CONTROLLED DOCUMENT
(The latest version is maintained on the CBE network):
This document is not a controlled copy once printed from the network.

Standard Operating Procedure **CBE/HTA-MI-SOP010**

Title: RISK MANAGEMENT AND CONTINGENCY PLANNING

Location: CBE Laboratories

Master Copy

1. PURPOSE

To describe the procedure for assessing and monitoring the risk, including contingency planning, relating to the practices and processes involved in the storage, use, transfer and disposal of HTA licensable material for research.

2. SCOPE

As part of the CBE Quality Management System (QMS) for research, this procedure applies to all individuals involved in research activities under the University's HTA licence, in accordance with the requirements of the HTA legislation, the HTA Codes of Practice and the University's HTA Licence Compliance Quality Manual. Risk management, as detailed in this SOP, refers to risk to HTA relevant material such as fridge/freezer failure or damage during transport. Project or study specific local Biological Risk Assessments should also be completed, detailing risks to the health and safety of individuals, facilities and equipment. Contingency planning refers to the activities required to limit the extent of the risk arising from an adverse event and for regaining control of the area as quickly as possible.

This procedure is supplemental to local contingency arrangements that are in place should there be an emergency situation that renders the premises unusable for the storage of relevant material for research.

3. RESPONSIBILITIES

3.1. Individuals working under the University HTA licence must read and understand the risk assessments of practices and processes related to their licensable activities so that they understand what is meant by an adverse event and can identify the likelihood and impact of any adverse events occurring.

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by : C.Kavanagh Date:04/12/23	Reviewed by: R.Thomas Date:13/12/2023	Approved by: M.Gleeson Date:28.01.2016 Review Approved by: Karen Coopman Date: 13/12/2023

3.2. All individuals working with HTA licensable material have the responsibility to report any actual or potential for, an adverse event, as it occurs or once it has occurred, or where it could be predicted to occur.

3.3. The departmental Quality Manager (dQM) shall ensure, where necessary, that steps are taken to prevent risks arising from planned maintenance, power or other utility disruptions.

3.4. The dQM shall ensure that the steps described in this SOP have been taken to limit the extent of the risk arising from an adverse event, for regaining control of the area as quickly as possible and for preventing recurrence.

4. REFERENCES

The Human Tissue Act (2004) and HTA guidance and Code of Practice E

The University HTA Licence Compliance Quality Manual

The CBE Quality Manual

5. PROCEDURE

5.1. Risk Assessment of Facilities, Practices & Procedures

5.1.1. A risk assessment of the CBE facility and its existing practices and processes must be completed using the local HTA Risk Assessment form (HTA-RA1-FORM/001).

Note: The risk assessment should be considered an active document under continual review, particularly when starting new project activities.

5.1.2. The risk assessment shall consider all potential hazards from procurement to use and storage, including package failure, delay or loss in transit, malfunction of storage facilities,

Master Copy

unauthorised access to samples of relevant material, incorrect procedures being carried out, untrained personnel handling relevant material and any other hazards that result in loss of relevant material.

5.1.3. The hierarchy of control and risk reduction measures employed should primarily be aimed at eliminating or reducing the hazards in a procedure/practice, followed by early detection of risks and contingency planning. For example, regular maintenance of storage facilities to prevent failure; followed by installation of an early warning system to detect changes in storage temperature; and finally alternative on-site storage facilities in the event of storage failure.

5.1.4. Once completed, a copy of the risk assessment must be read and understood by all relevant staff prior to commencing any new project activity involving the procurement, transport, use, storage or disposal of relevant material.

5.1.5. If there is a significant change in practice/procedure, work should not be started until the risk has been re-assessed and any additional control measures implemented.

5.1.6. The risk assessment must be reviewed at least once a year and all changes documented and all relevant staff have notified.

5.1.7. If there is a significant change in practice/procedure before the review date, for example there is new information on the hazard indicating a higher or lower level of risk, personnel changes, changes in equipment or substances used, change of location, or following an adverse event, the risk assessment should be revisited and reassessed. If required, work should cease until appropriate additional control measures are implemented.

