environmental assessments at regular intervals.

4) Personnel structure and qualifications

Objective:

Ensure that all staff involved in the organoid biobank's activities are properly trained, qualified, and continuously updated on best practices.

Key Elements:

a) **Organizational Structure:**

i. The biobank should have a clearly defined organizational structure with key personnel roles including:

- ✓ **Biobank Manager:** Responsible for overall operation, compliance, and quality control.
- ✓ **Cell Culture Specialists:** Skilled in maintaining and deriving organoid cultures, cryopreservation, and quality control.
- ✓ **QC/QA Officers:** Ensure adherence to SOPs, handle data integrity checks, and coordinate regular audits.
- ✓ **Data Management Staff:** Focus on secure data storage, compliance with ethical data use, and tracking all biobank activities.

b) **Qualifications:**

i. **Biobank Manager:** Must have a background in molecular biology, biotechnology, or a related field with several years of experience in laboratory management and organoid culture.
ii. **Cell Culture Specialists:** Preferably have advanced degrees (BSc or MSc) in cell biology, regenerative medicine, or related disciplines, along with hands-on experience in stem cell culture and organoid generation.
iii. **QA/QC Personnel:** Should be trained in quality management systems (e.g., ISO 9001) and have experience in maintaining compliance with regulatory guidelines.
iv. **Data Managers:** Must be proficient in data security protocols, including GDPR or equivalent, and have experience managing laboratory information systems (LIMS).

c) **Ongoing Education and Training:**

i. All personnel should receive initial training on all relevant procedures and biobank policies. Regular refresher training should be scheduled annually, including updates on new techniques and regulatory requirements.

5) Standard operating procedures (SOPs)

Objective:

To provide standardized protocols for all processes related to organoid derivation, maintenance, and distribution, ensuring reproducibility, compliance, and quality.

Key Elements:

a) **Development of SOPs:**

i. **Derivation SOP:** Details the process of deriving organoids from donor tissues, including tissue collection, initial isolation, and culture conditions.

ii. **Expansion SOP:** Guidelines on maintaining organoid cultures, including media formulations, sub-culturing, and quality control checks for morphology and viability.
iii. **Cryopreservation SOP:** Describes the freezing, storage, and thawing processes to preserve organoid integrity.
iv. **Quality Control SOP:** Specifies the methods for assessing organoid quality, including morphological assessment, viability tests, and screening for contamination.
v. **Data Management SOP:** Describes data recording, storage, and backup processes, ensuring compliance with data integrity and privacy requirements.

b) **Review and Revision:**

i. SOPs should be regularly reviewed (at least annually) and revised to incorporate new scientific advancements, technological improvements, or regulatory changes. Updates should be documented and communicated to all relevant personnel.

c) **Compliance:**

i. All SOPs must comply with national and international standards, such as Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP), where applicable. SOPs should align with the ISoOR-ISOB standards for organoid biobanks.

6) Ethics committee approvals and consent frameworks

Objective:

Ensure that all human-derived biological materials are obtained, handled, and utilized in strict adherence to ethical guidelines and with proper informed consent from donors.

Key Elements:

a) **Ethics Committee (EC) Approval:**

i. All activities involving human-derived samples must be approved by an independent institutional review board (IRB) or ethics committee (EC). Approval must be obtained prior to collection and use of biological materials.
ii. The EC review should focus on ensuring that the collection and use of human samples align with ethical principles, such as respect for autonomy, privacy, and beneficence.

b) **Informed Consent Framework:**

i. A comprehensive consent process should be in place, where donors are fully informed about the nature of the research, potential uses of the samples, and any risks involved.
ii. Consent should be documented in writing and kept on file, with clear protocols for handling withdrawn consent.

c) **Types of Consent:**

i. **General Consent:** Covers broad use of donated tissues for research.
ii. **Specific Consent:** Applies to particular studies or experiments.
iii. **Re-consent:** Where necessary, periodic consent for ongoing research uses.

d) **Ethical Guidelines Compliance:**

i. The biobank must ensure adherence to national and international ethical guidelines, such as the Declaration of Helsinki or the Nuremberg Code, and follow local laws and regulations regarding the use of human biological materials.

7) Data management and traceability systems

Objective:

Ensure complete, accurate, and secure management of all data associated with organoid biobank operations.

a) **Key Elements:**

i. **Data Categories:**

- ✓ **Donor Information:** Coded or anonymized details about tissue donors, including health status, age, and consent history.
- ✓ **Organoid Information:** Information on organoid derivation, expansion, quality control results, cryopreservation, and distribution.
- ✓ **Operational Data:** Tracking data related to SOP compliance, equipment calibration, inventory management, and quality assurance results.

b) **Traceability:**

i. A robust system (such as a **Laboratory Information Management System (LIMS)**) must be in place to track every sample's origin, processing steps, storage, and eventual use or distribution.
ii. **Chain of Custody:** Documentation that records the full movement of biological materials within and outside the biobank to ensure accountability.

c) **Data Security:**

i. Data should be securely stored, preferably in a digital format with multiple backup copies (including off-site backups). All data access must be restricted based on user roles.
ii. **Compliance with Data Protection Laws:** Ensure compliance with data protection regulations such as GDPR, HIPAA, or local equivalents concerning the privacy and confidentiality of donor information.

d) **Audit and Reporting:**

i. An audit trail must be maintained, documenting all data changes, including additions, deletions, and modifications. Audit logs should be reviewed periodically for compliance.