UCL

Standard Operating Procedure for the Recording & Reporting of Deviations, Violations, Potential Serious breaches, Serious breaches and Urgent Safety Measures

SOP ID Number: JRO/SPON/S15/06 (was generated by merging JBRU/SPON/S15/02: "SOP for the sponsor's Management of Protocol Violations and Deviations" and JBRU/INV/S06/02: "SOP for the recording and reporting of protocol deviations and violations for investigators")	**Effective Date:** 12/01/18
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Revision Chronology:

SOP ID Number:	Effective Date:	Reason for Change:	Author:
JBRU/07/S06/00	18/06/07	N/A	Adeeba Ashgar
JBRU/INV/S06/01	02/07/08	To make SOP specific to Investigator Responsibilities.	Yvanne Enever
JBRU/INV/S06/02	15/10/08	To implement a new JBRU formatting and numbering system as reflected in SOP on SOPs (JBRU/SPON/S01/02).	Ira Jakupovic
JBRU/SPON/S15/03	10/01/10	To **merge** 2 SOPs: 1. "SOP for the sponsor's Management of Protocol Violations and Deviations" (JBRU/SPON/S15/02) and 2. "SOP for the recording and reporting of protocol deviations and violations for investigators" (JBRU/INV/S06/02). To **incorporate:** 1. the requirement for the PI/CI/Labs to notify the Sponsor of any "serious breaches", in line with Regulation 29A:SI 2006/1928 2. the requirement for the PI/CI/Labs to record and report "urgent safety measures". Regulation 30 (SI 2004/1031) and the amendment to that Regulation:SI2009/1164 3. the use of the template from the MHRA "Serious Breaches Guidance Version 2" (Final, 15-10-09) 4. the use of the following logs in the recording process: 1. PI's Log of (Protocol &or GCP) Deviations/Violations/ "Potential Serious breaches/Serious breaches & Urgent Safety measures". 2. JBRU Log of "Potential Serious breaches/ Serious breaches" 3. JBRU Log of "Urgent Safety Measures". Format amended in line with revised SOP on SOPs to incorporate a UCL logo only, as UCLH no longer provides sponsorship for CTIMPs, an Acronyms table, eDocument file path, associated templates/log table, SOP dissemination and training and a signature page.	Ann Cochrane
JRO/SPON/S15/04	11/01/12	2 yearly review. Essentially NO changes to the process Some definitions were taken out. JBRU was changed to JRO	Gurjinder Kahlon and Shruti Aggarwal
JRO/SPON/S15/05	08/01/15	3 yearly review. A few minor changes to the process. Wording and order of SOP was tidied up. Responsibilities and reporting contacts updated. Appendix 1 and 2 removed. Referral to the MHRA guidance document and website has been included instead to ensure up to date information/documents are accessed by those carrying out the procedure.	Michelle Quaye
JRO/SPON/S15/06	11/01/18	Link to MHRA serious breach report template and urgent safety measure method have changed.	Helen Cadiou

ACRONYMS:	
JRO	Joint Research Office http://www.ucl.ac.uk/jro/
GCP	Good Clinical Practice
CTIMP	Clinical Trial of Investigational Medicinal Product
SOP	Standard Operating Procedure
ISF	Investigator Site File
PI	Principal Investigator
CI	Chief Investigator
CRF	Case Report Form
REC	Research Ethics Committee
USM	Urgent safety measures
TMF	Trial Master File

Standard Operating Procedure for the Recording and Reporting of (protocol &/or GCP) Deviations, Violations, Potential Serious breaches, Serious breaches and Urgent Safety Measures

1. PURPOSE

This Standard Operating Procedure (SOP) specifies the overall process and procedure for **Investigators and the JRO** to follow for a UCL sponsored clinical trial in the event of a **protocol and/or GCP deviation**. Criteria to follow are outlined in order to assess the impact of the **deviation** in light of the definition of **a potential serious breach** and /or **an urgent safety measure.**

This SOP describes the procedure for the Investigator to record the event and notify the JRO and/or the MHRA/REC and for the JRO to report to the MHRA and/or REC as and when necessary.

2. JOINT UCLH/RF/UCL RESEARCH (JRO) POLICY

All JRO SOPs will be produced, reviewed and approved in accordance with the JRO SOP on SOPs.