5.2. Contingency Planning

5.2.1 Storage equipment failure

Master Copy

- Emergency storage units have been identified at the CBE Holywell site and can be accessed and labelled on demand (see below).
- In the event of an alarm being triggered outside normal working hours, i.e. where storage units have in-built alarms, the Loughborough University security office is alerted during their rounds. The security office will contact designated CBE personnel.
- Koolzone Temperature Monitoring Software sends E-mail & text alerts to designated individuals when the storage unit temperature goes out of the set range. Designated individuals have access to the software to check the data.
- Upon receiving an emergency call from security , or E-mail/text alert from the Koolzone system designated personnel shall consult with each other to determine who will attend the incident if required after examining the data. On arrival at the site, designated personnel shall assess the conditions, and a decision on the need to re-locate the material to an emergency storage unit will be taken. If appropriate, the material will be moved to the emergency storage unit, which will be re-labelled to indicate that it contains HTA licensable material.
- Should there be an emergency situation at the CBE Holywell site that renders the storage units and/or the premises unusable then the HTA licensable material will be transferred, with permission, to the SSEHS for storage until such time that the CBE premises/storage units can be restored to a fully operational level.
- Should there be an emergency situation at the T208b (Wolfson School) site that renders the units/and or premises unusable then the HTA licensable material shall be transferred to the CBE Holywell Site and placed in appropriate storage. Double containment must be used for microbiological samples to reduce risk of cross contamination. Should the CBE Holywell site not be usable then the samples will be transferred with permission, to the

Master Copy

SSEHS for storage until such time that the T208b/CBE premises/storage units can be restored to a fully operational level.

5.2.2. Power failure

- In the event of a loss of power, (for example, in the event of a failure of the national grid) all fridges/freezers will be connected, where possible, to an emergency back-up generator as quickly as possible. SSEHS have access to two back up generators and an agreement is place for these to available for the CBE if required. In addition CBE has its own small back- up generator for designated equipment. Risk Assessment reference SAF/MEME 7135 .

Note: There have been very few unplanned power outage lasting more than an hour over the past 10 years.

Liquid Nitrogen(LN2) Cryostore(s)			Back-up LN2 cryostore(s)			
ID no: CBE/H31-D01		**Location:** CBE Labs H31	ID no:	CBE/H31-D02; CBE/H31-D03; CBE/H30-D04; CBE/H30-D05; CBE/H30-D06; CBE/H30 -D07 CBE/H34 – D08	Location:	H30, H31 and H34
Contingency	1	All staff are trained in the use and maintenance of LN2 cryostores according to local documented procedures				
	2	Cryostores are regularly inspected by the designated Responsible Person (dRP) as part of regular housekeeping duties. The dRP ensures that liquid nitrogen levels are maintained and records of each 'top up' recorded according to local procedures.				
	3	The cryostore temperature is continuously monitored to ensure environmental conditions are maintained. The cryostores are attached to the Koolzone Temperature monitoring system which send E-mail & text alerts to designated personnel if a storage unit temperature is out of range. Designated personnel have access to the software to check the data & act accordingly.				
Unit failure /	5	In the event of failure or malfunction, the dRP with the custodians of the stored material shall				

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by : C.Kavanagh Date:04/12/23	Reviewed by: R.Thomas Date:13/12/2023	Approved by: M.Gleeson Date:28.01.2016 Review Approved by: Karen Coopman Date: 13/12/2023

Master Copy

malfunction		transfer material to an available space within another cryostore. Transfer shall be recorded on the Procuro database.
Power failure / outage		In the event of unplanned long term facility/utility failure the dRP shall seek permission with the relevant authority to transfer the cryostore to another facility to allow continued maintenance. Transfer shall be recorded on the Procuro database.
Alarm Failure / malfunction	6	In the event of alarm/probe failure, the dRP shall ensure that the alarm/probe is repaired.

