St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

Management of Amendments for CTIMPs and non-CTIMP studies Sponsored and/or hosted by St George's

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Approved by:	Mark Cranmer	**Date:**	27.1.17
Signature of Authorisor			

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SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	Original Version	Priscilla Aryee
V2.0	The SOP was updated to ensure that study CIs are aware of their responsibility to sign the approved study protocol following amendment approval from the main REC and MHRA prior to R&D approval being issued.	Ira Jakupovic
V3.0	SOP template updated and version number corrected in line with true document history. Process of amendment approval updated to reflect the new process	Debbie Rolfe

V4.0	Typos corrected and the correct indexing used	Lucy Parker
V5.0	Corrections to process & New logo and name change to FT Trust and change of title to Head of Research Governance	Lucy Parker
V6.0	Reference to JREOWPD0004 MHRA submission format added	Lucy Parker
V7.0	Reviewed and updated to include HRA changes	Anika Kadchha
V8.0	Amendment Template log updated.	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 subsequent amendments thereto set out the legal requirements for notification and approval of 'substantial amendments' arising from Clinical Trials of Investigational Medicinal Products (CTIMPs). To breach these requirements constitutes a breach in criminal law.

Studies that are not considered CTIMPS must still apply for formal approval of any substantial amendments under the terms of the Research Governance Framework.

Amendments are changes made to a clinical trial after a favourable ethical opinion and/or approval by a Competent Authority (*i.e.* HRA/MHRA in UK) has been given (1). Amendments can be made to any information relating to a trial. An amendment to a clinical trial can be either substantial or non-substantial in nature. Substantial Amendments require favourable opinion from the REC that granted a favourable opinion for the trial and from the Competent Authority before they can be implemented. Substantial amendments submitted to REC post 1st April 2016 will also need HRA approval. Once the amendment has been assessed against HRA standards relating to the legal and regulatory aspects of the study, the HRA assessment team will issue a 'Confirmation of Amendment Assessment' letter. After the letter has been issued and relevant REC/MHRA approvals received, the amendment can be implemented. Non -substantial amendments need to be submitted to the HRA only. The HRA will then assess and approve the amendment before implementation at sites. For multi-site studies conducted in the UK, the amendments are further categorised and a presumed implementation following regulatory approval has been adopted. Unless an objection to the amendment within a reasonable time ~ (35 days) is raised the amendment will be implemented.

Amendments have been grouped into 3 different categories –

- A- Amendment to research that ALL participating NHS organisations are expected to consider
- B- Amendment to research that only sites affected by the amendment are expected to consider
- C- Amendment to research that participating sites are not expected to consider

The Sponsor must be aware of all amendments. The JREO, on behalf of St George's (acting as trial Sponsor) reviews and authorises all clinical research that takes place within St George's University Hospital's NHS Foundation Trust (SGHT) and/or St George's, University of London (SGUL).

The JREO must be notified of all amendments made to a clinical trial and confirmation of the continuity of R&D approval must be obtained prior to any amendments being implemented for both Sponsored and/or hosted studies.

The requirements have been incorporated into this Standard Operating Procedure (SOP) to define procedures undertaken by the Sponsor (SGUL) and/or (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 Hospital's NHS Foundation Trust (SGHT). St George's will be the official name used on all SOPs to represent both institutions acting as clinical trials Sponsor.

3. Scope

This SOP covers the management of 'substantial' and 'non substantial' amendments and Urgent Safety Measures.

It also outlines the submission process to the main Research Ethics Committee (REC), Health Research Authority (HRA) and where applicable, the MHRA for approval of substantial amendments and for notification of non-substantial amendments.

This SOP also details actions to be taken by the JREO for amendments submitted for externally-Sponsored studies hosted by St George's.

This SOP details the process for the Chief Investigator (CI)/Principal Investigator (PI) (or delegated trial personnel) conducting clinical trials Sponsored and/or hosted by St George's when undertaking:

- Classification and submission of CTIMP amendments to the JREO
- Submission of non-CTIMP amendments to the HRA and REC

4. Definitions

4.1 Substantial Amendment

A Substantial Amendment to the conduct of a clinical trial may arise from changes to the protocol or from new information relating to the scientific documents in support of the trial.

