	LCTU GCPLab **Standard Operating Procedure** **DEALING WITH DISASTER SITUATIONS IN THE LPRG**		
SOP Number:	GCLPTSS159/2	**Issue Date:**	
Effective Date:		**Review Date:**	

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Revision History

Version Number	Effective Date	Revision Date	Reason for Change	Change Control No:
1	21/12/2015	09/08/2017	Amend reference of PBRU to LPRG (including SOP title). Author changed	7112

CONTENTS

1. WHO?

This Standard Operating Procedure (SOP) applies to all staff in the Liverpool Pancreatitis Research Group (LPRG).

2. BACKGROUND

A disaster situation is any event, either expected or unexpected, which has a direct adverse influence on the general operation of the LPRG laboratories which must be followed to overcome that event.

3. PURPOSE

The purpose of this SOP is to describe the procedure to be followed in the event of a variety of disaster situations, which may arise within the LPRG laboratories. Liverpool Pancreatitis Research

4. SCOPE

This SOP applies to all staff in the and is to be followed when any event arises, either expected or unexpected which may have an adverse effect on the general operation of the LPRG.

5. PROCEDURE

5.1 RESPONSIBILITY

All LPRG personnel must comply with this SOP for each type of disaster described below.

5.2 PROTOCOL

5.2.1 Deviation from an SOP:

1. In the event of a deviation from an SOP, the Procedural Document (5.2.1.3) for dealing with a deviation from an SOP must be followed.
2. The deviation from the SOP must be clearly recorded in the person's laboratory notebook or notebook if staff do not hold a laboratory role.
3. Any deviation pertaining to non-laboratory work should be reported following the procedures set out in the Biobanks policy documents and to the biobank weekly committee meetings.
4. A GCP Facility Quality Incident form (GCLPFAC005) must be filled out and submitted to the QAM. The OD and QAM will recommend any further action to be taken according to the Procedural Document: GCLPPPD005 Deviation from a Standard Operating Procedure (SOP).
5. If the deviation highlights any additional training or amendments to a SOP it should be immediately carried out and all staff notified.

5.2.2 A Sample brought to the LPRG for which there is No Informed Consent Given by the Patient (excludes AP retrospective consent):

1. In the event that a sample arrives at the LPRG and the patient did not give informed consent for the sample to be taken, processed or analysed then the GCLP OD and QAM must be informed as quickly as possible. If processing is required immediately then the sample must be processed to a point where it can be safely stored.
2. In the case of a retrospective consent sample which has elapsed the three month storage one should complete a Quality Incident Form and forward to the QAM. The sample should be disposed of following the process according to SOP GCLPRPS024.
3. If the sample can be safely left until the GCLP OD or QAM have been informed then processing of the sample should not begin.
4. Once the OD and QAM have been informed they will recommend action, this can be processing of the sample to a point where it can be safely stored in the allocated quarantine shelf or immediate disposal of the sample. If the OD/QAM confirm that there is no consent for the sample then the sample must be destroyed according to the SOP GCLPRPS024 – Disposal of Hazardous Waste.
5. The sample information should be destroyed except for a written record of what happened, including any information on electronic databases/laboratory information systems.
6. Request a Facility Quality Incident GCP Form and a Sample Destruction Form from the DC (appendix 2).
7. The Facility Quality Incident GCP Form must be filled in and signed by the QAM and OD and recommended action taken.
8. The Sample Destruction form must be used to list all the samples and record their subsequent destruction.
9. The code used for the patient including kit number(s) should be made redundant (i.e. left on the database but without attached information relating to the patient other than the date received and the fact that the sample was destroyed due to lack of consent).

5.2.3 Unexpected Damage/Destruction of Samples:

1. If a sample from a patient becomes unusable or damaged inform the OD and QAM and adhere to their guidelines.
2. Any injuries to staff please refer to section 5.2.7. If the samples are damaged/lost through an accident then a Quality Incident form must be filled out.
3. A Quality Incident Form must be requested from the DC and filled out. The damaged sample must be destroyed according to SOP GCLPRPS004 – Disposal of Hazardous Waste.
4. However if the sample is destroyed during an adverse event (ex: accidental spillage) then clean-up must be performed according to SOP GCLPRPS024 – Disposal of Hazardous Waste.
5. The fate of the samples must be recorded on the Sample Destruction Form; request from the DC.
6. The LPRG Principal investigator will be informed via Biobank committee meeting.

