ISCB-RQ-20387 | Issue 1 - September 2026

Biobank Accreditation Requirements

Applies to organisations performing biobanking of biological material and associated data for research and development within a defined scope.

Primary standard	**ISO 20387:2018**
Document owner	International Services for Certification Bodies
Review trigger	Standard, scheme, regulatory or ISCB process change

Document status and use

This ISCB applicant guide states the evidence and operating controls normally expected for this programme. It does not reproduce or replace the applicable ISO or ISO/IEC standard. Applicants must hold an authorised current copy and comply with all applicable requirements, legislation, scheme rules and formally issued ISCB criteria.

References to IAF or ILAC publications identify technical criteria that may be relevant. They do not by themselves state or imply that ISCB is an IAF or ILAC arrangement signatory.

01

Applicable framework

The assessment hierarchy begins with the primary standard and includes applicable normative, regulatory, scheme-owner and ISCB documents. ISCB will identify the controlling criterion if requirements conflict.

- ISO 20387:2018 remains the published primary standard at this issue date and is under revision; ISCB will communicate transition arrangements after a replacement is published.
- ISO/IEC 17011:2017 governs ISCB's accreditation process and decisions.
- Ethical, consent, privacy, biosafety, biosecurity, transport and jurisdiction-specific requirements remain applicable.

02

Core organisational requirements

Legal status and responsibility

Be a legally identifiable entity, or a defined part of one, that can be held responsible for conformity-assessment activities, contracts and decisions.

Impartiality and independence

Identify, analyse, treat, monitor and record threats from ownership, finance, relationships, consultancy, commercial pressure and self-review.

Confidentiality and information security

Protect confidential information, personal data, intellectual property and electronic records; control any legally required disclosure.

Organisation and governance

Define authority, responsibilities, reporting lines and safeguards; assign technical work, review and decisions to competent and appropriately independent functions.

Competence and resources

Set role-specific competence criteria; evaluate, authorise, monitor and re-evaluate personnel; control facilities, equipment, software and external resources.

Controlled operations

Accept work only after confirming capability; use controlled methods and records; handle deviations; review outputs; base decisions on sufficient objective evidence.

Management system

Maintain document and record control, risks and opportunities, complaints, appeals, nonconforming work, corrective action, internal audit, management review and improvement.

Accreditation claims

Limit certificates, symbols and claims to the granted scope and amend them immediately after suspension, reduction, withdrawal or expiry.

03 Service-specific technical requirements

1. Define the scope by types of biological material and associated data, lifecycle activities, methods, storage conditions, locations and intended uses.

2. Establish governance for access, consent or lawful authority, confidentiality, custodianship, material transfer and permitted use.

3. Control acquisition, collection, transport, receipt, preparation, preservation, storage, retrieval, distribution and disposal with complete chain of custody.

4. Define and verify critical quality attributes, quality-control methods, acceptance criteria and fitness for intended purpose.

5. Qualify and monitor facilities, environmental conditions, equipment, alarms, backup systems, information systems and disaster-recovery arrangements.

6. Manage traceability, data integrity, inventory reconciliation, nonconforming outputs, excursions and communication with depositors and users.

04 Minimum application and readiness evidence

Submit current, approved documents and representative implementation records. Templates without operational evidence are not sufficient.

01	Legal identity, governance, ethics and impartiality controls
02	Proposed material/data scope and lifecycle map
03	Consent, access, privacy and material-transfer controls
04	Personnel competence and authorization records
05	Collection, processing, storage and distribution procedures
06	Equipment qualification, monitoring, alarm and continuity records
07	Quality-control, traceability and representative transaction records
08	Internal audit, management review, risk, incident and corrective-action records

05

Assessment, decision and continued accreditation

Application and scope review

ISCB reviews legal identity, requested scope, locations, resources, readiness and applicable criteria before quotation and assessment planning. Acceptance of an application is not a promise of accreditation.

Assessment

Assessment may include document review, office or remote assessment, on-site technical assessment, witnessing, interviews, record tracing and evaluation of representative activities. The mix depends on scope and risk.

Nonconformities and decision

The applicant must determine causes, correct the issue, implement proportionate corrective action and provide evidence of effectiveness within the notified period. Accreditation decisions are independent from assessment and limited to demonstrated competence.

Maintenance

Accredited bodies must remain competent, comply with surveillance and reassessment, notify significant changes without delay, cooperate with witnessing and record access, address complaints and nonconformities, and control all accreditation claims.

06

Principal references

- ISO 20387:2018
- ISO/IEC 17011:2017
- Applicable ethical, privacy, biosafety and transport requirements
- Relevant ISO and ILAC biobanking publications

External editions can change. The edition stated in the accreditation agreement, transition notice or other formal ISCB communication controls the assessment. Verify current editions before use.

Prepare	Complete the readiness assessment and organise objective evidence.
Apply	Submit the application and proposed scope for formal review.