Amendments to the trial are regarded as 'substantial' when they have a significant impact on:

- The safety or well-being of the trial subjects, or
- The scientific value of the trial, or
- The conduct or management of the trial, or
- The quality and safety of any IMP used in a clinical trial.

4.2 Non-Substantial Amendments

A 'non-substantial' amendment can be defined as a change to the details of a study which will have no significant impact for the trial subjects or the conduct, management or scientific value of a clinical trial. This may be referred to as "minor" or "modified".

4.3 Urgent Safety Measures

An urgent safety measure may be implemented by the Sponsor and/or Investigator in order to protect the trial subjects against any immediate hazard to their health. These safety measures (e.g. temporarily halting the trial) may be taken without prior authorisation from the REC, HRA and/or MHRA.

5. Responsibilities

This SOP is to be followed by the JREO Research Governance team: the Head of Research Governance (HRG), Regulatory Assurance Manager (RAM), Research Governance Officer(s) (RGOs), and the Clinical Trials Monitors (CTM). It is the responsibility of the HRG to ensure that the SOP is updated when necessary.

The assigned Research Governance Team member (RGT) will be responsible for updating ReDA , EDGE (the internal JREO databases) and uploading any documents onto the electronic file.

The RGT will inform the relevant finance contact of amendment processing to facilitate financial reimbursement where applicable or appropriate.

Study type specific responsibilities are:

5.1 Sponsored CTIMPs – JREO Responsibility

a) The CTM or RAM is responsible for submitting substantial amendments of all CTIMPs sponsored by SGHT and/or SGUL to the MHRA, following the initial review of documentation submitted to the JREO. The initial review will be undertaken by both the

CTM and RAM to ensure full knowledge of proposed change and that any change in risk assessment that may affect the monitoring plan is considered.

b) It is the responsibility of the CTM and/or RAM to assess the proposed amendment against the original risk assessment tool to identify whether risk scores originally assigned would change. In the event of changes, the monitoring plan must be reviewed and adjusted as necessary. This process must be documented and kept in the Sponsor Site file.

c) It is the responsibility of the CTM/RAM to forward a copy of the amended documents to the insurance broker to facilitate assurance that insurance conditions, cover and/or premiums have not changed. In the event the insurance assessment does require variation to the cover and/or premiums this must be communicated to the CI immediately.

d) The CTM/RAM is responsible for informing the CI of the outcome of the MHRA submission and also for providing the CI and Research Pharmacy with a copy of approved amended documents.

5.2 Sponsored CTIMP – Investigator Responsibility

a) It is the responsibility of the CI (or delegated personnel) for St George's clinical trials to notify the JREO of all trial amendments throughout the life cycle of a clinical trial. One or more members of the Investigator research team should be named on the study Delegation Log filed in the Trial Master File (TMF) as being responsible for the management and submission of substantial and/or non-substantial amendments to the JREO. The individual responsible for management and submission of amendments must ensure that all documents to be amended are submitted to JREO for initial review and subsequent continuity of R&D approval.

b) The CI (or delegated personnel) is responsible for submitting the substantial amendment documents to the REC and the HRA.

c) The CI (or delegated individual) is responsible for ensuring that all PIs and trials sites are informed of the outcome and that they all receive amended documents and any HRA/REC decision/approval documents. The PIs are responsible for providing all amended documents and approval documents to site support departments (*i.e.* Pharmacy, Laboratory) and for obtaining the necessary Research and Development (R&D) approvals at their respective sites.

5.3 Sponsored non CTIMP – JREO Responsibility

It is the assigned RGT's responsibility to review & approve amendments before they are submitted to REC & HRA for approval and subsequently for R&D approval.

5.4 Sponsored non CTIMP – Investigator Responsibility

It is the CIs responsibility to ensure that non-CTIMP amendments are submitted to JREO for review, to the main REC & HRA for approval and subsequently for R&D approval.

5.5 Hosted Studies – JREO Responsibility

The RAM, HRG, CTM and RGOs are authorised to give written permission on behalf of St George's for amendments to be implemented once all requirements are met. Written permission will be given in the form of an email. Physical letters will not be issued for amendments.