5.2.4 LIMS Failure:

1. If the LIMS system fails this should be reported to the GCLP Facility OD and the QAM immediately.
2. The OD and QAM will assess whether the LIMS failure is an in house problem, e.g. electrical fault or an external problem, e.g. with the server housed at the LCTU.
3. All staff within the laboratory should be informed by email that the LIMS system is not working.
4. If it is an internal problem then the 5th floor UCD main office will need to be contacted between the hours of 9:00am to 5:00pm (extension 4877).
5. However if it is out of hours then NHS estate maintenance will need to be contacted.
6. If the problem is an external problem with the server then the LCTU Computing Team should be contacted on either 0151 794 8814 or 0151 794 8938.
7. If the staff members at the LCTU cannot be contacted CSD helpdesk should be contacted directly. The time and other details should be recorded on the LIMS Failure form (see appendix 4).
8. At this point the LCTU staff will speak to CSD if they are not able to fix the problem.
9. The GCLP Facility OD and the QAM should determine a time when LIMS should be up and running regardless of whether the problem is internal or external.
10. Whilst LIMS is offline samples being processed should be recorded within the laboratory book located in the room 3.302A and on the worksheet related to the kit. The Quality Incident form (appendix 3) should also be filled in for all affected samples.
11. The following information should be recorded:
    - Date
    - Time
    - Sample ID
    - Kit number
    - All equipment used to process the sample e.g. centrifuges, cabinets, hoods.
    - Any problems related to the sample during processing.
12. Samples should be placed with locations recorded in a freezer, which is clearly designated.
13. Once LIMS is back online the QAM should inform all staff by email. The QAM will also sign off all laboratory books that have been used to recall the processing information.
14. Any samples processed whilst LIMS was offline should be added to the LIMS system from the laboratory book and/or worksheet.
15. For samples removed from the freezers the following information should be recorded:
    - Sample used
    - Freezer location
    - Data and time used
    - Sample ID
    - Equipment used
16. The QAM will write a Quality Incident form, which will list all the samples affected and the root cause of the LIMS issue. The LIMS form (Appendix 4)

will be attached to this document and will be filed with all other Quality Incident Forms.

17. All samples affected must have the LIMS failure logged against them on the LIMS system.

5.2.5 Data Loss:

1. A detailed record of the exact date, time and suspected source of the data loss must be carefully documented; the OD and QAM must be informed.
2. Electronic data should be restored from back up and carefully documented.
3. If a biobank database is accidentally deleted the NHS IT Helpdesk should be contacted on 0151 706 5499 preferably within six days of deletion. The NHS back up their systems every 24hrs.
4. The Laboratory Information Management System (LIMS) is backed up from the LCTU server and the Pharmagraph Monitoring System has data recorded to an external drive continuously.
5. Ensure new procedures are in place to overcome the suspected source of the data failure to prevent further losses in the future.

5.2.6 Governance Serious Incidents Requiring Investigation (IG SIRIs) reporting

1. For the definition and categories of a IG SIRI and a cyber IG SIRI please refer to the 'Checklist Guidance for Reporting, Managing and investigating Governance and cyber Security Serious Incidents Requiring Investigation, 29th May 2015, hscic supported by the Department of Health.

2. If you deem that any cyber incident has occurred please contact for the NHS, IT Helpdesk on extension 5499 and for University of Liverpool on 0151 794 4567.

5.2.7 Minor/Major Accidents in the LPRG Laboratories:

1. In the event of an accident occurring in the LPRG laboratories, contact the designated First Aider if required; inform the LPRG OD and QAM.
2. The accident must be reported using the University of Liverpool online Accident Form.
3. After the accident has been successfully managed make a detailed written record of the accident by filling in the University of Liverpool online accident form.
4. The form will be reviewed by the departmental safety committee and from this may come recommendations and new procedures to decrease the possibilities of such accidents reoccurring. SOPs may require updating and additional training may also be required.
5. For Incidents that pertain to NHS staff, staff should report using the Trusts Incident/Accident Reporting Procedure via their NHS Manager who will use Datix

5.2.8 Short and Long Term Absence of Laboratory Personnel:

1. Short Term Absence:

In the event of short term absence of personnel, up to 5 days, then their roles and responsibilities must be allocated to the remaining LPRG personnel.

2. **Long Term Absence:**

   In the event of long term absence of personnel, the LPRG principal investigator (LPRG PI) should be informed and the staff roles and responsibilities must be allocated.