-80C Freezer			Back-up -80C freezer	
ID no: CBE/H34-A (large) T208b		**Location:** CBE Labs H34, T208b	ID no: CBE/H34 – B CBE/H34-C (small)	Location: H34
Contingency	**1**	All staff are trained in the use and maintenance of the -80C freezer according to local documented procedures, including regular cleaning and defrosting.		
	2	The -80C freezer is regularly inspected by the designated Responsible Person (dRP) as part of regular housekeeping duties.		
	3	The freezer temperature is continuously monitored to ensure environmental conditions are maintained. Data is recorded and reviewed periodically by the dRP.The freezer has and internal audible alarm. This is checked & recorded monthly by manually challenging the storage unit. The alarms will warn users of significant fluctuations of internal temperature. All users are trained to respond to the alarm. The Loughborough University security team are alerted during their rounds if there is an alarm . The security office will alert designated personnel. The freezers are also are attached to the Koolzone Temperature monitoring system which send E-mail & text alerts to designated personnel if a storage unit temperature is out of range. Designated personnel have access to the software to check the data & act accordingly.		
	4	Remote alarms are regularly inspected by the dRP to ensure that they are working and probes replaced , as required . Local alarms and batteries are checked & replaced on a regular basis according to local procedures. Probes are calibrated annually by Koolzone.		
Unit failure / malfunction	**5**	In the event of failure or malfunction, the dRP with the custodians of the stored material shall transfer material to an available space within another CBE -80C freezer or to an available space within a cryostore. (T208b will use CBE as back up in first instance but use SSEHS if this is not viable) Transfer shall be recorded on the Procuro database.		
Power failure / outage –short term	**6**	In the event of a short-term power outage, all freezers in the CBE will be affected. To minimise the effect stored material, the freezer should not be opened during the power outage as well as an hour after power returns to allow the freezer to stabilise. The temperature log should be reviewed to assess the impact on the freezer contents.		

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by : C.Kavanagh Date:04/12/23	Reviewed by: R.Thomas Date:13/12/2023	Approved by: M.Gleeson Date:28.01.2016 Review Approved by: Karen Coopman Date: 13/12/2023

Master Copy

Power failure / outage –long term	**7**	In the event of a planned long term power outage, the dRP shall ensure that there is alternative source of power (generator) in for the duration of the power outage. In the event of unplanned long term power outage the dRP shall seek permission with the relevant authority to transfer material to the SSEHS facility. . (T208b will use CBE as back up in first instance but use SSEHS if this is not viable)Transfer shall be recorded on the Procuro database
Alarm Failure / malfunction	**8**	In the event of alarm failure, the dRP ensures that the alarm is repaired and batteries replaced, if applicable. The dRP checks the probes and alarm system regularly and ensures maintenance.

-20C Freezer			Back-up -20C freezer(s)	
ID no: CBE/H30-F01		**Location:** CBE Labs H30, T208b	ID no: CBE/H34-F01; CBE/H34-F02; CBE/H34-F03	Location: H34
Contingency	**1**	All staff are trained in the use and maintenance of the -20C freezer according to local documented procedures, including regular cleaning and defrosting.		
	2	The -20C freezer is regularly inspected by the designated Responsible Person (dRP) as part of regular housekeeping duties to ensure no overcrowding and/or schedule defrosting of the unit.		
	3	The freezer temperature is continuously monitored to ensure environmental conditions are maintained. Some freezers have an internal audible remote alarm which will warn users of significant fluctuations of internal temperature. All users are trained to respond to the alarm. The Loughborough University security office will alert designated personnel if they hear the alarms during their rounds. The freezers are attached to the Koolzone Temperature monitoring system which send E-mail & text alerts to designated personnel if a storage unit temperature is out of range. Designated personnel have access to the software to check the data & act accordingly.		
	4	Alarms are regularly inspected by the dRP to ensure that they are working and probes replaced as required. Local alarms and batteries are checked & replaced on a regular basis according to local procedures .Probes are calibrated annually by Koolzone.		
Unit failure / malfunction	**5**	In the event of failure or malfunction, the dRP with the custodians of the stored material shall transfer material to an available space within another CBE -20C freezer or to an available space within the -80C freezer. Transfer shall be recorded on the Procuro database.		
Power failure / outage – short term	**6**	In the event of a short-term power outage, all freezers in the CBE will be affected. To minimise the effect on stored material, the freezer should not be opened during the power outage and an hour after power returns to allow the freezer to stabilise. The temperature log shall be reviewed to assess the impact on the freezer contents.		

Master Copy

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by : C.Kavanagh Date:04/12/23	Reviewed by: R.Thomas Date:13/12/2023	Approved by: M.Gleeson Date:28.01.2016 Review Approved by: Karen Coopman Date: 13/12/2023

Power failure / outage – long term	**7**	In the event of a planned long term power outage, the dRP ensures that there is alternative source of power (generator) for the duration of the power outage. In the event of unplanned long term power outage the dRP shall seek permission with the relevant authority to transfer material to the SSEHS facility. . (T208b will use CBE as back up in first instance but use SSEHS if this is not viable) Transfer shall be recorded on the Procuro database
Alarm Failure / malfunction	**8**	In the event of alarm failure, the RP shall ensure that the remote alarm is repaired and probes replaced.