5.6 Hosted Studies – Investigator Responsibility

It is the Investigator's responsibility to ensure that amendments for hosted studies are submitted to the JREO for approval. It is their responsibility to ensure that the changes are not implemented before R&D approval is given.

6. Procedure

6.1 Is the amendment substantial?

The CI should first determine whether the amendment is substantial or non-substantial (see Section 4). If it is not clear to the CI whether the amendment is substantial or non-substantial, advice should be sought from the JREO *via* the assigned RGT. Examples of substantial and non-substantial amendments are also given in Appendix 8.1 of this SOP.

If the proposed amendment is to a CTIMP Sponsored by St George's, the amendment must be discussed with the HRG/RAM and the CTM; this is to ensure that the amendment is correctly classified as either a substantial or a non-substantial amendment.

6.2 Management of substantial amendments to CTIMPs Sponsored by St George's

6.2.1 Investigator Procedure

The procedure outlined in this section should be followed by the CI once he/she classifies a study amendment as substantial. Where possible, supporting documents to accompany the amendment should be submitted in MS Word format.

a) The CI (or delegated person) will complete the appropriate amendment form (Notice of Substantial Amendment) on IRAS. Each proposed study amendment should be submitted using a new form. The first page of the form should clearly identify if the amendment is a:
    - Request for authorisation to MHRA
    - Request for opinion of the REC & HRA
    - Notification for information only to the REC and/or MHRA.

b) The completed form should be either sent to the assigned RGT or sent to the JREO via e-mail to researchgovernance@sgul.ac.uk and entitled 'Substantial Amendment for review'.

c) The form must be accompanied by all relevant version-controlled supporting documents:
    - Any trial document that has been amended e.g. Protocol, Patient Information Sheet (PIS), and Informed Consent Form (ICF). Documents should show both the previous and new wording (Tracked change) and must be version-controlled (i.e. version number and date should be modified)
    - A covering letter detailing the amendment and the rationale to support it

d) If the amendment affects the information previously submitted, an updated XML and PDF file of the MHRA medicines (EudraCT) application form.
    Supporting data for the amendment, including where applicable:
    - summaries of data
    - updated overall risk benefit assessment
    - possible consequences for subjects already in the trial
    - possible consequences for the evaluation of results

e) The CI should submit a copy of all amended documents to the relevant REC for their opinion via IRAS.

f) The CI should check on the HRA website for the most up to date address details for the REC identified on the original study approval letter.

g) The CI should ensure a covering letter is provided to the REC to summarise the amendment details, documents and versions contained within the amendment pack.

h) The CI should log the amendment using the Study Amendments Log JREOLOG0007.

i) The assigned RGT may request further information from the CI. The CI should respond to queries as soon as possible to avoid delays in processing the submission of the amendment to the HRA, REC and MHRA.

6.2.2 JREO Procedure

Once the JREO receives all of the above documents, the amendment must be reviewed against the original risk assessment undertaken for the study to ensure that risk score has not changed. Document the risk assessment findings by endorsing the current monitoring plan with date and 'no change' if relevant, or date and begin work on new monitoring plan in accordance with JREOWPD0008.

A member of the RGT should review the amendment documentation prior to processing further. Once this review has been completed, then the amendment form can be signed electronically within IRAS. The RAM will submit the Amendment Form and supporting documents to the MHRA in the following manner:

a) If MHRA approval required the RAM will convert all documents to PDF versions to submit to the MHRA. The Annex 2 Form must contain an electronic signature of the authorised JREO signatory submitting the amendment in accordance with the JREOWPD0004 MHRA submission format
b) The RAM will complete JREODOC0021 Insurance confirmation and send together with copies of the amended documents to the insurance broker for assessment
c) The RAM will email the PI a copy of all the documents submitted to the MHRA for filing in the TMF (JREOSOP0019) including the covering letter.
d) The RAM will ensure a copy of all documents submitted are filed in the Sponsor Site File.
e) Once the REC, HRA and MHRA approve the amendment, the RAM will notify the CI to implement the amendment by providing him/her with a copy of the appropriate approval letters e.g. REC, HRA and MHRA along with the JREO R&D approval of the amendment which will be in the form of an email. No physical letters will be issued for amendments for studies taking place at St George's.
f) Ensure the amendment log as 6.2.1 (h) above is updated with the relevant approval requirements and dates of approval and a copy is forwarded to both the CI and the lead Research Pharmacist for their files. For multi-site studies or where a CTU/CRO is involved ensure a copy of the completed log and document set is sent.