3. BACKGROUND

All SOPs are written in accordance with applicable GCP requirements as outlined in Directives 2001/20/EC and 2005/20/EC (in the UK, these Directives were transposed into UK law by SI 2004/1031, SI 2006/1928) and subsequent

amendments and when applicable Regulation 536/2014 and subsequent relevant SIs. For convenience, this document will use the term 'Regulations' to cover the requirements of the UK SI legislation.

Regulation 29 "Conduct of trial in accordance with clinical trial authorisation etc." of the UK regulations (SI 2004/1031) 'The Medicines for Human Use (Clinical Trials) Regulations 2004' stipulates that all Clinical Trials of Investigational Medicinal Products (CTIMPs) must be conducted in accordance with a protocol that has been approved by a Research Ethics Committee (REC) and the Competent Authority (MHRA in the UK).
It is the Sponsor's responsibility to oversee the conduct of all CTIMPs and to ensure compliance with the approved protocol and prevailing UK regulations.

The JRO **does NOT allow the use of "protocol waivers" or departures from the approved inclusion/exclusion criteria of the protocol.** Occurrences of this nature may constitute a serious breach and be reportable to the MHRA.

The Investigator/Institution should only conduct the trial in accordance with the **approved protocol** unless an urgent safety measure must be taken, according to SI 2004/1031 under Regulation 30 and in section 3.4 below.

The Investigator, or person designated by the Investigator (in the trial delegation log), should **document and explain any deviation** from the approved protocol.

Definitions used throughout this document

3.1 Protocol Deviation: A deviation is usually an **un-intended** departure from the expected conduct of the trial (approved trial protocol, trial documents or SOPs).

It is recognised that minor deviations from approved clinical trial protocols and GCP occur commonly in CTIMPs.

Examples of deviations are:
- Isolated incident of a missed or incomplete study procedure (e.g. lab test);
- A protocol visit date deviation outside the study visit window;
- Failure to report an SAE/R/SUSAR to the JRO;

3.2 Violations: A violation can occur when there is a departure from the expected conduct of the trial (approved trial protocol, trial documents or SOPs) and which may affect participant safety or integrity of the research.

Examples of violations include but are not limited to:
- Failure to obtain informed consent (i.e. no documentation in source data or an Informed Consent form);
- Enrolment of subjects that do not meet the inclusion/exclusion criteria;
- Undertaking a trial procedure not approved by the REC and/or the MHRA (unless for immediate safety reasons);
- IMP dispensing/dosing error;

A violation could constitute a serious breach of the protocol and/or GCP or an urgent safety measure, see below for further definitions.

3.3 Serious Breaches of the protocol and/or GCP

Under Regulation 29A of the Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031], as amended by SI 2006/1928, there is a requirement for the notification of "serious breaches" of GCP and/or the trial protocol:

"29A. (1) The sponsor of a clinical trial shall notify the licensing authority in writing of any serious breach of -
*(a) **the conditions and principles of GCP** in connection with that trial; or*
*(b) **the protocol** relating to that trial, as amended from time to time in accordance with regulations 22 to 25, **within 7 days** of becoming aware of that breach.*

*(2) For the purposes of this regulation, a "serious breach" is a breach which is **likely** to effect to a significant degree –*
(a) the safety or physical or mental integrity of the subjects of the trial; or
(b) the scientific value of the trial".

Note: Article 52 of EU 536/2014, below, is remarkably similar to the above 29A definition of SI 2006/1928. Once the new legislation is to be implemented, the main difference will be that the portal will be the means of reporting.

Article 52 Reporting of serious breaches
1. The sponsor shall notify the Member States concerned about a serious breach of this Regulation or of the version of the protocol applicable at the time of the breach through the EU portal without undue delay but not later than seven days of becoming aware of that breach.
2. For the purposes of this Article, a 'serious breach' means a breach likely to affect to a significant degree the safety and rights of a subject or the reliability and robustness of the data generated in the clinical trial.

Examples of serious breaches including but not limited to:

- Participant administered an incorrect IMP/administered an IMP by the incorrect route of administration;
- Failure to report AEs, SAEs or SUSARs in accordance with the UK legislation, such that subjects are put at risk;
- Proof of fraud relating to clinical trial records or data that impacts on the integrity of trial subjects or scientific value of the data.

See MHRA "Guidance for the notification of serious breaches of GCP or the trial protocol", document for further examples https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials#report-a-serious-breach

See section 6.2 below for the procedures for notifying the JRO of a potential serious breach.

