ATTACHMENT 2 - Quality Assurance and Quality Control Implementation and Auditing

The following are key issues for Quality Assurance (QA)/Quality Control (QC) implementation and auditing:

Staff proficiency

- Organisational chart/structure.
- Research biorepository staff job/position descriptions (HR) details base requirements, purpose, responsibilities.
- Staff Performance Appraisal and Development Plan (PAD).
- SOPS for roles and responsibilities of differing staff – dependent on level, key responsibilities (eg SOP updates, equipment QC etc).
- Other training and competency programs for personnel as appropriate.
- Occupational immunisation requirements.
- Documentation of staff non-compliance with SOPs. Records of non-compliance as part of staff audits or errors found which could jeopardise QC/QA and or put organisation at risk.
- Risk register, Risk mitigation, disaster response, and emergency preparedness.
- Lists of initials, signatures and research biorepository staff names (past and present) for audits.
- Conferences attendance – specific to research biorepository.

Facility infrastructure

- Equipment validation and change control, calibration, maintenance, repair procedures and environmental monitoring (eg temperature monitoring of freezers).
- Supplier management program, including inspection and validation of reagents and other supplies.

Biospecimen control and documentation

- Control of biospecimen collection, processing, and tracking in accordance with Databases, Tracking, Records and Documentation Procedure (PR2017/109).
- Documentation of biospecimen collection, processing, and tracking, with detailed annotation of pre-analytical parameters.
- Measurement and analysis of key process indicators to drive quality improvement.
- System security.

Recordkeeping and document control

- Employment of a data quality management, assessment and reporting system.
- Clinical data records.
- Accessibility of SOPs.
- Appointment of Designated Officers for informed consent process; list of all officers (if required).
- Documentation records, including audit reports, deviation reports and corrective action/preventive action reports.
- External document monitoring to ensure that the facility remains up to date with relevant laws, standards, and best practice publications.
- Staff training records, including record of staff adherence to training schedules.
- Data quality management (source documentation and electronic records), assessment of reporting system.
- Supply records.
- Site Specific Assessment (SSA).
- Approved research– annual/biannual feedback reports to the Metro South Health Human Research Ethics Committee Office and/or Research Governance Office.

Internal audit of program and its SOPs scheduled and unscheduled

- Audit for accuracy of all annotation data; e.g. the biospecimen is where it is purported to be, in the purported volume, with the appropriate labels/identifiers.
- Audit for accuracy of patient/participant data associated with biospecimen (eg age, gender, diagnosis etc).
- Audit of compliance of research biorepository with Metro South Health policies and procedures (eg human subjects and privacy and confidentiality protections, prioritisation of biospecimen use etc).
- Audit of SOPs for all activities and processes.
- Each research biorepository ensures that SOPs are written, reviewed, and appropriately approved.
- Process exists for review and updating at designated time intervals.

Handling patient/participant and researcher complaints (or donors next of kin)

- Handling patient/participant/donor withdrawal notifications.
- Handling researcher complaints - reason for complaint or withdrawal, documentation required; applicable references (eg Research Protocol, SOP for process; referral, resolution, completion and review of process).