6.2.3 What to expect from REC, HRA and MHRA

a) The main REC will write within 5 working days to confirm if the notice of amendment is valid. It is anticipated that an ethical opinion will be issued within a maximum of 35 working days from the date of receipt of a valid notice of amendment. The Sponsor may

submit a modified amendment if an unfavourable ethics opinion is received. Modified amendments will be addressed within 14 days.

b) The MHRA will also write within 5 days to acknowledge receipt of a valid amendment notification. MHRA will also review the amendment and issue their opinion within 35 working days from the receipt of an acknowledgement letter.

c) Once the amendment has been submitted to REC, REC will share the documents with the HRA. The HRA Assessment Team will categorise the amendment according to the UK amendments process and inform the CI within 5 days. If there are participating NHS/HSC sites in other nations, the HRA will share the amendment and categorisation with the other participating nations.

d) The CI can then send the amendment and the categorisation information to participating NHS organisations so that, where necessary, arrangements can be put in place to continue the site's capacity and capability to deliver the study. It is the CI's responsibility to communicate the categorisation and the amendment to English sites.

6.2.4 Investigator procedure for dissemination of information following approval of a substantal amendment

Following receipt of the amendment approval letter the CI will ensure that:

a) Actions required by the REC, HRA and MHRA in the approval letter are undertaken (*i.e.* re-consenting patients);

b) The JREO amendment approval email and supporting documentation are filed in the appropriate section of the TMF. Old versions of the amended documents should be filed in the superseded section of the TMF dated and marked as 'superceded'.

For a multi-centre trial, the CI must ensure that:

a) All trial sites, PIs and support departments (if relevant) receive the approval letters and supporting amended documents and that they are all prepared to abide by the changes.

b) PIs inform their respective R&D departments of all amendments and that if required, the host site confirms continuity of host site approval.

c) Staff involved in the study conduct and/or study management are aware of any amendments to the clinical trial and comply with amendments. If the amendment pertains to the protocol, it might be necessary to re-train the trial staff to the protocol. The CI/PI must carefully document that such training is required/has taken place.

d) The CTM may assist the CI with the training on and/or the dissemination of any changes in the protocol or study related documentation to study personnel upon request.

e) Any training conducted or received will be documented on the training log JREOLOG0016 and filed in the TMF/ISF as appropriate.

6.3 Managment of substantial amendments to non-CTIMPs Sponsored by St George's

a) Once the CI has classified the amendment as substantial, the CI will generate the notice of substantial amendment (NOSA) form via IRAS. The CI will submit the NOSA to the JREO *via* the lead RGO before being submitting to REC for review. The NOSA form must be accompanied by all the supporting documentation which includes:

- Any trial documents that have been amended (e.g. Protocol, PIS). All documents should show both the previous and new wording via Tracked changes and must show version control (see Section 6.2.1)
- A covering letter detailing the amendment and the rationale to support it

b) Once REC has issued favourable opinion of the amendment, and HRA has also approved the amendment, the CI must inform the JREO to ensure that continuity of R&D approval is obtained prior to any amendment being implemented. The JREO aim to issue approval within 35 days of receiving a valid amendment application.

6.4 Procedure for reporting non-substantial amendments

- Non-substantial amendments should be reported to the HRA & the JREO by email. Non- substantial amendments that do not require REC review should be submitted by email to hra.amendments@nhs.net using the non –substantial amendment form. The non- substantial amendment form can be found at: www.hra.nhs.uk/resources/during-and-after-your-study/nhshsc-rd-notification-non-substantialminor-amendment-form . The form will need to be submitted to the HRA with any modified documents. There should be clean and tracked changes version of the documents submitted.

Details of non-substantial amendments may be requested at any time. Details of any previous non-substantial amendments must be included when a substantial amendment is next submitted for regulatory approval. Where trial documents are modified as a result of non-substantial amendment, version control should apply, and copies of the updated documents should accompany the letter to JREO and should be included in the changes made with the next substantial amendment to be submitted for approval.