2-8C Fridge			Back-up fridge(s)	
ID no: CBE/H17-F01/ T208b/F01		**Location:** CBE Labs H17 – Cold Store T208b Lab	ID no: CBE/H20-F01	Location: H20
Contingency	1	All staff are trained in the use and maintenance of the 2-8C fridge according to local documented procedures, including regular cleaning.		
	2	The 2-8C fridge is regularly inspected by the designated Responsible Person (dRP) as part of regular housekeeping duties.		
	3	The fridge temperature is continuously monitored to ensure environmental conditions are maintained.. Some fridges have an audible remote alarm which will warn users of significant fluctuations of internal temperature. All users are trained to respond to the alarm. The Loughborough University security office will alert designated personnel if they hear alarms during their rounds. The fridges are attached to the Koolzone Temperature monitoring system which send E-mail & text alerts to designated personnel if a storage unit temperature is out of range. Designated personnel have access to the software to check the data & act accordingly.		
	4	Alarms are regularly inspected by the dRP to ensure that they are working and probes replaced as required. Local alarms and batteries are checked & replaced on a regular basis according to local procedures .Probes are calibrated annually by Koolzone.		
Unit failure / malfunction	5	In the event of failure or malfunction, the dRP with the custodians of the stored material shall transfer material to available space within another CBE 2-8C fridge. Transfer shall be recorded on the Procuro database.		
Power failure / outage – short term	**6**	In the event of a short-term power outage, all fridges in the CBE/T208b will be affected. To minimise the effect on stored material, the fridge should not be opened during the power outage and an hour after power returns to allow the fridge to stabilise. The temperature log shall be reviewed to assess the impact on the fridge contents.		

Master Copy

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by : C.Kavanagh Date:04/12/23	Reviewed by: R.Thomas Date:13/12/2023	Approved by: M.Gleeson Date:28.01.2016 Review Approved by: Karen Coopman Date: 13/12/2023

Power failure / outage – long term	**7**	In the event of a planned long term power outage, the dRP ensures that there is alternative source of power (generator) for the duration of the power outage. In the event of unplanned long term power outage the dRP shall seek permission with the relevant authority to transfer material to the SSEHS facility. (T208b will use CBE as back up in first instance but use SSEHS if this is not viable). Transfer shall be recorded on the Procuro database
Alarm Failure / malfunction	**8**	In the event of alarm failure, the RP shall ensure that the remote alarm is repaired and probes replaced.

Temperature Controlled Incubator(s)			Back-up incubator(s)	
ID no: CBE/H21-I01; CBE/H21-I02; CBE/H21-;CBE/H23-I01; CBE/H23-I02; CBE/H23-I03; CBE/H25-I01; CBE/H25-I02; CBE/H25-I03; CBE/H27-I01; CBE/H27-I02; CBE/H29-I01; CBE/H30-Biostation		**Location:** Variable	ID no: CBE/H21-I01; CBE/H21-I02; CBE/H23-I01; CBE/H23-I02; CBE/H23-I03; CBE/H25-I01; CBE/H25-I02; CBE/H25-I03; CBE/H27-I01; CBE/H27-I02; CBE/H29-I01	Location: Variable
Contingency	**1**	All staff are trained in the use and maintenance of the incubator according to local documented procedures, including regular cleaning, decontamination and maintenance of water levels in the humidifier.		
	2	CO_2 supplied to the unit is maintained by an automatic switch over to prevent any loss of gas levels outside of working hours. Spare cylinders are maintained to ensure that there is always sufficient supply.		
	3	The incubator is regularly inspected by the designated Responsible Person (dRP) as part of regular housekeeping duties.		
	4	The incubator has an audible alarm which will warn users of significant fluctuations of internal temperature or in percentage CO_2 levels. All users are trained to respond to the alarm.		
Unit failure / malfunction	**5**	In the event of failure or malfunction, the dRP with the custodians of the incubated material shall transfer material to available space within another CBE incubator. Transfer shall be recorded on the Procuro database.		
Power failure / outage – short term	**6**	In the event of a short-term power outage, all incubators in the CBE will be affected. To minimise the effect on stored material, the incubator should not be opened during the power outage and an hour after power returns to allow the incubator to stabilise. The temperature, relative humidity and CO_2 logs should be reviewed to assess the impact on the incubator contents.		
Power failure / outage – long term	**7**	In the event of a planned long term power outage, the dRP ensures that there is alternative source of power (generator) for the duration of the power outage. In the event of unplanned long term power outage the dRP shall seek permission with the relevant authority to transfer material to the SSEHS facility. Transfer shall be recorded on the Procuro database		
Alarm Failure /	8	In the event of alarm failure, the RP shall ensure that the alarm is repaired.		

