St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

Reporting of Adverse Events for CTIMPs Sponsored by St Georges

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Signature of Authorisor			

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The master document is posted on the JREO website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JREO website for the most recent version.
They may print off this document for training and reference purposes.

SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	Original Version	Ailsa Withers
V2.0	To update SOP with new PV procedure and new SOP numbering system	Ailsa Withers
V3.0	To update SOP with new PV procedure adopted by JRO since January 2010 to ensure compliance with PV requirements of the UK Clinical Trials regulations.	Ira Jakupovic
V4.0	To update with new procedure for reporting Adverse Incidents to SGHT Risk Management Department	Ira Jakupovic
V5.0	A typographical error in section 9 corrected to ensure Part 2 of ASR reports line listing of all SARs	Ira Jakupovic

V6.0	Revision of V5.0	Ira Jakupovic
V7.0	Updated in line with current MHRA reporting guidelines; new JREO SOP template; ID issue number and to incorporate new JREO process and procedure	Debbie Rolfe
V7.0	Updated in line with current MHRA reporting guidelines; new JREO SOP template; ID issue number and to incorporate new JREO process and procedure	Debbie Rolfe
V8.0	Updated appendices AE log and SAE reporting form added to the SOP, added definition and clarifications on CI and PI responsibilities. Updated nres hyperlink in Appendix 8.3	Debbie Rolfe
V9.0	Updated with New Foundation Trust status & Code break for blinded studies	Debbie Rolfe
V10.0	Urgent Safety Information timelines corrected. Updated JREO actions in line with actual office procedures	Debbie Rolfe

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1. Background

The European Clinical Trials Directive (EUCTD) 2001/20/EC was transposed into UK Regulations by The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) on the 1st May 2004. 'UK Regulations' will be the term used to cover the UK legislation and the EUCTD in this document. UK Regulations and its subsequent amendments set out the legal requirements for Adverse Event (AE) recording, management and reporting in clinical trials. These regulations apply to all Clinical Trials of Investigational Medicinal Products (CTIMPs) and specify 'Pharmacovigilance (PCV)' reporting requirements. To breach these requirements constitutes a breach in criminal law. The requirements have been incorporated into this Standard Operating Procedure (SOP) to define procedures undertaken by the Sponsor (St George's' University of London (SGUL) and/or St George's University Hospitals NHS Foundation Trust (SGHT)) to comply with the UK Regulations.

2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JREO acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHT). St George's will be the official name used on all SOPs to represent either institution acting as Sponsor.

3. Scope

This SOP describes the procedure to be used by all Investigators for recording and reporting of Adverse Events (AEs), including Adverse Reactions (ARs), Serious Adverse Events (SAEs), Serious Adverse Reactions (SARs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) that require reporting in accordance with the UK Regulation and that occur in subjects participating in CTIMPs sponsored by St George's. It also provides details of the responsibilities of the Investigator (Section 5).

Where there may be trial related responsibilities delegated by the JREO to a third party (e.g. Clinical Research Organization (CRO) or an external Clinical Trials Unit (CTU)), this SOP must be followed. The same must apply to international trials.

This SOP does not describe the procedure for reporting of **Adverse Incidents** (AIs) to the Trust Risk Management Department Database "Datix" by Investigators for all clinical research registered with the JREO.

Adverse Incidents Reporting Policy and Procedures can be accessed following this link:

http://stginet/Units%20and%20Departments/Governance/Risk%20Management/Advers%20Incident%20Reporting/Adverse%20Incident%20Reporting.aspx

This SOP also does not cover safety reporting for non CTIMP studies. That is covered by JREOSOP0033.

4. Definitions

4.1 Investigator

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the **principal investigator (PI)** .

4.2 Chief Investigator (CI)

An investigator assigned the responsibility for the coordination of participating principal investigators at participating sites in a multicentre trial.

4.3 Investigational Medicinal Product (IMP)

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

4.4 Sponsor

An individual, company, institution or an organisation which takes on the responsibility for the initiation, management, and/or of the financing of a clinical trial.

