Attachment 2 - Selection of Research Biorepository Informatics Management Systems

Organisational requirements

Research biorepositories should engage all stakeholders (IT office, clinicians, researchers etc) in the requirements gathering phase to identify system features and functionality. The organisational requirements for a tracking system should reflect the needs of all users and should comply with data protection policies. The uses of case scenarios are a recommended tool to document the needs of all users.

Technical requirements

Research biorepositories should identify the minimum set of requirements such as:

- computing platforms
- scalability requirements
- performance requirements
- connectivity requirements

Common requirements to gather and evaluate are: biospecimen tracking, biospecimen processing and history, data entry, data verification, querying and reporting, label printing/scanning, audit trails, interoperability, security, scalability, validation and implementation requirements, infrastructure requirements, IT support requirements, number of users, cost for purchase and maintenance. NB it is critical to ensure database security/data encryption//host/server/access/firewalls/shared drives is considered especially the database is hosted outside of Metro South Health.

Information management systems evaluations

Research biorepositories should use criteria identified above to judge mature and commercially available systems, taking into account the specific organisational and technical requirements. It is critical that the original stakeholders are involved at all phases of the evaluation process.

As part of the evaluations, an assessment of the system provider must be performed for their capability to provide implementation, support, and ongoing maintenance.

Build V buy system

This is a complex question with many considerations on resources, personnel, schedules, budgets, politics, and organisational bias. Building a customised system will allow research biorepositories to have the interface to exactly meet the operational requirements and workflow, but requires resources, funding, and a commitment to ongoing maintenance. Purchasing a system allows research biorepositories to take advantage of existing technology at a reduced cost and implementation timeline, but with an interface that does not precisely map to the original needs. There is no standard answer to this question; individual research biorepositories must review the system requirements and make a strategic decision on the best path forward for the organisation.

Recommended database requirements

The following are some of the recommended features that are also applicable to research biorepository databases.

Administration

- Security – addressed security–related regulatory compliance issues (i.e. an encryption functionality to protect against unauthorised access through other database tools. Encryption of sensitive data will information stored within the database in the event that an unauthorised intrusion attempts to copy data files.
- Defined user accounts and access permission levels.
- Management of all LOVs (List of Values); Tissue Sources, Collection and Biospecimen Types; WHO Version and Diagnosis Codes – maintains standardisation and allows growth of facility.
- Allows creation of new research biorepository storage entities. Manages size configuration, sample types held, temperature conditions, layout, naming conventions for each additional storage unit
- Audit history – patient/participant, consent, collection, results, biospecimen/sample.

Clinical annotation

- Patient/participant demographics.
- Patient/participant consent management.
- Unique de-identified code given to donor samples, re-identifiable only to research biorepository staff.
- Patient/participant diagnosis history, treatment stage and disease status recorded at each collection time point.
- Record linkage – upload of associated reports and data. Entry of critical path test results per time point to allow increased patient/sample search functionality.
- All samples associated with their Quality Control results — eg DNA (260/280), RNA (RIN) etc.

Inventory management

- Business rules - inbuilt Quality Control checks and audit functionality.
- Tissue classified via internationally recognised schema (ie World Health Organisation (WHO) categories).
- Automated sample storage position generation.
- Hierarchal structure — annotates primary specimen and all related derivative products.

- Biospecimen Tracking: Freezer, Shelf, Rack, Box and Sample.
- Biospecimen Usage History — (eg Discard (reason), Dispatch (whom).
- Reagent usage per time point (lot #, expiry date).

Query and reports

- Standard and ad hoc reporting functionality — reports of all collected research biorepository data.
- Automated reports of current sample and patient/participant numbers within research biorepository collection.
- Breakdown per type.

Management of research applications and sample consignment

- Ability to Lock and Quarantine samples for applications under review and automatically when consent expires (prevents usage prior to approval and removal).
- Record researcher publications and presentations arising from sample usage.
- Record details of all dispatched samples.
- Record date of committee approval — date of dispatch, sample types dispatched, dispatch number, approved researcher application, HREC approval and financial approval.
- Only provide de-identified samples to researchers.
- Only re-identifiable to research biorepository personnel.

Database search functionality

- Complex search functionality to facilitate rapid tracking of resources (multiple input fields searched simultaneously via auto-generated SQL Syntax).
- Ability to export data.
- Ability to assign selected samples to researcher — quarantine until ready to dispatch.