

ISoOR-AB Guidance for Conformity Assessment Bodies (CABs)

Version 1.0

June 18, 2026

Prepared by

ISoOR Accreditation Body (ISoOR-AB)

International Society of Organoid Research (ISoOR)

Table of Contents

1. Introduction
 2. Purpose and Scope
 3. Principles Governing CAB Participation
 4. Roles and Responsibilities
 5. Use of CAB Information in the ISoOR-ISOB Accreditation Process
 6. Requirements for CAB Information and Reports
 7. Review and Acceptance of External Information
 8. Confidentiality and Impartiality
 9. Limitations of CAB Participation
 10. References
-

1. Introduction

The ISoOR Accreditation Body (ISoOR-AB) administers the ISoOR-ISOB accreditation program for organoid biobanks.

ISoOR-AB performs assessments primarily through assessors appointed by ISoOR-AB. However, external organizations, technical experts, and Conformity Assessment

Bodies (CABs) may provide additional information that can support or reinforce the evaluation process.

ISoOR-AB retains full authority and responsibility for all accreditation decisions.

Participation by CABs does not imply delegation of accreditation authority.

2. Purpose and Scope

This document provides guidance regarding the use of information generated by external Conformity Assessment Bodies (CABs) and other qualified organizations during the ISoOR-ISOB accreditation process.

This document does not establish an accreditation program for CABs and does not constitute recognition, approval, or accreditation of CABs by ISoOR-AB.

3. Principles Governing CAB Participation

The use of external information shall be guided by:

- Impartiality.
- Competence.
- Confidentiality.
- Transparency.
- Technical rigor.
- Evidence-based decision making.

External information shall complement, but not replace, assessments conducted by ISoOR-AB.

4. Roles and Responsibilities

ISoOR–AB

ISoOR-AB:

- Maintains responsibility for all accreditation decisions.
- Evaluates the relevance and reliability of external information.
- May conduct additional assessments when necessary.
- Determines whether external evidence supports accreditation activities.

CABs and External Organizations

CABs and external organizations:

- May provide reports, findings, technical evaluations, or inspection data.
- Shall maintain competence, impartiality, and confidentiality.
- Shall disclose potential conflicts of interest.
- Shall cooperate with ISoOR-AB when clarification is required.

Submission of information does not imply acceptance by ISoOR-AB.

5. Use of CAB Information in the ISoOR–ISOB Accreditation Process

External information may be considered during:

- Documentation review.
- Initial assessment.
- Corrective action review.
- Surveillance activities.
- Reassessment.
- Investigation of complaints.
- Scope extensions.

Information provided by CABs may include:

- Inspection reports.
- Technical evaluations.
- Quality system assessments.

- Biosafety reviews.
- Laboratory audits.
- Equipment verification records.
- Corrective action follow-up reports.

ISoOR-AB may use such information to supplement its own assessments and strengthen confidence in accreditation decisions.

6. Requirements for CAB Information and Reports

Reports submitted to ISoOR-AB should include:

- Identification of the issuing organization.
- Date and scope of the activity.
- Description of methods used.
- Findings and conclusions.
- Evidence supporting conclusions.
- Identification of personnel involved.
- Declaration of conflicts of interest.

ISoOR-AB reserves the right to request additional information or clarification.

7. Review and Acceptance of External Information

ISoOR-AB evaluates external information according to:

- Relevance to the accreditation scope.
- Technical adequacy.
- Competence of the organization generating the information.
- Objectivity and impartiality.
- Traceability of evidence.
- Consistency with ISoOR-ISOB requirements.

Acceptance of external information is determined on a case-by-case basis.

8. Confidentiality and Impartiality

Information received from CABs shall be handled according to ISoOR-AB confidentiality policies.

All parties shall disclose actual or potential conflicts of interest.

Confidential information shall only be disclosed when authorized by the applicant or required by applicable laws or regulations.

9. Limitations of CAB Participation

CAB participation does not:

- Constitute accreditation by ISoOR-AB.
- Authorize CABs to issue ISoOR-ISOB certificates.
- Transfer accreditation authority from ISoOR-AB.
- Guarantee acceptance of external reports.

ISoOR-AB may disregard external information when its reliability, relevance, or impartiality cannot be adequately demonstrated.

10. References

- ISO/IEC 17011 — Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies.
- ISBER Best Practices.

- OECD Best Practice Guidelines for Biological Resource Centres.
- Relevant WHO guidance documents.
- ISOOR-ISOB Accreditation Pathway.
- ISOOR-AB policies and procedures.