4.5 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical trial subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an IMP whether or not related to that IMP.

4.6 Adverse Reaction (AR)

Any noxious and unintended response to an IMP where a causal relationship between the IMP and an AE cannot be ruled out.

4.7 Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR)

Any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalisation or prolongation of hospitalisation, results in persistent or significant disability/incapacity or is a congenital anomaly or birth defect.

NB: hospitalisation is defined as an inpatient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Therefore subjects do not need to be hospitalised overnight to meet the hospitalisation criteria.

Hospitalisation for an elective procedure or for a pre-existing (prior to study entry) condition which has not worsened is not defined as an SAE.

4.8 Other SAEs or SARs

Important medical events that may jeopardise the subject or may require intervention to prevent one of the outcomes listed in **4.5** should also be considered as serious e.g. overdoses (accidental or intentional), pregnancy (of subject or their partner), AE and/or laboratory abnormalities which are listed in the trial protocol as critical to safety evaluations and require reporting.

4.9 Suspected Serious Adverse Reaction (SSAR)

An AR that is classed in nature as serious and which is consistent with the information about the IMP listed in the relevant reference documentation e.g. Summary of medicinal characteristics (SmPC) for a licensed product being used according to licensed doses and indications or an Investigator's brochure (IB) for any other IMP or for an IMP being used outside of its SmPC.

4.10 Unexpected Adverse Reaction (UAR)

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (SmPC or IB as specified in 4.7).

4.11 Suspected Unexpected Serious Adverse Reaction (SUSAR)

An adverse reaction that is classed in nature as both serious and unexpected.

4.12 Other Serious Safety issues

Other safety issues that might materially alter the current risk-benefit assessment of an IMP or that would be sufficient to consider changes in the IMP administration or in the overall conduct of the trial also need to be considered serious, e.g.:

- An increase in the rate of occurrence or qualitative change of an expected SAR which is judged clinically important;
- Post study SUSARs that occur after the patient has completed a clinical trial and are reported by the Investigator to the Sponsor;
- New events related to the conduct of the trial or the development of the IMPs and likely to affect the safety of the subjects, such as:
    - An SAE which could be associated with the trial procedures and which could modify the conduct of the trial;
    - A significant hazard to the subject population such as lack of efficacy of an IMP used for a life threatening disease;
    - A major safety finding from a newly completed animal study (e.g. carcinogenicity);
    - Any anticipated end or temporal halt of a trial for safety reasons and conducted with the same IMP in another country by the same Sponsor;
- Recommendations of the Data Monitoring Committee (DMC), if any, where relevant for the safety of subjects.
- Any pregnancies that occur in clinical trial subjects as soon as the investigator becomes aware of the event. It may be necessary to monitor the pregnancy of a woman whose male partner is the trial subject.

4.13 Urgent Safety Measure

It may be necessary to undertake a procedure that is not defined in the protocol but has to be taken without any authorisation from the MHRA and/or REC, in order to protect the trial subjects from any immediate hazard to their health or safety. The PI/CI/Lab will need to report this immediately to the JREO & submit a summary of the discussions with the competent Authority within 3 days to the MHRA with an expected timeline of amendment preparation. The JREO/CI must co-ordinate effective communication to ALL key staff at all participating sites.

4.14 Adverse Incident

An 'adverse incident' is any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, members of the public or staff. This includes breaches of confidentiality, serious adverse events, serious adverse reactions, which requires a hospital admission and has a severity grading of severe or critical.

