brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

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Standard Operating Procedures
CIRU Laboratory deviation, corrective and preventative actions (CIRU LAB DCAPA)

SOP Reference:	**SOP/CIRULAB/021**
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Version	Date	Reason for Change
1.0	05 Apr 2013	
2.0	15 Jan 2014	Update of procedure
3.0	21 Sep 2016	Update of procedure

1.0 PURPOSE

The purpose of this SOP is to define the procedures and actions undertaken as a result of all deviations occurring within the scope of CIRU laboratory responsibilities which do not conform to GCLP, GCP, local SOPs or study specific protocols.

The SOP describes the process for identifying, documenting, reporting and retention of information about incidents, deviations and serious breaches.

2.0 ABBREVIATIONS AND DEFINITIONS:

SOP:	Standard operating procedure
GCLP:	Good Clinical Laboratory Practice
GCP:	Good Clinical Practice
BSUH:	Brighton and Sussex University Hospitals
OMG:	Operational Management Group
RGQAC;	Research Governance and Quality Assurance Committee
R&D:	Research and Development Department
PI:	Principal investigator
CIRU:	Clinical Investigation and Research Unit
MHRA:	Medicines and Healthcare Products Regulatory Agency
DCAPA:	Laboratory deviation, corrective and preventative actions
Incident:	Any procedure or action which does not conform to GCLP, GCP, local SOPs or study specific protocols and which **does not have** the potential to result in harm to trial subjects or have an impact on the scientific value of the trial, e.g. logistical and/or administrative deviations.
Deviation:	Any procedure or action which does not conform to GCLP, GCP, local SOPs or study specific protocols and which **has the potential** to result in harm to trial subjects or could potentially affect the scientific value of the trial.
Serious Breach:	Any procedure or action which does not conform to GCLP,GCP, local SOPs or study specific protocols and which **is likely** to affect to a significant degree the safety or physical or mental integrity of the subjects of the trial or the scientific value of the trial.
Standard Practice:	Actions and procedures that are defined by GCLP, GCP, local SOPs or study specific protocols.

3.0 INTRODUCTION

This SOP is to be applied to the process for identifying, documenting, reporting and retention of information about any incidents, deviations and serious breaches from standard laboratory practice recognised by CIRU laboratory staff and designated personnel working on the studies.

A departmental database (CIRU lab DCAPA Database) will document incidents, deviations and serious breaches, and any corrective and preventative actions taken as a result.

A notification email regarding a deviation will be emailed within 24h to the clinical Team Leader of the staff member concerned, most likely a Senior/Lead Research Nurse or the CIRU Lab Technical Manager. Each deviation recorded will be documented, revised and retained in the CIRU lab DCAPA Database and Study Site File and, if appropriate, Study Lab Folder.

Serious breaches will be immediately emailed to the CIRU Laboratory Technical Manager, clinical Team Leader of the staff member running the particular study and the Study Monitor. Each serious breach recorded will be documented, revised and retained on the CIRU lab DCAPA Database, Datix, Study Site File and, if appropriate, Study Lab Folder.

Additionally, a summary/analysis of the documented incidents, deviations and serious breaches will be presented by the CIRU Laboratory Technical Manager at the monthly OMG Meeting to R&D Management and the Team Leaders of the clinical research staff. All serious breaches and deviations from BSUH sponsored studies will also be reviewed at the RGQAC monthly meetings.

4.0 RESPONSIBILITIES

4.1a CIRU Laboratory staff and designated personnel working on the study are responsible for:

- Reading and understanding the CIRU lab DCAPA SOP and Database in accordance with the task they are performing.
- Ensuring that all CIRU lab incidents, deviations and serious breaches that have occurred are entered on the first section of the CIRU Lab DCAPA database, regardless of culpability or individual bias.
- Ensuring that a notification email regarding a deviation is sent within 24h to the clinical Team Leader of the staff member involved or the CIRU Lab Technical Manager as applicable.
- Ensuring that all serious breaches are immediately reported and emailed to the CIRU Lab Technical Manager, clinical Team Leader of the staff member running the study, Study Monitor and entered into Datix.