3.4 Urgent Safety Measures (Implementing a Protocol Deviation under an emergency)
An Urgent Safety Measure is defined under UK Regulation 30:

"The sponsor and investigator may take appropriate urgent safety measures to protect clinical trial subjects from any immediate hazard to their health and safety. The measures should be taken immediately".

This allows an Investigator to implement a deviation from, or a change of the protocol to eliminate an immediate hazard(s) to trial subjects **without** prior approval from the REC/MHRA, however a **notification must be submitted within 3 days** (7 days, when applicable in 2019/2020) of the urgent safety measure having taken place.

See section 6.13 below for the REPORTING procedures.

3.5 A Trust Reportable Incident

Each investigator is reminded to report any Incident to the NHS Trust as per their local Trust Incident reporting policy under the UK Policy Framework for Health and Social Care Research These incidents may also need to be notified to your local R&D office in line with their local reporting requirements. Please ensure you are aware of how to report such incidents before your trial commences.

4. SCOPE OF THIS SOP

This SOP details the process (for Investigators and for the JRO regarding UCL sponsored clinical trials) to follow for the recording and reporting of CTIMP protocol deviations and violations. It describes what consideration must be taken into account to assess whether the deviations and violations also meet the definition of a potential serious breach or urgent safety measure and the reporting requirements.

Where this has been delegated to a partner organisation (e.g. Clinical Research Organisations, Clinical Trials Units etc.) via a MoU or through a Service Level Agreement (SLA) it will be the responsibility of that partner organisation to report the "serious breaches" and "urgent safety measures" to the Competent Authority & REC under contractual obligations.

International Trials

For UCL sponsored international trials, UCL delegates the responsibility for reporting "serious breaches" and "urgent safety measures" to regulatory authorities (RAs) and ethics committees (ECs) outside the UK, to the coordinating organisation (e.g., CRO, CTU), in line with the regulatory requirements of each country. These responsibilities should be set-out in contractual obligations.

5. RESPONSIBLE PERSONNEL

The PI/CI must ensure deviations and violations are documented on site, in the CRF and on the PI/CI Log of (Protocol and/ or GCP) Deviations/Violations/"Potential Serious breaches"/"Serious breaches"/"Urgent Safety Measures" and implement a file note where required. Any corrective and preventative action should also be documented and retained in the trial master file/investigator site file. The CI/PI has the responsibility to record and report any violations and potential serious breach to the JRO within the agreed timeframes and in accordance with this SOP. The PI/CI must report any urgent safety measures taken to the MHRA, REC and JRO within 3 days (7 days, when applicable in 2019/2020).

If the Investigator is unsure whether a deviation or violation is a potential serious breach they should notify the JRO as soon as possible and provide as much information as possible.

The JRO must report serious breaches to the competent authority and REC within the regulatory timelines and consider the following actions:
- Receipt and Assessment (i.e. assessment of deviations/violations by JRO/ delegate);
- Investigation;
- Corrective and Preventative Action (CAPA);
- Reporting to competent authority;
- Compliance with 7-day reporting timescale.

The JRO should assess the impact of the breach on the scientific value of the trial; this can be carried out in conjunction with the PI/CI. If a potential serious breach is identified by a member of the JRO, the JRO QA manager should also be alerted as soon as possible with a further discussion with the CI/PI in order to clarify the situation and take appropriate corrective and preventative action. The JRO would then inform the competent authority and REC of the serious breach.

The regulatory timeline will only commence once the JRO has assessed the event as being a serious breach.

6. PROCEDURE

Please check that this version of the SOP is the latest by going on www.ucl.ac.uk/jro

6.1 Identification and recording of deviations and violations

6.1.1 Deviations

Recording: Record in the Source data, CRF , and PI/CI Log of (Protocol and/or GCP) Deviations/ Violations/ "Potential Serious breaches"/"Serious breaches"/"Urgent Safety Measures" provided by the JRO and file note if necessary.

Reporting: minor deviations are not required to be notified to the sponsor. Where a deviation is reoccurring and may result in identification of a serious breach, this should be notified to the sponsor.

Escalation: Corrective and preventative actions should be implemented for deviations.
It is recommended that reoccurring deviations be discussed at any trial meetings and if required detailed in the clinical study report.

6.1.2 Violations

Recording: Record in the source data, case report form, PI/CI Log of (Protocol and/or GCP) Deviations/ Violations/ "Potential Serious breaches"/"Serious breaches"/"Urgent Safety Measures" provided by the JRO and file note if necessary.

