Overview of the requirements for biodiversity biobanks

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Background:

This document serves to provide an overview of the main requirements for biobanks participating in the BBSA. Further detailed policies, standard specifications and workflows will be determined at a later stage, but there is some urgency in terms of initiating the upgrading of priority aspects, and given the variety of taxa and associated specific requirements, it is difficult to develop general standards and workflows.

The intention for institutions participating in the BBSA is to work towards achieving all the requirements over time, with support from the BBSA and institutions. The checklist is also intended to illustrate the requirements if an institution wishes to establish a biobank so that there is some understanding of the investment and commitment needed.

The information provided in the table below is based on various documents related to biobanks.

CATEGORY	TYPE	SPECIFIC REQUIREMENT	DETAILS OF WHAT SHOULD BE COVERED
GOVERNANCE	**Documents**	Biobank protocol	• Purpose of biobank (objectives and scope) • Strategy • Staffing structure with roles and responsibilities and reporting lines • Committees and roles • Contingency plan in case of closure
		Organisational chart	• Structures and relationships between them, and other stakeholders (in institution, funding agencies, donors, users)
		Policies	• Sample access and use • Storage options • Safety of staff and visitors • Transportation of materials • Disposal of materials • Ethical issues, including permits • Benefit sharing policy • Intellectual property related to knowledge generated • Risk assessment and disaster management • How termination of biobank would be handled

		SOPs and workflows	All biobank activities: • staff training; • biosafety; • the collection, receipt, processing, and storage of samples; • sample QC; • laboratory QA; • data collection, recording, storage, and management; • data protection; • the monitoring, calibration, maintenance, backup, and repair of equipment; • the procurement and monitoring of supplies (disposables and reagents); • the distribution (including packaging and transport) and tracking of samples; • disposal of waste; • reporting of non-conformity and complaints; • disaster management / recovery.
		Standard for SOPS	SOP documents should include the following: • Title – a unique name which captures the essence of the practice described. • Number – a unique number that can be used for easy reference. • Date – date the procedure was first introduced as well as the date of the most recent version. • Version Reference – system for tracking version number and/or date to ensure the most recent version is used. • Department/Division/Staff Covered – individuals to whom the SOP will apply. • Purpose – brief description of the utility of the process(es) described in the SOP. • Protective Wear – protective equipment that should be worn by staff when performing the procedure described. • Equipment – list of the equipment needed to perform the procedure. • Supplies – all materials and supplies needed to perform the procedure should be recorded.

			• Step-by-Step Guidance – the procedure should be written in specific detail to ensure that it can be repeated in a reproducible fashion to include the order of steps that should be followed, the times allowed for each step (as needed), and the temperatures at which the steps are to be performed. • Safety – describes any safety steps or references to any relevant SOPS and addresses appropriate regulatory compliance (*i.e*., institution and/or country-specific) associated with the procedures.
		Standards	• Specifications for all equipment, consumables, chemicals used in the biobank
		Monitoring and auditing system documented, to review implementation of policies and SOPS	• Monitoring and evaluation process, including indicators, schedule, roles and responsibilities, reporting
		Reporting system for researchers who have used biobank materials	• Form to be completed by researchers • Filing / database system for recording use and outcome (eg. sequence data, product development, linked to samples)
		Reporting system for any adverse events	• Form to be completed • Filing system for reports
		Record of all audits, maintenance done on equipment / storerooms	• Form to be completed • Filing system for forms / records
		Forms / templates	• Access request form • Material transfer agreement • Donor form • Filing / data recording system for forms
	Document management system	Document management policy / procedure	• What documents are retained, for how long, where, in what form and any sign off required
		Standards for documents	• Numbering and versioning system for documents • Recording amendments / updates to documents • Sign off procedure for documents
	Structures	Steering Committee	• Membership • Terms of Reference
		Ethics Committee	• Membership • Terms of Reference
		Laboratory Safety Committee	• Membership

			• Terms of Reference
		Data / Sample Access Committee	• Membership • Terms of Reference
		Operations Management Committee	• Membership • Terms of Reference
	Staffing	Director	• Responsible for implementing biobank policies
		Biobank manager or co-ordinator	• Responsible for operations of biobank • (not a researcher who uses the biobank for their own work)
INFRASTRUCTURE & CONSUMABLES:	**Digital Infrastructure**	Database software	• Specify is an appropriate system; standardised terminology for fields and data entries allows interoperatbility across datasets and internationally
		Inventory of samples	• Each sample / sample group should be listed, with source species, sample type and access conditions, collection data (date, collector, locality). • Each sample should have a unique identifier. • Where there is a full specimen voucher, the sample must be linked to this in the database.
		Sample tracking through life cycle	For each sample: • Sample preparation method, • Location in biobank, • Record of use, • Any adverse events, • Link to any sequence data, publications from use of sample
			• Clear demarcation of data or samples where data or access is restricted (eg. locality data for threatened species)
			• User ID and tracking system for changes made to database
		Documentation related to sample collection, sample processing, sample sharing and shipment – linked to samples in database	• Collecting permits, export permits, Section 20 permits • MTAs • Shipping documents
		Backup system for database	• Regular backups automatically performed, with date, retained (not replaced) • Off-site storage of backups
	Safety systems / equipment / PPEs	Notices	• Safety notices and protocols clearly displayed in the biobank area
		Liquid N_2 storage	• Oxygen level sensors in the case of LN_2 storage