4.1a CIRU Laboratory Technical Manager is responsible for:

- Ensuring that CIRU lab staff read and understand the CIRU Lab DCAPA SOP and Database.
- Recording comments and corrective and preventative actions on the CIRU Lab DCAPA database for deviations, incidents and serious breaches involving CIRU lab staff.
- Generating and completing the CIRU lab DCAPA Report Form and filing it into the Study Site File and Study Lab Folder, when applicable.
- Implementation of corrective and preventative actions taken as a result of all deviations, incidents and serious breaches reported in collaboration with CIRU lab staff.
- Review and presentation of all incidents, deviations and serious breaches at the monthly OMG meeting.
- Periodically reviewing all incidents and deviations to assess whether, collectively, they meet the criteria for a serious breach, and reporting to the clinical Team Leaders ,Study Monitors and Datix.,

4.1c Clinical Team Leader is responsible for:

- Ensuring that their personnel working with study samples read and understand the CIRU Lab DCAPA SOP and Database.
- Recording comments and corrective and preventative actions on the CIRU Lab DCAPA database for deviations and serious breaches involving their personnel.
- Generating and completing the CIRU Lab DCAPA Report Form and filing it into Study Site File.
- Implementation of corrective and preventative actions to be taken, in collaboration with designated personnel working on the studies, as a result of all deviations, incidents and serious breaches reported..

4.1e Study Monitor is responsible for:

- Review and assessment of all deviations, incidents and serious breaches identified.
- Review of serious breach notifications prior to submission to PI, Sponsor and/or MHRA .
- Feedback about deviations and serious breaches to CIRU team and/or PI, Sponsor, MHRA as applicable.

5.0 PROCEDURE

All procedures or actions which does not conform to GCLP, GCP, local SOPs or study specific protocols re classified as an incident, deviation or serious breach.

5.1 Identifying, documenting, reporting and retention of information about incidents:

- Upon finding an incident, CIRU Laboratory staff and/or designated personnel working on the study must complete the first section of the CIRU Lab DCAPA Database:

Link: T:\Research & Development\CIRU\Labs/CIRU Lab DCAPA Database/CIRU Laboratory deviation, corrective and preventative actions

- Comments and corrective and preventative actions will be recorded on the CIRU Lab DCAPA Database by the CIRU Laboratory Technical Manager.
- All incidents will be reviewed and presented by the CIRU Laboratory Technical Manager at the monthly OMG meeting.
- Corrective and preventative actions will be implemented by the clinical Team Leader or the CIRU Lab Technical Manager, where appropriate.
- All incidents will be periodically reviewed by the CIRU lab Technical Manager to assess whether, collectively, they meet the criteria for deviation or serious breach reporting.

5.2 Identifying, documenting, reporting and retention of information about deviations:

- Upon finding a deviation, CIRU Laboratory staff and/or designated personnel working on the study must complete the first section of the CIRU Lab DCAPA Database:

Link: T:\Research & Development\CIRU\Labs/CIRU Lab DCAPA Database/CIRU Laboratory deviation, corrective and preventative actions

- A notification email regarding a deviation will be sent within 24h to the clinical Team Leader of the relevant study or to the CIRU Lab Technical Manager, where applicable.
- The clinical Team Leader or CIRU lab Technical Manager will review the deviation and instigate further action and/or escalation at their discretion.
- Comments and corrective and preventative actions will be recorded on the second section of CIRU Lab DCAPA database by the clinical Team Leader or CIRU Laboratory Technical Manager as applicable.
- Each deviation recorded on the CIRU Lab DCAPA Database will generate a 'Deviation Reporting' form (appendix 1) which should be printed by the clinical Team Leader or CIRU Lab Technical Manager as applicable.

