CORE CONCEPT

Biobank Operations and Biorepository Management Course (ISO 20387)

11 – 15 July 2027
Riyadh - KAFD district five-star

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Ref: 1959_29106 **Date:** 11 – 15 July 2027 **Location:** Riyadh - KAFD district five-star **Fees:** 20000 SAR

Introduction:

Biobank operations and biorepository management to ISO 20387 is a 1-week course for biobank management, laboratory direction and research governance teams that ends with a Biorepository Operating and Access Governance Plan for a case research hospital. Research organisations lose irreplaceable donor material and credibility when consent scope is unclear, freezers fail without contingency, aliquots cannot be located and release decisions are made informally. Nominees already oversee sample collections or repository staff, and the course is taught through case studies on donor records, freezer logs and access requests. CoreConcept Training Center delivers this biobank operations and biorepository management course.

Course Objectives:

- Define the biobank's collection purpose, custodianship model and ISO 20387 scope, and assign duties to the biobank director, quality lead and access committee
- Design consent and donor withdrawal arrangements, choosing between broad, tiered and dynamic consent for each collection
- Write collection, processing, aliquoting and labelling procedures with recorded preanalytical variables for blood, tissue and derived nucleic acids
- Run cryostorage in ultra-low temperature freezers and liquid nitrogen vapour phase tanks with alarm escalation, split-location replicates and freezer failure contingency
- Verify biospecimen fitness for purpose through processing method validation, integrity indicators and custody reconciliation from receipt to release
- Prepare a Biorepository Operating and Access Governance Plan covering access review, material transfer terms and benefit-sharing for a case research hospital

Target Audience:

- Biobank management staff responsible for collection strategy, repository budgets and the day-to-day running of research sample stores
- Laboratory direction staff in research hospitals responsible for processing facilities that supply specimens to biorepositories
- Research governance and ethics office staff responsible for donor consent, access committee business and material transfer approvals
- Repository quality staff responsible for biobank procedures, custody records and internal audit against ISO 20387
- Translational research and cohort study leads responsible for planning sample collections and requesting release of stored material

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Course Outline:

Day 1: Biobank Purpose, Collection Types and Current-State Review

- Population, Disease-Specific and Hospital Biobank Models Compared
- Custodianship Versus Ownership of Donor Material and Linked Data
- Collection Purpose Statement and Biobank Service Catalogue
- Biobank Director, Quality Lead and Access Committee Duties
- Current-State Repository Walk-Through With Freezer and Records Inventory

Day 2: ISO 20387 Requirements, Donor Consent and Ethical Governance

- ISO 20387 Competence, Impartiality and Consistent Operation Requirements
- ISO/TR 22758 Implementation Guidance Mapped to Biobank Processes
- Broad, Tiered and Dynamic Consent Model Selection
- Donor Withdrawal, Recontact and Incidental Findings Policy Drafting
- WHO and CIOMS Ethical Guidance Applied to Stored Specimens

Day 3: Collection, Processing, Cryostorage and Chain of Custody

- Preanalytical Variable Record for Blood and Tissue Collection
- Aliquoting Scheme, Cryovial Selection and Two-Dimensional Barcode Labelling
- Ultra-Low Temperature Freezer Farm Layout and Rack Mapping
- Liquid Nitrogen Vapour Phase Storage Using the ISBER Addendum
- Chain of Custody Log From Donor Draw to Release

Day 4: Biospecimen Quality, Storage Failure Risks and Access Decisions

- ISO 21899 Processing Method Validation and Verification Approach
- Nucleic Acid Integrity and Sample Fitness-for-Purpose Indicators
- Freezer Alarm Escalation, Backup Capacity and Sample Rescue Drill
- Pseudonymisation and Separate Clinical Dataset Linkage Controls
- Access Committee Scoring of Sample and Data Requests

Day 5: Case Study on a Research Hospital Biorepository Plan

- Case Hospital Collection Profile, Donor Records and Freezer Logs
- Case Consent Scope Check Against Pending Access Requests
- Case Custody Reconciliation and Storage Contingency Gap Scoring
- Material Transfer Agreement Terms and Benefit-Sharing Clauses Drafted
- Biorepository Operating and Access Governance Plan Completion and Review

Skills You Will Gain:

- Biobank Collection Design
- Donor Consent Modelling
- Preanalytical Variable Control
- Cryostorage Contingency Planning
- Biospecimen Custody Reconciliation
- Sample Fitness Assessment
- Access Request Adjudication
- Material Transfer Negotiation

Why Attend This Course:

- Deliver a Biorepository Operating and Access Governance Plan for a case research hospital to the biobank director, the research ethics committee and the hospital research office
- Decide which access requests a collection can support on the basis of consent scope, remaining aliquots and sample fitness evidence
- Avoid lost donor material, unusable degraded specimens and disputed releases caused by weak storage contingency and informal access decisions
- Share preanalytical record sheets, custody log templates and access scoring forms with processing, repository and governance colleagues

Conclusion:

Back at work, the participant presents the Biorepository Operating and Access Governance Plan to the biobank director, the research ethics committee and the hospital research office. They use it to approve the consent model for new collections, fund freezer contingency and split-location storage, and confirm the terms under which samples and linked data are released to investigators. After the first access committee cycle under the plan, the biobank should review request turnaround, custody discrepancies and sample fitness results against the baseline and update the plan.

Frequently Asked Questions FAQ:

What should participants know before a biobank operations and biorepository management course?

Participants should already supervise sample collections, a processing laboratory or research governance work. No prior ISO 20387 experience is needed. Bringing anonymised consent forms, freezer logs or access request templates helps them test the case study methods on their own biorepository.

How does a biobank operations and biorepository management course differ from a clinical laboratory quality course?

It manages stored research material over years rather than patient results over hours. Clinical laboratory quality courses cover examination accuracy and reporting, while this course covers consent, long-term cryostorage, custody, sample fitness and decisions about releasing material to researchers.

Why does biobank operations and biorepository management need an access committee?

An access committee checks that each request matches donor consent, scientific merit and remaining stock before samples leave. It protects scarce material, keeps release decisions consistent and records the terms, such as material transfer and benefit-sharing, under which researchers receive specimens and data.

What do participants take back from the biobank operations and biorepository management course?

Participants take back a Biorepository Operating and Access Governance Plan for a case research hospital, with a consent model choice, preanalytical record sheet, custody log, storage contingency plan, access scoring form and material transfer terms ready to adapt.