			• PPEs for working with LN_2 : Heavy gloves, a face shield, and a protective garment (shoes)
		Hazardous chemicals used in preparation of samples	• Hazardous chemicals appropriately stored and labelled
		Freezers: electrical systems	• Freezers properly wired to adequate sources of electrical supply, and grounded.
		Biological hazards: potentially Infectious samples	• Compliance with Section 20 for animal diseases • Non-proliferation of weapons of mass destruction for microbes – all infrastructure in place for compliance
			• Biological safety hood for working with samples
			• Access control for potentially hazardous samples
			• Equipment / consumables required in an emergency available
		Health & Safety (OHS compliance)	• All requirements according to OHSA met
		Cleaning / hygiene	• Biobank storage and preparation areas cleaned according to procedure / standards document • Documented cleaning / decontamination
	Storage infrastructure	Freezers / cryopreservation systems	• Storage system appropriate for the type of biospecimen, the intended period of storage, the frequency of use of biospecimens, the biomolecules and analyses of interest, the intended purpose of the sample
			• Backup systems: Continuous power supply, and backup systems in case of freezer breakdowns (10% of capacity spare), loss of power, and other emergencies
			• Regular servicing and maintenance of freezers
			• Independent temperature monitoring system with alarm to alert staff of temperature change
		LN_2 storage	• Appropriate air flow systems in storage room to prevent build-up of N_2; O_2 level monitoring system
			• Adequate LN_2 stock
	Storage consumables	Cryotubes	• Appropriate size and composition for sample type and storage conditions. Composition of plastic, potential interaction with some analytes, and

			resistance to ultra-low storage temperature must be considered.
		Racks	• Appropriate for storage requirements
		Containers for samples not stored in freezer	• Appropriate for sample size and type, and to allow ease of access
		Labelling materials for different containers	• Barcodes and barcode readers; indelible ink pens; printers and print medium
	Storage rooms / environment	Climate control	• Air conditioned rooms with temperature maintained at max 22°C
			• Temperature, humidity and oxygen monitoring system, especially if samples stored at ambient temperature, but also for temperature where freezer compressors may increase temperature
		Security and safety	• Access to biobank controlled
			• Alarm system for break ins
			• Fire alarm and suppression system
		Space	• Adequate space to accommodate freezers / storage infrastructure with sufficient airflow; allow easy access to monitor, retrieve, deposit samples. • Sufficient space for growth of biobank in accordance with strategy / protocol document
			• Appropriate, dedicated laboratory space for processing, preparation and analysis of samples
QUALITY CONTROL & ASSURANCE	**Sample quality**	Security	• Duplication of high importance samples in separate locations (freezer and room / building)
		Sample collection	• Appropriate consumables for taking samples, for holding samples, for labelling, for data capture in field
			• Equipment / consumables for transport of samples to the biobank
		Sample processing before integration	• Verification of sample identity, quality • Recoding of anything that may have caused sample degradation before integration into biobank
		Sample labelling	• Labelling of types / containers must survive all potential storage conditions, in particular dry ice and LN_2 and potentially water bath. Ink used on the label should be resistant to all common laboratory solvents.

		Labelling system for rooms, freezers, shelves	• Location of each sample in the biobank can be determined from the storage locality in the database
		Shipping of samples	• Appropriate packaging of samples, with minimum of three layers, and insulation where required • Appropriate transport of samples, using cold chain where required. • Package content labelling: itemized list of contents enclosed between the secondary packaging and the outer packaging. • Packages must have shipper details and consignee details (name of institute, address, contact name, number), and copies of required permits.
		Vouchering	• Where applicable, vouchers must be deposited in an appropriate collection, and all samples must be linked to the voucher in the database. E-vouchers (photographs of the specimen) should be taken if the whole specimen cannot be collected, together with other data (measurements, colour etc.). Where more than one type of sample exists from the same origin these must be linked in the database (live culture, frozen material and DNA extract from the same specimen)
	Audit / monitoring	Sample quality control monitoring at regular intervals	QC monitoring (may be external) to check following aspects of samples: • Authenticity: correctly assigned identity. • Purity: freedom from contamination (when applicable). • Stability: capability of a sample material to retain the initial value of a measured quantity for a defined pe-riod of time within specific limits when stored under defined conditions. • Consent: required permits linked to samples
		Laboratory / preparation process quality assurance	• Calibration of all instruments as required by manufacturer, with results recorded

			• All equipment maintained and serviced according to manufacturer requirements, with records kept
		Validation processes: methods, instruments, materials	• Use only validated methods for processing samples to ensure accuracy, reliability, and consistent intended performance • Use only validated equipment, instruments and materials in specimen collection, processing, storage, distribution.
LEGAL COMPLIANCE	Certification / registration	Registration as a scientific institution for ToPS and / or CITES	• Indigenous plant and animal samples
		Standing permit for holding CITES and / or TOPS material	• Indigenous plant and animal samples
		Section 20 biobank certification	• Animal samples
		Certification with DTI for culture collections (Non-proliferation of weapons of mass destruction)	• Microbial cultures
		Collecting permits (NEMBA and Regulations, provincial legislation, Section 20)	• All
		Export permits (BABS, Section 20, CITES)	• All
		Shipping of materials: IATA requirements	• All
		Ethical approval and processes	• Different according to taxon
		OHSA	• Compliant with the requirements (H&S Committee, assessments of environments, health assessments for staff where required, communication, labelling)
TRAINING		Health & Safety	• Staff trained in all relevant aspects of health and safety • All training documented
		Laboratory procedures	• Relevant staff trained in specific biobank procedures • All training documented
		Biobank management	• Relevant staff training in all aspects of biobank management
		Data management	• Use of the data management system / LIMS