Reporting: Violations of GCP, protocol and regulations must be notified to the sponsor (compliance oversight advisor, sponsor regulatory advisor/manager **AND** CTIMPS@ucl.c.uk) **within 3 calendar days** of becoming aware of that violation.

Escalation: Corrective and preventative actions should be implemented for violations.

It is recommended that reoccurring violations be discussed at any trial meetings and if required detailed in the clinical study report.

If a violation is identified by or reported to the JRO and could be a potential serious breach, the case must be discussed with the QA manager as soon as possible and senior management notified if the QA manager is not available.

A violation may necessitate the JRO to undertake a triggered monitoring visit. All violations must be resolved to conclusion. Depending on the nature of the violation it may constitute a Serious Breach of GCP and further follow up and reporting maybe required by the JRO in line with current regulations as set out below.

6.2 Identifying, recording and notifying the JRO of a potential Serious Breach

The judgment on whether a breach is likely to have a significant impact on the scientific value of the trial depends on a variety of factors e.g. the design of the trial, the type and extent of the data affected by the breach, the overall contribution of the data to key analysis parameters, the impact of excluding the data from the analysis etc.

6.2.1. If the Site Team has identified a serious breach they should call the JRO to discuss the breach in the first instance. The site team must complete the "Notification of Serious Breaches of GCP or Trial Protocol form" downloaded from the MHRA website https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials#report-a-serious-breach). All available details pertaining to the breach should be documented on the form, including details of what corrective and preventative action has been taken (CAPA).

6.2.1.1. The completed Notification of Serious Breaches of GCP form should be sent to the JRO team (Compliance Oversight Advisor, Sponsor Regulatory Advisor/Manager **AND** CTIMPS@ucl.c.uk).

6.2.1.2. The PI must log the "Potential serious breach" in the PI's Log of (Protocol and/ or GCP) Deviations/Violations/"Potential Serious breaches"/"Serious breaches"/"Urgent Safety Measures".

See MHRA "Guidance for the notification of serious breaches of GCP or the trial protocol", document for detailed guidance on the information that should be included in the form.

6.3 Assessment by the JRO

6.3.1. If a potential serious breach has been identified by the JRO, this should be discussed with the QA manager or Clinical Trials Operations Manager in the first instance. The relevant member of the JRO should gather as much information as possible on the event to assess whether the event meets the criteria of a serious

breach. If the Serious Breach definition is met the JRO will be responsible for completing the "Notification of Serious Breaches of GCP or Trial Protocol form" downloaded from the MHRA website https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials#report-a-serious-breach).

6.3.2. On receipt of the "Notification of Serious Breaches of GCP or Trial Protocol" form from a trial site, the JRO must assess and collate information relating to the event to determine whether it is a serious breach.

The JRO will assess potential serious breaches through:

- Discussion with appropriate team members (e.g. Compliance Oversight Advisor, Sponsor Regulatory Advisor, Pharmacovigilance Manger, ATMP Regulatory Manager) and document the rationale for the decisions taken.

- Identifying which relevant GCP, regulatory or protocol section the breach relates to;

- Evaluate whether the breach fulfils the competent authority (MHRA) definition of a serious breach;

Serious breaches must be notified to the MHRA and REC as set out in section 6.5 <u>within 7 days</u> of the decision that the event is a serious breach.

If following assessment the JRO remains unsure whether the event is a serious breach, it should be sent to the MHRA as a POTENTIAL serious breach, detailing the information at hand and requesting the MHRA to assess the event. The JRO may seek clarification from the MHRA on a potential serious breach by contacting the GCP inspectorate. Ensure a clear trail of what information is passed on to and received from the MHRA is maintained.

6.3.3. The JRO must also asses any additional regulatory actions or reporting requirements as a result of the serious breach.

In addition, the JRO might have to submit a substantial amendment/ urgent safety measure report if necessary. Other relevant MHRA units may require notification to comply with other legislation e.g. notification to the Clinical Trials Unit (CTU) if the breach constitutes an Urgent Safety Measure or if a substantial amendment is required due to a temporary halt in the study or the Defective medicines Report Centre if the breach involves defective medicines or IMP recall etc. and/or if the REC needs to be notified.

6.4 Corrective and Preventative Actions (CAPA)

The JRO and the CI/PI must agree on the appropriate corrective and preventative action to be taken and this should be documented and detailed within the body of the notification report.