5.2.9 Defective Laboratory Equipment:

1. All laboratory personnel must make a written record of the date and time that the fault was discovered, with the laboratory equipment in the laboratory notebook, located in the Rm3.302A UCD
2. Inform the appropriate personnel responsible for maintaining laboratory equipment. If it is equipment which is used for processing biobank samples, inform GCLP OD and QAM.
3. All possible corrective actions, such as calling out the required equipment engineer, must be made to primarily prevent the failure of all laboratory equipment and secondarily to minimise the time the equipment is unavailable.
4. If a piece of laboratory equipment fails during procedure, alternative equipment must be used where available; a written record of this deviation should be documented in laboratory notebooks and worksheets.
5. If alternative equipment is not available inform the LPRG PI and or/ GCLP OD/QAM if the equipment is needed for processing samples for the biobanks. Detailed records of all deviations must be fully documented.

5.2.10 Infections in Cell Cultures:

1. All cell lines must be tested for Mycoplasma contamination by a support technician in the DMCCM.
2. If there is a mycoplasma contamination, or another obvious contamination of the cells in culture, then the cells must be destroyed according to the SOP GCLPRPS024 – Disposal of Hazardous Waste.
3. The procedures for decontamination of laboratory areas and equipment listed below must be followed.
4. The OD and QAM must be informed and a quality incident form filled out. All equipment which comes into contact with cells must be quarantined and thoroughly disinfected via the procedures as outlined in the SOPs for the specific management before processing future samples.
5. The following laboratory equipment must be thoroughly disinfected according to the manufacturer's instructions:
   - All Class 2 biohazardous safety cabinets
   - CO_2 Incubators
   - Bench top Centrifuges
   - Pipettes All bench tops in the LPRG laboratory
6. Discard all opened batches of reagents using SOP GCLPRPS024 – Disposal of Hazardous Waste, including serums, media and freezing medium, which may have been in contact/used in procedures using the infected cells.

5.2.11 Fridge/Freezer Failure:

1. In the event of Failure of Fridges or Freezers within the LPRG the SOP GCLPEQU027 – Defrosting Ultra Low Temperature Freezers should be

consulted. This details the procedures required for the transfer of samples between freezers and moving of samples on LIMS between freezers.
2. The freezer that the samples are being moved to should be identified and samples should be moved as soon as possible.
3. It's particularly important that the names of all the people involved are clearly noted on the paperwork. The person recording the event on LIMS should be named. Any discrepancies related to the position of samples either within the freezer or on LIMS should be noted on the Disaster Event Form. If serious an entire report should be produced.

5.2.12 Expected Electrical Power Cut:

1. All laboratory personnel must ensure that experiments requiring the use of electricity can be completed before the start of the power shortage.
2. If this is not the case then the experiment/procedure must not be started.
3. Any laboratory equipment (including under bench fridges and freezers and the long term storage -80^{o}C freezer must be powered down and disconnected from the main electricity supply in order to prevent power surges from damaging sensitive equipment.
4. The LPRG laboratory consists of three circuits. Staff should transfer all necessary electrical equipment on to other circuits that are not affected.
5. Fridges and freezers must be kept closed. Temperatures will be monitored by LPRG staff. If in the long term the fault is not fixed all staff must be available if freezers require relocating to a new electrical source.
6. Once the main electrical power supply has been restored, reconnect all equipment by following the SOPs for each specific type of equipment.

5.2.13 Unexpected Electrical Power Failure:

1. If a power failure occurs during office hours (9:00am – 5:00pm) then all laboratory personnel must follow local rules and regulations regarding the loss of electrical power; contact Carillion on 2567.
2. If one circuit is disrupted staff should transfer all equipment onto a separate circuit. If all circuits are disrupted the GCLP OD and QAM should be notified.
3. Once electrical power has been restored and it is safe to enter the laboratories, (as stated by local laws and regulations and approved by the safety officer) all laboratory equipment must be checked to ensure it is fully functional by following the SOPs for each specific type of equipment. A written record must be made in the laboratory notebook to state the date of the power failure and record any damage caused.

5.2.14 Expected Water Cut:

1. Facilities management will alert all staff when an expected water cut is due.
2. All laboratory personnel must ensure that experiments requiring the use of the main water supply are completed before the loss of the water supply. If not then the experiments/procedure must not be undertaken.
3. The Millipore water purifier and ice machine must be switched off according to specific SOPs in order to prevent damage to the equipment.
4. Once the main water supply has been restored, reconnect all equipment by following the SOPs for each specific type of equipment.

