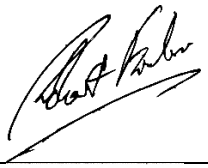
UNIVERSITY OF SUSSEX

School of Life Science
Risk Assessment – HTA
Loss of Donor Confidentiality

RA Reference:	**RA/HTA/004**
Version Number	**1.0**
Date:	**24/05/2018**
Review by:	**30/05/2020**

Author: Dr Robert Fowler **Designation:** Persons Designate – School of Life Sciences	**Signature** 	**Date** 24/05/2018
Authorised By: Dr Georgios Giamas **Designation:** Designated Individual School of Life Sciences HTA Research Licence		24/05/2018
Expert Authorisation **Designation:** **Contact Details**		

Version	Date	Reason for Change

Risks should be evaluated using the following system, assessing the Likelihood (L) of the risk and the Severity (S) of the risk if it was to occur:

Likelihood of risk	**5**	Almost Certain	**5**	**10**	**15**	**20**	**25**
	4	Very Likely	**4**	**8**	**12**	**16**	**20**
	3	Likely	**3**	**6**	**9**	**12**	**15**
	2	Unlikely	**2**	**4**	**6**	**8**	**10**
	1	Very Unlikely	**1**	**2**	**3**	**4**	**5**
			No tissue damage/loss	Minor tissue damage/loss	Significant tissue damage/loss	Tissue destroyed but replaceable	Tissue destroyed and irreplaceable
			No risk to personnel	Minor risk to personnel	Medium risk to personnel	Significant risk to personnel	Major risk to personnel
			1	**2**	**3**	**4**	**5**
			Severity of risk				

Score Action to be taken:
0-5 No further action needed.
6-9 Appropriate additional control measures should be implemented
10-25 Work should not be started or should cease until appropriate, additional, control measures are implemented.

Reducing risk: procedural planning, contingency planning, personnel training and re-evaluation of procedures can be considered to reduce risk.

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Section 1 – Storage

SCHOOL : LIFE SCIENCES	GROUP : HTA	TASK / ACTIVITY: Confidentiality for Volunteers/Patients

Section 2 - Identifying Hazards		**Section 3 - Existing Control Measures**	**Section 4 – Evaluating** Risk	**Section 5 – Action Plan**				
Hazard	**Persons/material at risk and how affected**	**Existing Control Measures**	**Risk Rating** (LxS=R)	**Action required to control risk**	**Risk Rating** (LxS=R)	**Action by Whom**	**Deadline for action**	**Date completed**
Example	*Type the text in here to describe the hazard*	*Describe any existing control measures*	*4 x 5 = 20*	*Type the text in here to describe the action required to reduce the risk to an acceptable level*	*4 x 1 = 4*	*The name of the person given the action – they must agree to it!*	*The date by which the action is to be completed*	*Date actually completed*
Loss of confidentiality during consent process	- Breach of confidentiality from person receiving consent - Inappropriate access to confidential documentation	- Full consent training for all personnel obtaining consent - SOP/HTA/03 & SOP/HTA/04 - Consent documents kept in locked rooms/cupboards and only accessible by PI, PD or DI. - Untrained personnel are not allowed to handle confidential documents unless supervised by a suitable, trained person	1 x 3 = 3	.				
Labelling of samples	- Breach of anonymity between donor and researcher	- Anonymised code for samples labelling - No identifiable information to be present on sample tubes -	2 x 3 = 5	Some samples in GDSC collected before 2006 still have labels with patient names. However, to remove the samples from cryo-storage to relabel would risk the integrity of the samples. It has been decided that no further action is to be taken as the access to these samples is restricted and the likelihood of				

		Donor link document to be held separately from samples		researchers accessing this information being very unlikely.				
ItemTracker database	- Unauthorised person accessing the ItemTracker database	- ItemTracker database is help on a remote server that only authorised persons can open and access. - Individual log-ins and passwords for each user - Each user can only access/edit those samples or areas they have, PDs only have access to their own area's samples.	1 x 3 = 3					

lth monitoring required?	Yes
Is a more detailed assessment (e.g. Clinical Risk, COSHH, Manual Handling, Display Screen Assessment) required? Please state which one:	No, unless the samples are suspended in something which could be considered a hazardous chemical, then COSHH should be completed.
Is further information or investigation required to complete risk assessment?	No

Section 7 - Assessment Sign Off

ASSESSOR'S NAME : ROBERT FOWLER	JOB TITLE : TECHNICAL COORDINATOR

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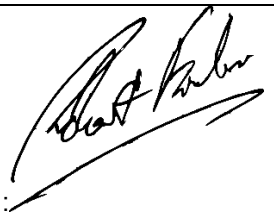
DATE OF ASSESSMENT : 24/05/2018	REASSESSMENT DATE : 30/05/2020
	A
	B
	C
	D
	E
ASSESSOR'S SIGNATURE : 	SAFETY OFFICER'S SIGNATURE :

PERSON INVOLVED NAME	SIGNATURE	DATE
Dr Georgios Giamas		