5. Responsibilities

5.1 Investigator Responsibilities

a) It is the responsibility of the investigators within the research team at any participating site to follow this SOP and keep records of all AEs that occur in trial subjects in accordance with the protocol.

b) It is the responsibility of the CI to ensure that the protocol references expected AEs/ARs where known, and defines those which do not require reporting to the JREO.

c) Safety reporting can be delegated by the PI to another suitably qualified team member via the study delegation of responsibilities log.

d) The Investigator must be familiar with the appropriate use of the IMP(s), as described in the protocol, IB, SmPC, IMP dossier or other source of information.

e) The Investigator must ensure that all other research team members are trained in the use of the IMP(s). The investigator must update all other research team members on any new information relating to the IMP(s). This training should be documented on the training log JREOLOG0016 and retained in the Investigator Site File (ISF).

f) The Chief Investigator should review and update the IB and IMP dossiers annually and request these documents from IMP manufacturers where applicable. Any updates to this reference safety Information must also be communicated to the JREO and the participating sites' Pharmacy departments

g) The Investigator must ensure annual updates to the IB and IMP dossiers are filed in the ISF.

h) The Investigator must record all AEs and/or ARs in trial subjects in the patient's medical notes, the Case Report Form (CRF), Sponsor AE log (appendix 1) **and** where required according to definition on the Sponsor SAE recording form (appendix 2)

i) The Investigator must assess each event for seriousness/intensity, causality and expectedness.

j) The Investigator must review all study AE logs every 2 months to facilitate trend/signal analysis on any specific AE recorded within the trial. The investigator must document any analysis findings communicated and file in the TMF. Any AEs that, upon review, collectively require escalation due to increased frequency and/or severity must be reported to the JREO within 24 hours of the review.

k) The Investigator must report any SAEs within 24 hours of becoming aware of the event to the JREO using the SAE/SAR recording form.

l) The Investigator must respond to any SAE queries raised by the JREO as soon as possible.

m) The Investigator must forward any follow up information to that reported SAE/SAR to the JREO using the SAE recording form within 14 days of any new information obtained. The SAE form must clearly be marked as 'follow up'

n) The Investigator must continue to follow the reported SAE/SAR to resolution ensuring that updated information is forwarded to the JREO on a regular basis. The reporting timelines will be as agreed in the monitoring plan.

o) All SUSARs must be reported to the JREO immediately and at least within 24 hours of the investigator becoming aware of the event.

p) The Chief Investigator is responsible for ensuring notification of confirmed SUSARs and/or Urgent Safety Measures to all sites.

q) All SAE/SAR reports and any SUSAR information must be filed in the ISF in the appropriate section for pharmacovigilance.

r) It is the responsibility of the Investigator to ensure that those SAEs which they consider to fall within the definition of an Adverse Incident (AI) are entered onto the Trust Risk Management Database (DATIX) as outlined in Trust Adverse Incidents Reporting Policy and Procedure, available via the trust Intranet. If the incident is at an external NHS Trust – their policy of reporting incidents must be followed.

5.2 JREO (Sponsor) Responsibilities

a) It is the responsibility of the Head of Research Governance and Delivery Manager to ensure that this SOP is updated and audited where necessary.

b) The assigned Clinical Trial Monitor (CTM) or Regulatory Assurance Manager (RAM) will ensure that acknowledgement of receipt of SAE recording forms is communicated via email to both the reporter and the Chief Investigator within 1 working day.

c) The CTM/RAM will assess all AE/AR logs and SAE reporting forms upon receipt for accuracy and completeness and respond with any queries or points for clarification to the study team within 2 working days.

d) The CTM/RAM will submit an initial report for any notified SUSARs electronically to the MHRA within 24 hours of first knowledge.

e) The CTM/RAM will forward a copy of the saved electronic SUSAR report file to the Chief Investigator to facilitate notification/escalation to all other site investigators

f) The CTM/RAM will update any electronically filed pharmacovigilance databases with the reported events and update with any follow up information to facilitate accurate analysis by the Research Governance Committee, the Research Ethics Committee and the Medicines and Healthcare products Regulatory Agency (MHRA) where necessary.

g) Once signed by the CTM, the CTM/RAM will upload a copy of any SAE recording forms into the electronic Sponsor site file as a PDF file.

h) The CTM/RAM will forward a copy of the pharmacovigilance database and any new or updated SAE reporting forms to the Chief investigator at monthly intervals to ensure medical oversight.

