

## University of Sheffield

### Risk Assessment – Loss of Donor Confidentiality

<b>PERSONS AT RISK:</b> Employees ( X ) Contractors ( ) Public (X) Visitors ( ) Others (X)			<b>Reference number: RA-BIO-104</b>		
<b>RISK (H) High (M) Medium (L) low (O) No Risk</b>			<b>Environment: Biorepository</b>		
<b>TASK or ACTIVITY:</b>		<b>INITIAL RISK LEVEL</b>			<b>FINAL RISK LEVEL</b>
<b>Significant Hazard</b>	<b>Potential Consequences of Hazard</b>		<b>Existing Control Measures</b>	<b>Additional Control Measures (If Required)</b>	
Loss of confidentiality during consent process	Breach of confidentiality from person receiving consent - Inappropriate access to confidential documentation	H	Full consent training for all personnel obtaining consent - Consent documents kept in locked rooms/cupboards and only accessible by PI, Untrained personnel are not allowed to handle confidential documents unless supervised by a suitable, trained person	GCP training also undertaken	L
Labelling of samples	- Breach of anonymity between donor and researcher.	H	- Anonymised code for samples labelling - No identifiable information to be present on sample tubes.	Some samples do have patient names on. Prior to dispensation from the Biorepository samples will be transferred to anonymised tubes/ slides/ blocks	L
Item Tracker database	Unauthorised person accessing the database	H	- database is held on a remote server that only authorised persons can open and access. - Password protected		L

	<b>Overall Risk:</b>	H			L
<b>Comments:</b>					
<b>Additional References, Tasks Etc</b>					
<b>Additional Information:</b>					
<b>Undertaken By:</b>					
Kevin Corke					
<b>Date:</b>	21/03/2019		<b>Revision Date: 21/03/2021</b>		

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.