



University of Sheffield

Risk Assessment – Biorepository Data Management

PERSONS AT RISK: Employees (X) Contractors () Public (X) Visitors () Others (X)			Reference number: RA-BIO-102		
RISK (H) High (M) Medium (L) low (O) No Risk			Environment: Data management, Royal Hallamshire Hospital		
TASK or ACTIVITY:		INITIAL RISK LEVEL			FINAL RISK LEVEL
Significant Hazard	Potential Consequences of Hazard		Existing Control Measures	Additional Control Measures (If Required)	
Safe storage of confidential records	<p>To comply with the Human Tissue Act donor records must be kept within safe and secure systems.</p> <p>Failure to control access to these records, which are both physical and electronic, would breach conditions of licence.</p>	H	<p>CloudLIMS is used for storage of all sample information and is securely encrypted.</p> <p>Any excel sheets detailing sample or patient information are kept on secure password protected network drives.</p> <p>All filing cabinets have locking mechanisms and are within rooms only accessible to Biorepository staff.</p> <p>RHH security staff onsite 24 hours a day.</p> <p>All electronic files transferred are encrypted.</p>		L
Donor confidentiality	Donor confidentiality must be safe guarded and sample	H	Coded references are associated with samples so		L

	information databases should not provide information that directly identifies a donor.		as not to directly identify personal donor information. Electronic records are either kept on secure systems or encrypted during transfer.		
Loss of relevant material through faulty record keeping	Loss of records by file systems becoming disorganised, leading to material being untraceable. Unidentified material could be moved to unsuitable locations or fall into the wrong hands.	H	All sample data is kept on securely backed up excel sheets or within the online CloudLIMS database. Only Biorepository staff have access to samples and authority to change locations.		L
Loss of relevant material through faulty record keeping during transport	Loss of records by file systems becoming disorganised, leading to material being untraceable. Unidentified material could be sent to unsuitable locations or fall into the wrong hands.	H	MTAs are mandated for transfer of relevant material out of the Biorepository. SLAs are in place with couriers to ensure safe and secure transport. SOPs detail procedures for sample transport by staff.		L
Loss of traceability of samples in the Biorepository	Any rearrangement without updating records would lead to a loss of easy traceability of samples. Records or samples that are lost would lead to audit failures and inability to quickly access samples.	H	Samples are labelled and traceable by position within a specific rack assigned to a predefined storage location. Procedures are laid out in SOPs to maintain databases and limit access to Biorepository staff.		L

	Overall Risk:	H			L
Comments:					
Additional References, Tasks Etc					
Fire Risk Assessment					
Undertaken By:					
Steven Haynes					
Date:	19/05/2016		Revision Date: 19/05/2017		
			Revision Date:	19/05/2018	
			Revision Date:		

Use the table given on the risk matrix to score your hazard or activity for the probability ('L') likelihood harm will occur and the severity ('S') of the outcome.