- Completed Deviation Reporting forms will then be filed by the clinical Team Leader in the relevant Study Site File.
- If a deviation was made by the CIRU lab team, a copy of the Deviation Reporting form will be kept in the relevant Study Lab Folder and the original form will be sent to the clinical Team Leader for filing in the Study Site File.
- Corrective and preventative actions will be implemented by the clinical Team Leader or CIRU Lab Technical Manager where appropriate.
- All deviations will be reviewed and presented by the CIRU Laboratory Technical Manager at the monthly OMG meeting.
- All deviations will be periodically reviewed by the CIRU Lab Technical Manager to assess whether, collectively, they meet the criteria for serious breach reporting.
- All deviations from BSUH sponsored studies will also be reviewed at the RGQAC monthly meetings.
- The Study Monitor should review, assess and feedback on deviations during study monitoring visits or upon request.

5.3 Identifying, documenting, reporting and retention of information about serious breaches:

- Upon finding a serious breach, CIRU Laboratory staff and designated personnel working on the study must complete the first section of the CIRU LAB DCAPA Database:

Link: T:\Research & Development\CIRU\Labs/CIRU Lab DCAPA Database/CIRU Laboratory deviation, corrective and preventative actions

- A notification email regarding a serious breach will be immediately sent to the CIRU Lab Technical Manager, clinical Team Leader for the staff running the particular study and the Study Monitor.
- The Study Monitor will determine whether it meets the serious breach criteria and therefore requires reporting to the Sponsor and/or MHRA.
- The clinical Team Leader or CIRU Lab Technical Manager will review the serious breach and further action and/or escalation will be taken at their discretion.
- Comments and corrective and preventative actions will be recorded on the second section of CIRU Lab DCAPA database by the clinical Team Leader or CIRU Laboratory Technical Manager as applicable.
- Each serious breach recorded on the CIRU Lab DCAPA Database will generate a 'Deviation Reporting' form (appendix 1) which should be printed by the clinical Team Leader of the designated personnel working on the study or CIRU Lab Technical Manager as applicable.
- Completed Deviation Reporting forms will then be filed by the clinical Team Leader in the relevant Study Site File.
- If a serious breach was made by the CIRU lab team, a copy of the Deviation Reporting form will be kept in the relevant Study Lab Folder and the original form will be sent to the clinical Team Leader for filing in the Study Site File.

- All serious breaches will be reviewed and presented by the CIRU Laboratory Technical Manager at the monthly OMG meeting.
- All serious breaches and will also be reviewed at the RGQAC monthly meetings.

6.0 TRAINING

This is a 'read and understand' SOP. To evidence that you have read and understood this SOP, please complete the training record RD/TR/001 (appendix 2).