6. Procedure

6.1 Investigator Procedure

a) The Investigator must complete all required information on the AE log or SAE reporting form and communicate the information to the JREO either via fax: 020 8725 0794 or via email adverseevents@sgul.ac.uk. AE logs are to be submitted to the JREO bi-monthly and SAE reports within 24 hours of first knowledge.

b) The first submission of an SAE reporting form must clearly be marked as 'initial'

c) Any subsequent SAE reporting forms for that event (including that of corrections) must be clearly marked as 'follow up'.

d) Any amendments, corrections or additional information must be dated and initialled.

e) All SAE/SUSARs must be signed off as reviewed by the Chief Investigator or by the PI at a site.

f) SUSAR reports must be sent to the JREO within 24 hours of first knowledge. **Not all fields require completion at this point**. However, any information that is missing must be forwarded to the JREO at the earliest opportunity.

g) SUSAR follow up information must be sent to the JREO within 7 days of the initial report.

h) The PI on a multisite trial Sponsored by St Georges should ensure that the CI is aware of the SAE. The PI will forward the reviewed report to the JREO within 24 hours.

i) If an SAE/SUSAR report is reported outside of the defined reporting guidelines according to the protocol or regulatory guidelines, a reason should be provided to the JREO and the event recorded on the protocol deviation/violation form JREOLOG0005 in accordance with JREOSOP0012.

6.2 JREO Procedure

a) The CTM/RAM will ensure that both the email address adverseevents@sgul.ac.uk **and** the JREO fax is checked on a daily basis for study SAEs.

b) The CTM/RAM will check the SAE form to ensure all fields are complete and accurate, and that the Chief Investigator has been informed.

c) For double blinded studies the code break should be performed in accordance with the protocol instructions ensuring the Investigator is not inadvertently unblinded

d) Acknowledge receipt of the SAE form by email to the sender ensuring the Chief Investigator, study co-ordinator and the CTM is copied in – this may be the opportunity to address any initial queries or clarifications required.

e) Cross check the SAE details with the SmPC, IB (whichever is relevant) and the protocol to assess and confirm expectedness.

f) If the Investigator has assessed the event as serious, unexpected and the causality has been assessed as definite, possible, probable or not assessable then report **as a SUSAR** as point f below. The event can be down graded to an SAE at a later date if reassessed as not fulfilling the SUSAR definition.

g) The JREO HoRGD ,RAM, and CTMS can log onto the MHRA website at the following link https://esusar.mhra.gov.uk/ and follow the instructions.

h) The CTM/RAM must save the submitted form into the electronic Sponsor study file in the pharmacovigilance section and ensure the Chief Investigator is in receipt of the form to facilitate correspondance with collaborating investigators and the study team.

i) The CTM/RAM must ensure any follow up information to the SUSAR is submitted to the MHRA via the link in (f) above within the reporting timelines. Any fatal or life threatening SUSARs must be reported to the MHRA within 24 hours of the JREO being made aware of the SUSAR. Follow up reports must be sent no later than 8 days after the initial report. Any non-fatal or non-life threatening SUSARs must initially be reported within 15 days.

j) The CTM/RAM must forward any reported SUSARs to the relevant ethics committe accompanied by the "Clinical Trials of Investigational Medicinal Products Safety Report to the Research Ethics Committee form" (see appendix three.)

k) Select option 1 : Expedited report(s) of SUSAR in the UK and complete the form fields with relevant details as required.

l) Ensure a copy of the signed form and the SUSAR report is sent to the Ethics committee together with a cover letter by registered post.

m) Place the registered post sticker (given by the post room) onto the copy of the documents in the JREO Trial file

n) Ensure a copy of the ethics notification (and upon receipt) the ethics confirmation of receipt is forwarded to the CI to be filed in the TMF

o) If an SAE or SUSAR is reported outside of the reporting window as defined either by the protocol or regulatory body, ensure it is noted on the protocol deviation log as per JREOSOP0012 . On the line-listing in the annual trial Developmental Safety and update report (JREODOC0046), acknowledgement of the late report should be noted