This completed updated Log of amendments JREOLOG0006 and all modified documents highlighting non-substantial changes should be kept in the Investigator Site File (ISF) and

the Trial Master File (TMF) and must be made available upon request for the purposes of monitoring, audit or inspection.

6.5 Management of substantial amendments to studies hosted by St George's

All clinical research studies hosted by St George's and sponsored by external institutions require continuity of host site approval if the study Sponsor decides to implement an amendment.

The RGO will review the supporting documentation to ensure the amendment can be implemented and that appropriate changes/modifications to the study R&D approval are considered. The JREO will require the following documents:

a) REC Amendment Approval Letter – The lead RGO will ensure that the documentation submitted has been approved by REC and that the correct versions have been submitted.
b) HRA Amendment Approval Letter-The RGO will ensure that the documentation submitted has been approved by the HRA and that the correct versions have been submitted.
c) MHRA Approval (if applicable) – The lead RGO will ensure that all amendments for CTIMP studies hosted by St George's received MHRA approval of the amendment. Amendments to PIS and ICFs are usually sent to MHRA for information only. However this will depend on the change being made and will be confirmed by the study Sponsor and/or JREO.
d) Notice/Notification of Substantial Amendment (NOSA) - The lead RGO will review the IRAS Form to ensure that the amendment does not affect the current host site approval in place. The lead RGO will ensure that any supporting departments are aware and agree with changes proposed by the Sponsor.
    - *Agreements Amendment/Authorisations* – If the amendment involves changes related to departmental responsibilities that may have not been agreed initially the Clinical Trial Agreement (CTA) will have to be amended. The lead RGO will ensure that the amended agreement and/or documentation are forwarded to all departments involved, allocating responsibilities and payment details to be agreed prior to any R&D authorisation being issued.
    - *Financial Arrangements* – Any amendments to financial agreements will be reviewed by the relevant JREO Finance contact. Once approved by the finance

team, the RGO will upload the fully executed contract amendment onto the JREO governance database. (EDGE/ReDA)

e) The lead RGO will notify the Investigator and the Sponsor of all internal actions taken to facilitate continuation of host site approval in relation to all amendments submitted to the JREO for trials hosted by St George's.

f) The lead RGO will also ensure that progress is recorded on the JREO governance database. (EDGE/ReDA)

If the amendment is not in compliance with St George's policies and procedures, the lead RGO will inform the PI within a reasonable timeframe by e-mail (no more than 10 working days). If no resolution can be reached, the Trust/University will be unable to authorise the amendment to be implemented and host site approval may be suspended or withdrawn.
If the JREO agrees with proposed changes being made to the trial, the lead RGO will aim to issue the R&D approval of the amendment within 35 days of receipt of all of the above documents and/or any other documents that may require JREO review.

6.6 Investigator procedure for reporting Urgent Safety Measures

It is recommended that the CI/PI contacts the JREO within 24 hours, should they plan to implement or have already implemented any urgent safety measures as defined in Section 4.

Once an urgent safety measure has taken place on site the following procedure must be followed by the CI/PI:

a) Immediately telephone the MHRA Clinical Trials Unit (CTU) and discuss the issue with a medical assessor.

b) Submit a written summary of the MHRA conversation and an agreed action plan within 3 days along with any relevant supporting documentation to notify the REC, MHRA and JREO of the urgent safety measure.

c) CI must ensure all participating sites and support departments such as Research Pharmacy are kept informed of the urgent safety measure and ongoing study participants medical management.

d) File the notification in the ISF or TMF along with all the other documents submitted above.

e) Log the event in the Log of Amendments clearly marking it as an urgent safety measure.

f) Ensure that acknowledgements from all of the above organisations are received and if in doubt telephone the REC, MHRA, and JREO to request acknowledgement of receipt of the event notification.

g) Ensure that any acknowledgements (and/or any other correspondence related to the event reported above) from the REC and MHRA, are forwarded to the JREO.

h) The JREO will ensure that such notifications/acknowledgements are filed in the Sponsor Site File or JREO internal trial drop file

i) Ensure a full amendment is prepared and submitted together with any supporting documentation as described in section 6.2

7. References

NIHR Clinical Trials Toolkit www.ct-toolkit.ac.uk

MHRA
www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/ManagingyourCTA/Amendments/Whattosend/index.htm

HRA www.hra.nhs.uk

8. Appendices

8.1 Examples of Substantial and Non-substantial amendments

8.2 JREOLOG0006; Amendment Log

8.3 JREOLOG0016; Study Training log

8.4 Flowchart of Amendment Process- Studies Sponsored by St George's

Appendix 8.1 Examples of Substantial and non-substantial amendments

Listed below are examples of aspects of a trial where amendments may need to be notified as substantial. This list is not exhaustive. Some of the amendments listed are applicable only to CTIMPS. If in doubt, check with the JREO.