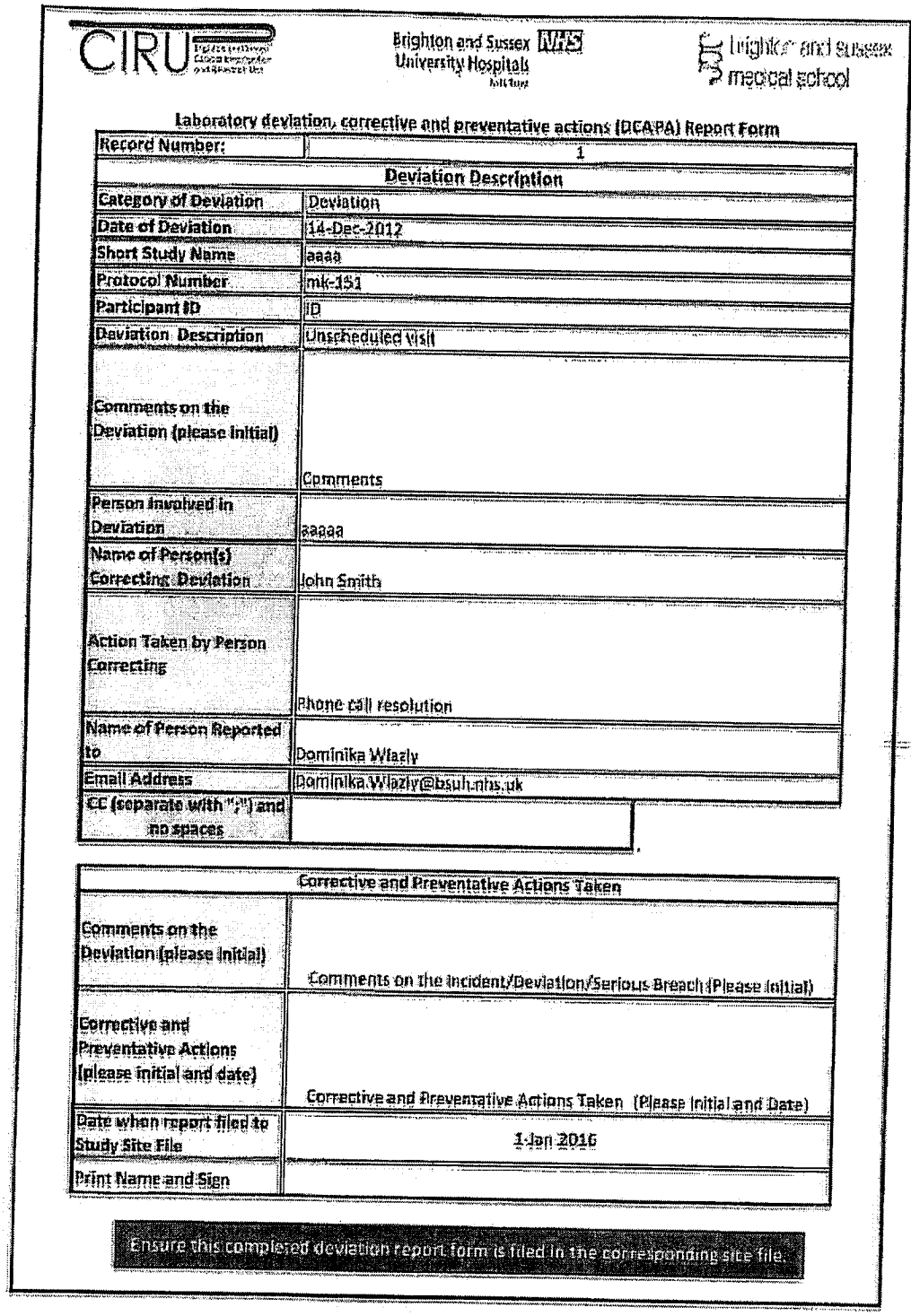
7.0 Cross Reference SOPs

SOPRD003-Notification of Serious Breaches of GCP and the Study Protocol

8.0 References

No references.

Appendix 1



CIRU

Brighton and Sussex University Hospitals NHS Trust

Brighton and Sussex medical school

Laboratory deviation, corrective and preventative actions (DCAPA) Report Form

Record Number:	1
Deviation Description	
Category of Deviation	Deviation
Date of Deviation	14-Dec-2012
Short Study Name	aaaa
Protocol Number	mk-151
Participant ID	ID
Deviation Description	Unscheduled visit
Comments on the Deviation (please initial)	Comments
Person involved in Deviation	saaaa
Name of Person(s) Correcting Deviation	John Smith
Action Taken by Person Correcting	Phone call resolution
Name of Person Reported to	Dominika Wlazly
Email Address	Dominika.Wlazly@bsuh.nhs.uk
CC (separate with ";") and no spaces	

Corrective and Preventative Actions Taken	
Comments on the Deviation (please initial)	Comments on the Incident/Deviation/Serious Breach (Please initial)
Corrective and Preventative Actions (please initial and date)	Corrective and Preventative Actions Taken (Please Initial and Date)
Date when report filed to Study Site File	1-Jan-2016
Print Name and Sign	

Ensure this completed deviation report form is filed in the corresponding site file.

Appendix 2

Brighton and Sussex University Hospitals NHS Trust

Training Record

SOP Reference/Title: _____

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This training record should be completed by the employee and line manager once the SOP has been read and understood.

Employee Name	
Employee Job Title	
Line Manager Name	

SOP Ref	Version/Date	Training Date	Employee Signature	Line Manager Signature
SOP_____	Version: _____ Date: _____			

RD/TR/001 Training Record for BSUH SOPs, version 1.0, 27-Sep-2012