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by : C.Kavanagh Date:04/12/23	Reviewed by: R.Thomas Date:13/12/2023	Approved by: M.Gleeson Date:28.01.2016 Review Approved by: Karen Coopman Date: 13/12/2023

Master Copy

malfunction		

5.3. Adverse Events

5.3.1. Any adverse events involving HTA relevant material must be reported according to the local procedure for Adverse Event Reporting.

5.3.2. Following an adverse event all relevant risk assessments must be reviewed and updated if necessary.

6. DOCUMENTATION

The following records are outputs of this SOP:

6.1. HTA-MI-FORM/008 Adverse Event Report Form

6.2. Data entry into the Pro-curo electronic database

These records shall be stored on the CBE network and/or stored in the CBE Office or otherwise archived for future review or retrieval.

Master Copy

CONTROLLED DOCUMENT
(The latest version is maintained on the CBE network):
This document is not a controlled copy once printed from the network.

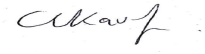
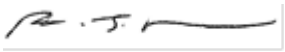
Title: RISK MANAGEMENT AND CONTINGENCY PLANNING

Location: CBE Laboratories

SOP Version History

Version Reviewed	Date Revised/ Reviewed	DCN No	Revision Summary	New Version Number
1.0	4th December 2017 by C.kavanagh	N/A No changes	No Amendments required Minor editorial only including revision details.	1.0 New version not required.
1.0	2nd December 2019 by C.Kavanagh	003	Addition of contingency plan arrangements to include samples stored in T208b (Wolfson School).	2.0 New
2.0	6th December 2021 by C.Kavanagh	0013	Addition of information about temperature Monitoring system 'Koolzone'. Added the statement in appropriate area The XXX are attached to the Koolzone Temperature monitoring system which send E-mail & text alerts to designated personnel if a storage unit temperature is out of range. Designated personnel have access to the software to check the data & act accordingly.	3.0
3.0	4th December 2023 by C.Kavanagh	0017	In power failure section : In addition CBE has its own small back- up generator for designated equipment. Risk Assessment reference SAF/MEME 7135 . Added additional detail in contingency section (alarm section). Added statement 'Probes are calibrated annually by Koolzone'.	4.0

Master Copy

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by : C.Kavanagh  Date:04/12/23	Reviewed by: R.Thomas  Date:13/12/2023	Approved by: M.Gleeson Date:28.01.2016 Review Approved by: Karen Coopman  Date: 13/12/2023

Standard Operating Procedure CBE/HTA-MI-SOP010

Title: RISK MANAGEMENT AND CONTINGENCY PLANNING

Location: CBE Laboratories

SOP Withdrawal Date:	

Master Copy

Document Control

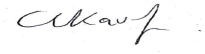
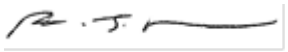
The Master Copy of all SOPs is filed by the dQM. The latest version is maintained on the CBE network. This document is not a controlled copy once printed from the network. If this SOP appears inadequate or outdated it is the responsibility of all staff to bring this to the attention of the dQM or their Supervisor immediately.

Security Statement

This SOP is the intellectual property of the CBE within Loughborough University, and as such, must not be circulated outside of the University without the written approval from the dQM and the author.

Acknowledgements

This SOP has been produced with advice and input from colleagues and with reference to Loughborough University School of Sport, Exercise and Health Sciences (SSEHS) SOPs and publically available SOPs used at a number of other UK universities. We also acknowledge the contributions of Andreea Iftimia-Mander to the original draft versions of this SOP.

Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by : C.Kavanagh  Date:04/12/23	Reviewed by: R.Thomas  Date:13/12/2023	Approved by: M.Gleeson Date:28.01.2016 Review Approved by: Karen Coopman  Date: 13/12/2023