Amendments related to the protocol

- Purpose of trial
- Design of trial
- Informed consent
- Recruitment procedure
- Measures of efficacy
- Schedule of samples
- Addition or deletion of tests or measures
- Number of participants
- Age range of participants
- Inclusion criteria
- Exclusion criteria
- Safety monitoring
- Duration of exposure to the investigational medicinal product(s) (if applicable)
- Change of comparator (if applicable)
- Statistical analysis

Amendments related to the trial arrangements

- Change of the principal investigator or addition of new ones (CTIMPS only)
- Change of the co-ordinating investigator
- Change of the trial site or addition of new sites (CTIMPS only)
- Change of the Sponsor or legal representative
- Change of the CRO assigned significant tasks
- Change of the definition of the end of the trial

Amendments related to the IMP (if applicable)

- Changes to investigational medicinal product quality data concerning:
- Change of name or code of IMPs

- Immediate packaging material
- Manufacturer(s) of active substance
- Manufacturing process of the active substance
- Specifications of active substance
- Manufacture of the medicinal product
- Specification of the medicinal product
- Specification of excipients where these may affect product performance
- Shelf-life including after first opening and reconstitution
- Major change to the formulation
- Storage conditions
- Test procedures of active substance
- Test procedures of the medicinal product
- Test procedures of non-pharmacopoeia excipients

Changes to non-clinical pharmacology and toxicology data where this is relevant to the ongoing trials (i.e. altered risk: benefit assessment)

For example concerning:

- Results of new pharmacology tests
- New interpretation of existing pharmacology tests
- Result of new toxicity tests
- New interpretation of existing toxicity tests
- Results of new interaction studies

Changes to clinical trial and human experience data where this is relevant to the ongoing trials (i.e. altered risk: benefit assessment)

For example concerning:

- Safety related to a clinical trial or human experience with the investigational medicinal product
- Results of new clinical pharmacology tests
- New interpretation of existing clinical pharmacology tests
- Results of new clinical trials
- New interpretation of existing clinical trial data

- New data from human experience with the investigational medicinal product
- New interpretation of existing data from human experience with the investigational medicinal product

Examples of non-substantial amendments might be as follows:

- correction of typographical errors in the protocol or other study documentation
- other minor clarifications of the protocol
- updates of the Investigator's Brochure (unless there is a change to the risk/benefit assessment for the trial)
- changes to the Chief Investigator's research team (other than appointment of key collaborators)
- changes to the research team at particular trial sites (other than appointment of a new Principal Investigator)
- changes in funding arrangements
- changes in the documentation used by the research team for recording study data
- changes in the logistical arrangements for storing or transporting samples
- extension of the study beyond the period specified in the application form

Appendix 8.2

AMENDMENT LOG

Short Study Title:			IRAS ID:	
Site:		JREO number:		
Chief Investigator (CI):		EudraCT Number:		
Initial approvals:	MHRA: R&D: REC: HRA:	Protocol Date & Version Approved:		

Amendment Code/ Number	Date of Amendment (dd/mm/yy)	Classification		Purpose of Amendment (HRA classification)	Date Approved (dd/mm/yyyy) or acknowledged (NSA)				
		Substantial	Non Substantial		Document New Version Date & number	JREO	REC	MHRA	HRA

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Appendix 8.3

STUDY TRAINING LOG

Reason for Training :	
Study Name & Protocol Number (JREO number):	
Date:	
Name of Trainer & Study Role:	
Purpose of Training (include details of what sections of the study protocol and/or study procedures trained)	

The following study personnel listed below attended the training as detailed above
*The Chief Investigator / Principal Investigator/ Lead Investigator * delete as appropriate confirms that the study personnel have received adequate training prior to performing any study protocol related activities*