6.5 Notification to the MHRA and REC.

6.5.1. The completed form should be sent to the MHRA and REC **within 7 days** of the JRO having assessed an event as a serious breach.

If the sponsor obtains clear and unequivocal evidence that a serious breach has occurred, the default position should be for the JRO to notify the MHRA and REC first, within 7 days, investigate and take action simultaneously or after notification. In this case, the JRO should not wait to obtain all of the details of the breach prior to notification. Updates to the report are acceptable. In such cases, plans should be indicated with projected timelines for completion on follow up reports.

Submit the "Notification of Serious Breaches of GCP or Trial Protocol form" as per instructions on the MHRA website https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials#report-a-serious-breach.

In cases where an external organisation is obliged contractually to report serious breaches on behalf of JRO, all regulatory timelines remain applicable (notification to the MHRA within 7 days of becoming aware of serious breach).

6.5.2. The JRO staff member reporting the serious breach must update the "JRO Log of "Potential Serious breaches"/"Serious breaches" on the S:drive. If a "potential serious breach" is investigated but does not become a serious breach, it should be logged as a "potential serious breach".

6.5.3. The log must be reviewed periodically by the QA manager or delegate to help identify any trends, in particular those relating to recurrent findings that may require additional training or monitoring visits to site.

6.6 Follow up reports

6.6.1. Follow up reports should be made in writing (the serious breaches form can also be used for this) and should ideally:

- Be clearly identified as a follow up report;
- Identify the unique GCP ID allocated when the initial report was acknowledged by the MHRA and REC;
- Be forwarded to the initial inspector and REC administrator dealing with the case.

6.7 Escalation and dissemination process

6.7.1 Escalation by CI/PI:

The line manager(s) (both Trust and University) of the Investigator from the site where the breach took place must be notified of the "notification of serious breach" having been sent to the MHRA and been informed of what CAPA is in place. The line manager(s) of these organisations will have to inform their QA and senior management if necessary and according to their own SOPs.

The breach should be circulated to relevant staff for inclusion of relevant information in to the study report or publication.

6.7.2 Escalation by JRO:

This will be dependent on the nature of the breach and may include other sites and pharmacies affected, other MHRA departments, Ethics Committees etc.

The R&D Department of the site where the serious breach took place must be informed of the CAPA in place.

The serious breach may be notified to the Safety Committee, the Sponsorship Oversight Committee or the Clinical Research Governance Committee as deemed appropriate.
The GCP trainers should be informed on a regular basis of the serious breaches having been reported by the JRO to the MHRA.

UCL reserves the right to withdraw sponsorship for the trial as and when necessary.

6.8 Further actions:

Until the serious breach has been fully resolved and given the amount of resources diverted from the JRO to process/address serious breaches, **the JRO will not be carrying out any activities on trials that the CI may have in set up at their discretion**.

6.9 Notification of an Urgent Safety Measure (SI 2004/1031, Regulation 30) by a site

6.9.1. The CI/PI should phone the Clinical Trial Unit at the MHRA, 020 3080 6456 and discuss the issue with a safety scientist/medical assessor once an urgent safety measure has been implemented at a site ideally within 24 hours.

6.9.2. The CI/PI must send a follow-up email to the MHRA assessor spoken to on the phone, to summarize the information exchanged and the advice provided by the MHRA. MHRA will tell you how to do this when you speak to them. The MHRA should be requested to confirm that the email's content (info provided and advice given) is correct. The **substantial amendment** covering the changes made as part of the Urgent Safety Measure is anticipated **within approximately two weeks of notification of the MHRA**. Any potential reason for delay to submission of the substantial amendment should be discussed and agreed with the MHRA at the time of initial notification or through a follow up call if necessary. Submission of the substantial amendment should not be delayed by additional changes outside of those taken and required as an urgent safety measure. Unrelated and unacceptable changes may result in rejection.

6.9.3. The CI/PI must notify the MHRA, the REC and the JRO, of the measure taken and the reason for the measure **within 3 days** (7 days when applicable ~~in 2016~~) as set out below. The local R&D Department might need to be informed in accordance with local requirements. HC 15/01/18

In the case of research during a pandemic period, Point 3 of The Medicines for human Use (Miscellaneous Amendment) Regulations (SI2009/1164) has amended this timeline to "as soon as possible". See http://www.legislation.gov.uk/uksi/2009/1164/pdfs/uksi_20091164_en.pdf

6.9.4. The notification should include a substantial amendment form (http://ec.europa.eu/health/documents/eudralex/vol-10/index_en.htm), a covering letter detailing the measures taken, the reason for them, the medical assessor contacted and any supporting documentation. See also the Sponsor SOP 13 on Amendments.

