The Sheffield Biorepository

Standard Operating Procedure: Quality Assurance & Quality Management Procedures

Document History	
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The University Of Sheffield.

1. Background

The following document provides general considerations with respect to Quality Assurance and Quality Management Systems and an overview of the Audit procedures in place.

2. Responsibilities.

QA, QC, QMS and audit are the responsibility of the director of the biorepository and its management committee.

3. Quality Assurance (QA)

This term describes an integrated system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process, or item, is of the type and quality needed for the project. The QA systems in place will be covered in general by 'standard operating procedures' (SOP) and will be made up of the following essential components:

- Title – Each SOP should be given a unique name which captures the essence of the practice described.
- Number – Each SOP should be given a unique number that can be used for easy reference. The numbering system should include the revision number for the practice so that the most recent version can be easily identified.
- Date – The date the procedure is to be reviewed as well as the date of the most recent version. The date format should be based on the ddmmyyyy system where d represents day, m represents month and y represents year.
- Protective Wear – Protective equipment that should be worn by staff when performing the procedure described.
- Equipment – A list of the equipment needed to perform the procedure.
- Supplies – All materials and supplies should be recorded.
- Step-by-Step Guidance – The procedure should be written in specific detail to ensure that the procedure 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 performed.

All SOPs before implementation or after revision will be approved by the management committee before implementation. Previous versions of all documentation will be stored electronically, with only the current versions available in the biorepository file.
All SOPs will be reviewed on an annual basis by the management committee.

4. QUALITY MANAGEMENT SYSTEM (QMS)

The QMS describes the biorepository's commitment to quality and approaches for ensuring that the requirements of the QA program are met.

Security

- The facility is in a secure, locked area with limited access.
- Records are maintained of all access to the facility, detailing name, date & time and reason for entry.

Training

- Personnel should be trained in all procedures and successful completion of such training is documented with evidence of updates as required, on a periodic basis.

Equipment

- Records are maintained with respect to the purchase of new equipment, maintenance and repair activities, as well as equipment disposal.
- *Records should also be maintained for critical materials and reagents used by the biorepository.*

Standard operating procedures

- Policies and procedures are documented in SOPs that are approved by the management committee and are changed or updated only under strict document control rules.

Incident reporting

- Any incident within the biorepository will be documented and follow a set SOP detailing its management and investigation.
- Deviation reports are produced for all events that fall outside SOPs.

Detailed audit procedures will be in place to ensure compliance with the facilities policies and procedures as well as regulatory agencies policies. These will be monitored by the Biorepository management committee and the University HTA Committee.

5. Associated Documents

	Document	Document Reference
1	Records management policy	BIO:Policy:03
2	Change Control	BIO:SOP:14
3	Change control form	BIO:FORM:07
4		
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