Study Personnel Name (PLEASE PRINT)	Position	Institution	Signature

Signed: _____ Date: _____ (Trainer) Signed: _____ Date: _____ (CI/PI

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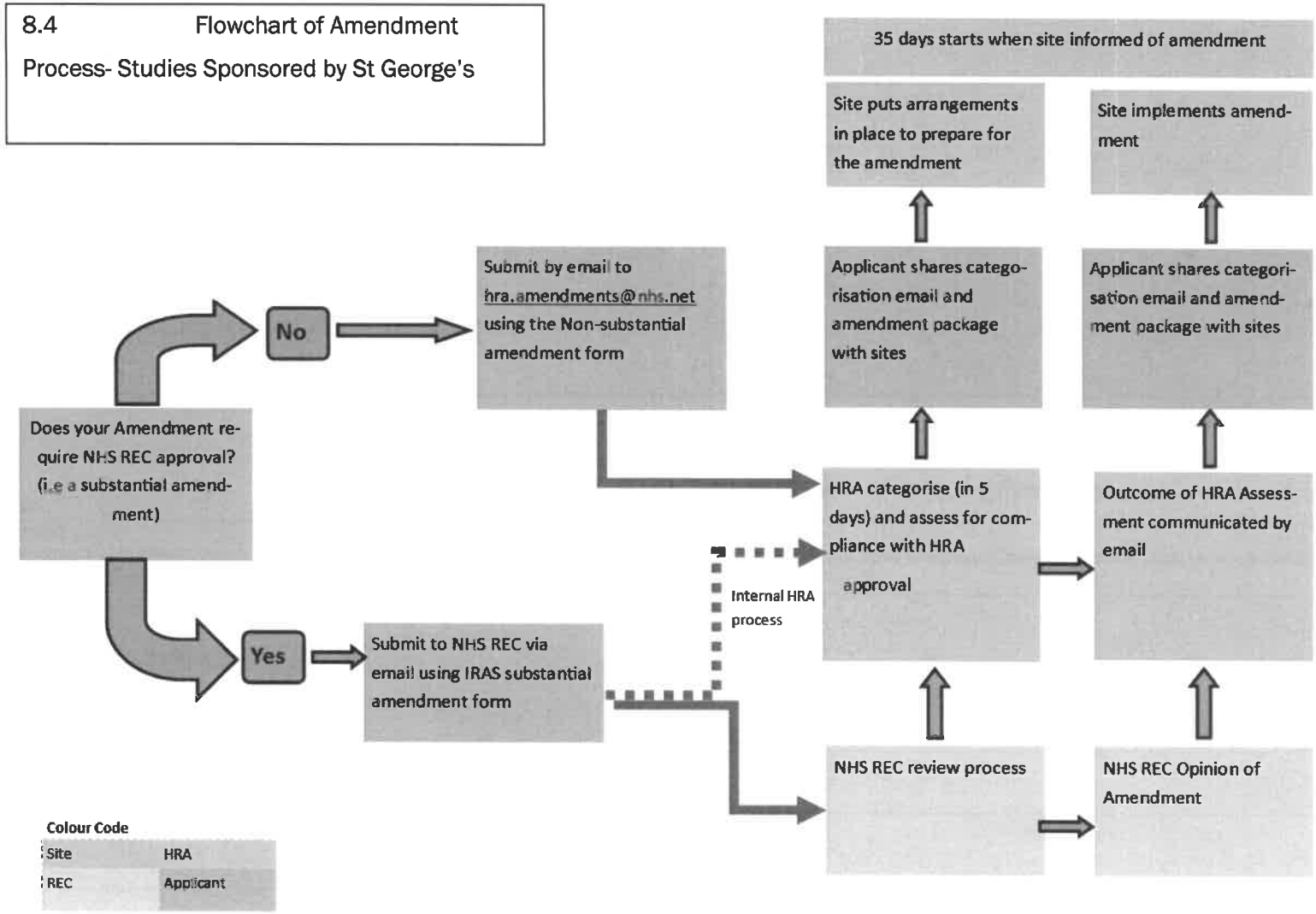
8.4 Flowchart of Amendment Process- Studies Sponsored by St George's



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