7. References

St George's DATIX system
http://stginet/Units%20and%20Departments/Governance/Risk%20Management/Advers%20Incident%20Reporting/Adverse%20Incident%20Reporting.aspx
MHRA eSUSAR system https://esusar.mhra.gov.uk
HRA Safety Reporting for CTIMP studies
http://www.hra.nhs.uk/research-community/during-your-research-project/safety-reporting/

8. Appendices

Appendix 8.1: JREOLOG0007 AE report log

Appendix 8.2: JREODOC0012 SAE Reporting form

Appendix 8.3: Safety Report Form (CTIMPs) (HRA)

Appendix 8.1 JREOLOG0007 AE Log

St George's University of London

Adverse Events (AEs) Recording and Reporting Log

St George's University Hospitals NHS
NHS Foundation Trust

Short Study Title:			
Site:		**R&D number:**	
Principal Investigator (PI):		**EudraCT Number:**	

NOTE: ALL AEs *should be recorded on this log unless otherwise agreed in the study protocol. Please continue to record AEs in source data and CRFs as well. This Log must be kept on site for each trial and sent to the trial Chief Investigator for trend analysis at agreed intervals (as per monitoring plan). The Chief Investigator will escalate to Sponsor (via JREO) upon request and report any TSC or DMC subsequent findings and/or recommendations within 3 working days to the JREO governance team*

[1]**Key:** 1 = not related, 2 = Possibly Related, 3 = probably related, 4 = definitely related, 5 = Unlikely (Please note: 2-4 qualifies an AE as an AR)

[2]**Key:** 1 = mild, 2 = moderate, 3 = severe *(Please indicate a document you used to assess severity: Protocol, IB, IMPD or SmPC)*

Patient Trial No.	AE brief description	Is AE Serious? Y/N	Date of Onset	Date of Resolution	Causal Assessment[1]	Severity Grade[2]	Medication given to treat event? Y/N	Verified by CRA Y/N

Date Log was sent to JREO: _____/_____/_____

Appendix 8.2 JREODOC0012 SAE Form

JOINT RESEARCH & ENTERPRISE OFFICE

SERIOUS ADVERSE EVENT REPORTING FORM

Fax to 020 8725 0794 or email adverseevents@sgul.ac.uk within 1 working day of identification of event

Section A: Study Information

Initial Report ☐ or Follow up ☐ number..... ? ☐

STUDY ID:	EudraCT ID	
JREO:	Chief Investigator	Study Site PI:
Sponsor : SGH or SGUL	Rec Reference	

Section B: Patient information

Patient Initials:	Patients Trial/study ID:	
Patient DOB:	Patient Gender M or F	Study arm/Cycle Number
Reporting Site ID:		

Section C: Details of SAE event

Main event or symptom in 1st row followed by any associated symptoms. One MAIN event per form – if two events use two forms	Severity/Intensity Mild/moderate/severe	Date of Onset dd/mm/yy	SAE status 1 = resolved 2= Resolved with sequelae	Date Resolved

		approx. time of onset if available	3= on-going 4= worsened 5 = fatal	dd/mm/yy
Associated Symptoms				
Why was Event Serious? 1 = Resulted in death 2 = Life threatening 3 = Required in-patient hospitalisation or prolongation of existing hospitalisation 4 = Persistent or significant disability/incapacity 5 = Congenital anomaly/defect 6 = Other important medical condition please specify.....		Where did the SAE take place? 1 = Hospital 2 = Out-patient Clinic 3 = Home 4 = Nursing home 5 = Other, specify.....		
Date PI or site was notified or became aware of SAE				