The urgent safety measure notification should be:

- Sent as PDF documents on disk to: Information Processing Unit, Area 6, Medicines and Healthcare products Regulatory Agency, 151 Buckingham Palace Road Victoria, London, SW1W 9SZ;
- Sent to the REC which approved the study using the REC safety reporting cover sheet;
- Sent by email to the JRO (Compliance Oversight Advisor, Sponsor Regulatory Advisor/Manager **AND** CTIMPS@ucl.c.uk).

6.9.5. The PI should copy this notification and file it in his TMF/ISF.

6.9.6. The PI should log the event into the PI's Log of (Protocol and/ or GCP) Deviations/Violations/"Potential Serious breaches"/"Serious breaches"/"Urgent Safety Measures".

6.9.7. Once the JRO has received the substantial amendment notifying of an "urgent safety measure", the Compliance Oversight Advisor/Regulatory Managers ATMPs/ QA manager will log it into the "JRO Log of Urgent safety measures" reported by the PI/CI/Lab to the JRO on UCL sponsored CTIMPs. The notification of "urgent safety measures" should be filed in the "urgent safety measures" folder held by the QA manager. Acknowledgement from the MHRA and REC should also be filed in this folder.

7. REFERENCES

http://www.ucl.ac.uk/jro/

MHRA - Guidance for the Notification of Serious Breaches of GCP or the Trial Protocol Version 5 (06/01/14)

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The Medicines for Human Use (Clinical Trials) Amended Regulations 2006 (SI 2006/1928)

The Medicines for Human Use (Clinical Trials) Amended Regulations 2009 (SI 2009/1164)

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

8. APPENDICES

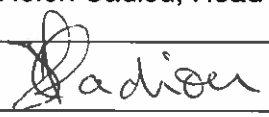
9. TEMPLATES/LOGS ASSOCIATED TO THIS SOP:

1	**PI's Log of (Protocol &/or GCP) Deviations/Violations/Potential serious breaches/Serious breaches/ Urgent safety measures**
2	**JRO Log of "Potential Serious breaches"/"Serious breaches" reported to the JRO on UCL sponsored CTIMPs**
3	**JRO Log of "Urgent Safety Measures" reported to the JRO, MHRA and MREC on UCL sponsored CTIMPs**

10. SOP DISSEMINATION & TRAINING

This SOP will be provided to the PIs prior to, or at initiation at the latest. All staff trial team concerned by this SOP will sign the SOP training log (12. SOP TRAINING LOG) part of this SOP. These documents should be filed in the ISF

11. SIGNATURE PAGE

Author and Job Title:	Helen Cadiou, Head of QA
Signature:	
Date:	11/01/18
Authorised by: Name and Job Title	Rajinder Sidhu, Deputy Director, Research Support
Signature:	
Date:	11/01/18

12. SOP TRAINING LOG:

	Name of Staff (Capital letters):	Job Title and Department:	Training Date	I confirm that I understand & agree to work to this SOP: SIGNATURE	Name of Trainer (if applicable)	Signature	Date
1	FARHAT GILANI	JRO PV MANAGER	15/1/18		–	–	–
2							
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	Name of Staff (Capital letters):	**Job Title and Department:**	Training **Date**	**I confirm that I understand & agree to work to this SOP: SIGNATURE**	**Name of Trainer** (if applicable)	**Signature**	**Date**
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	Name of Staff (Capital letters):	**Job Title and Department:**	Training **Date**	**I confirm that I understand & agree to work to this SOP: SIGNATURE**	**Name of Trainer** (if applicable)	**Signature**	**Date**
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	Name of Staff (Capital letters):	**Job Title and Department:**	Training **Date**	**I confirm that I understand & agree to work to this SOP: SIGNATURE**	**Name of Trainer** (if applicable)	**Signature**	**Date**
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	Name of Staff (Capital letters):	**Job Title and Department:**	Training **Date**	**I confirm that I understand & agree to work to this SOP: SIGNATURE**	**Name of Trainer** (if applicable)	**Signature**	**Date**
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