5.2.15 Unexpected Plumbing Failure:

1. In the event of a water leak contact NHS Estates on extension 2156. Inform the LPRG PI if deemed severe.
2. If the leak is severe, all experiments must be stopped and all electrical equipment local to the leak, must be switched off.
3. Once the leak has been addressed by the appropriate personnel who have deemed it safe, restart electrical equipment according to relevant SOP.

5.2.16 Reporting of Fires

1. If a fire is found in the LPRG or a broken glass of a fire alarm a call should be made to switchboard using the Emergency number 2222.
2. All staff should congregate to their Fire assembly point located on the Fire safety notice situated in the corridor of theLPRG labporatories.
3. Employees should only re-enter the building when the alarm has stopped sounding and a delegated member of staff instructs to do so.
2. Any damage to equipment or offices the OD should be notified.

6. ABBREVIATIONS

AP	Acute Pancreatitis
DC	Document Controller
DMCCM	Department of Molecular and Clinical Cancer Medicine
GCLP	Good Clinical Laboratory Practice
hscic	Health & Social Care Information Centre
OD	Operations Director
QA	Quality Assurance
QAM	Quality Assurance Manager
LPRG	Liverpool Pancreatitis Research Group
LPRG PI	Liverpool Pancreatitis Research Group Principal Investigator

7. OTHER RELATED PROCEDURES AND DOCUMENTS

Documents:

GCLPFAC005	GCP Facility Quality Incident Form (previously known as an Adverse Event Form)
GCLPPPD005	Deviation from a Standard Operating Procedure
GCLPPPD017	Recording and reporting Quality Incidents

SOPs:

GCLPEQU027	Defrosting Ultra Low Temperature Freezers
GCLPRPS011	Use of LIMS to Record Kit Construction, QC, Storage and Dispatch
GCLPRPS024	Disposal of Hazardous Waste in the PBRU.
GCLPTSS088	Reporting of Laboratory Adverse Events and the Matrix LIMS

8. APPENDIX

8.1 Appendix 1: Example of a Sample Destruction Form

<table>
<tr><td colspan="3">Name:</td></tr>
<tr><td colspan="3">Trial:</td></tr>
<tr><td colspan="3">Site</td></tr>
<tr><td>Kit Code:</td><td colspan="2">Sample Type:</td></tr>
<tr><td colspan="2">Name and Signature:</td><td>Date:</td></tr>
<tr><td colspan="2">Quality Assurance Manager:</td><td>Date:</td></tr>
<tr><td colspan="2">GCLP Operations Director</td><td>Date:</td></tr>
</table>

8.2 Appendix 2: Example of a Quality Incident Form

GCP Facility Quality Incident Form

Name:
Trial:
Site:
Samples/Kits affected:
Date Quality Incident Occurred:
Logged on LIMS: Yes/No Date _ _ / _ _ / _ _ Classification: _ , _ , _ , _ , _ , _
Describe Nature of the Quality Incident: (Include any corrective action taken at the time)
Recommended Action:
Signature: **Date: _ _ / _ _ / _ _**
GCP Operations/Strategic Director: **Date: _ _ / _ _ / _ _**
QA Manager **Date: _ _ / _ _ / _ _**

GCLPFAC005/F1/3

8.3 Appendix 3: Example of a LIMS Failure Form

NAME:		**POSITION:**	
DATE:		**TIME:**	

Internal or External Problem	**YES**	**NO**	**TIME**
Internal			
External			

Internal Problem: ACTION	**YES**	**NO**	**N/A**	**TIME**
Operational Director contacted				
QA Manager contacted				
5th floor main office contacted				
NHS estates maintenance contacted				
External Problem: ACTION	**YES**	**NO**	**N/A**	**TIME**
Primary contact at LCTU informed				
Secondary contact at LCTU informed				
CSD contacted as LCTU staff unavailable				

DETAILS OF LIMS REINSTATEMENT			
DATE:		**TIME:**	
CONFIRMED BY:		**POSITION:**	
DETAILS OF BACK UP DATA USED			
DATE USED:		**TIME USED:**	
SAMPLES EFFECTED BY LACK OF LIMS			
SIGNED OFF BY:			
USER:		**DATE:**	
OD:		**DATE:**	
QAM:		**DATE:**	