Section D: IMP or Study drug information

Trial drug Frequency and dose as per protocol	Date of 1st administration dd/mm/yy	Date of most recent administration dd/mm/yy	Actual dose given at most recent administration Provide with units and frequency	Route 1 = oral 2 = Intravenous 3= Subcutaneous 4= Intramuscular 5 = other – specify	Causal relationship to SAE 1 = Definitely 2 = Probably 3= Possibly 4 = Unlikely 5 = Not related 6 = Not assessable	Expectedness Was the event one of the recognised undesirable effects of trial medication 1 = expected 2 = unexpected	Action taken due to SAE 1 = None 2= dose reduction 3 = Treatment delayed 4 = Treatment reduced and delayed 5 = Treatment stopped 6 = Code Break (blinded studies only)

Describe Serious adverse event (include manifestation & progression of event any treatments given to any response to the event, including dose and route, and any relevant tests carried out- continue on a separate sheet if necessary)

Diagnostic tests : Please attach reports Number of reports attached ☐

Test Name					
Date					
Normal range					
Result (+ units)					

Section E: Concomitant medication

Concomitant Treatment taken at time of the event/Medication taken to treat event (generic name)	Total Daily Dose	Route 1 = oral 2 = Intravenous 3= Subcutaneous 4= Intramuscular 5 = other – specify	Indication for prescription	Start Date dd/mm/yy	Ongoing 1 = yes 2 = No	End date dd/mm/yy

Do you consider this event likely to have been caused by anything other than the treatments listed previously on this form 1= yes 2 = No If yes specify : including medical history, drug or alcohol abuse, family history or findings from special investigation	☐

Section F: CI or PI information (Signed on delegation log)

Reporting Site Personnel details Name:	Contact details
Signed by Clinician (Responsible person) Print Name :	Contact Number : Date of Completion :

Section G: JREO

JREO Review	Date Checked by Reviewer
SAE ☐ SAR ☐ SUSAR: 7 DAY ☐ SUSAR 15 DAY ☐	SAE Number nb- Enter on PV database
Code Break Requested (for blinded studies Only) by whom:	Date Code break performed: NB- CONSULT PROTOCOL TO CONFIRM WHOM TREATMENT ALLOCATION CAN BE REVEALED TO – DO NOT ATTACH TO THIS REPORT IF COPY RETURNED TO TMF
If SUSAR – Date reported to MHRA	Name & Signature of JREO RGT member :
CI Informed: Y/N	Date CI informed:

Appendix 8.3 CTIMP Safety Report to REC

CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

SAFETY REPORT TO RESEARCH ETHICS COMMITTEE

Please indicate which type(s) of safety report you wish to notify with this cover sheet (tick all that apply). Use a separate sheet for notifications relating to different trials. Please send by email to the main REC for the trial concerned together with enclosures. For further guidance see:

http://www.hra.nhs.uk/research-community/during-your-research-project/safety-reporting/

1. **Expedited report(s) of SUSAR in the UK** ☐
   Notify only Suspected Unexpected Serious Adverse Reactions occurring in the concerned trial at a UK site. SUSAR reports must follow the ICH E2B format.

2. **Annual safety report / DSUR**

   ASRs must follow the ICH E2F format for Development Safety Update Reports(DSUR). Include a global list of all SSARs (Suspected Serious Adverse Reactions) related to the IMP and occurring in the reporting period. ☐

3. **Other**
   For example, report of Data Monitoring Committee or other safety review. ☐

Full title of study:	
EudraCT number:	
Research Sponsor:	
Name of Chief Investigator:	
Name of main REC:	
Main REC reference number:	

Contact details for person making this notification

Name:	
Address:	

Telephone:	
Fax:	
Email:	
Date of this notification:	

List of enclosed documents

Please list each report submitted with this notification (insert extra rows in table as required).

1. Expedited SUSARs (UK only)

Sponsor's report no. / reference	**Trial site**	**Date SUSAR first reported to Sponsor**	**Is this a 7 or 15 day report?**

2. Other reports

Type of report	**Date of Report**

Acknowledgement of receipt by main REC (please insert name):

The [ ] Research Ethics Committee acknowledges receipt of the above.

Signed:	
Name:	
Position on REC:	
Date:	

Signed original to be sent back only to the Sponsor (or other person submitting the report).
Copy to be kept for information by main REC.