Standard Operating Procedure for Recruitment Closure, End of Trial Notification and Trial Close-Out

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Revision Chronology:			
Version Number	**Effective date**	**Reason for change and Summary of changes**	**Author**
01	09/Jan/2006		Faye Owen
02	05/Mar/2010	1. Template change 2. CTC procedural review	Joanne Rickett
03	02/May/2012	• Update to new SOP template • Inclusion of timelines for end of trial declaration • Clarifications made to procedure section • Removal of obsolete associated templates and addition of a new tracking spreadsheet	Allan Hackshaw and Rachel Partridge
04	11/Nov/2015	• Planned review • Inclusion of procedure on closure of trial recruitment • Addition of section on temporary halt in trial • Minor clarifications made throughout procedures section • Addition of reference to end of trial report submission to EudraCT for CTIMPs	Nicky Gower
05	11/Nov/2015	• Minor administrative change from v4	Nicky Gower
06	30/Nov/2018	• Clarification on site closure before the end of a trial: i.e. If changes to the Principal Investigator (PI) or site personnel result in the investigational site being unable to meet obligations to conduct the trial per protocol and/or per local regulation(s) then recruitment should be suspended or stopped. A site can only be closed when all patients enrolled at the investigational site have completed participation in the trial.	Nicky Gower

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		• **In the event that the end of trial declaration has not yet been submitted, but a site is to be closed, notification for site closure must be sent to HRA as a non-substantial amendment.** • **More detail provided on trial close-out procedure for non-UCL sponsored trials** • **Clarification of requirements for end of trial reporting including guidance for notifying EC and/or CA if end of trial reporting will be delayed.**	

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ACRONYMS:	
AE	Adverse Event
CA	Competent Authority
CCC	Country Coordinating Centre
CI	Chief Investigator
CLS	Country Lead Site
CTA	Clinical Trial Authorisation
CTC	CR UK and UCL Cancer Trials Centre
CTIMP	Clinical Trial of an Investigational Medicinal Product
EC	Ethics Committee
EU	European Union
EUCTD	European Clinical Trials Directive 2001/20/EC
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
IDMC	Independent Data Monitoring Committee
ISF	Investigator Site File
PI	Principal Investigator
PSF	Pharmacy Site File
SDV	Source Data Verification
SI	Statutory Instrument
SOP	Standard Operating Procedure
STC	Senior Trial Coordinator
TC	Trial Coordinator
TGL	Trials Group Lead
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

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Standard Operating Procedure for Recruitment Closure, End of Trial Notification and Trial Close-Out

PURPOSE

This Standard Operating Procedure (SOP) describes the procedures for:

- managing recruitment closure,
- formal notification to the relevant Competent Authorities (CAs) and Ethics Committees (ECs) of the end of a trial; and
- closure of a participating investigational site(s),

by the Cancer Research UK and UCL Cancer Trials Centre (CTC), where the CTC has been delegated these duties by a sponsor.

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CTC SOP POLICY

All SOPs produced in the CTC must be used in conjunction with applicable UCL policies and procedures.

Central CTC SOPs are written in accordance with applicable Good Clinical Practice (GCP) requirements as outlined in Directives 2001/20/EC and 2005/28/EC (in the UK these Directives were transposed into UK law by Statutory Instrument (SI) 2004/1031 **(Reference 1)**, SI 2006/1928) and subsequent amendments and, where applicable, incorporate elements of International Conference on Harmonisation (ICH) GCP tripartite guidelines (E6) **(Reference 2)**.

The EU Clinical Trials Regulation (EU No 536/2014) entered in to force on 16 June 2014 **(Reference 3)**, but does not apply at the time of this SOP release. This SOP will be reviewed prior to the regulation coming into effect, which may be before the next planned SOP review date.

See CTC/04/T01 Standard Operating Procedure for the Preparation, Review, Approval and Release of Central CTC Standard Operating Procedures for the full SOP policy **(Referenced SOP 1).**

BACKGROUND

The definition for the end of a trial must be included in the trial protocol. Any change to this definition is submitted for approval by the CA (CTIMP only) and EC as substantial amendment to the protocol.

Applicable international and/or local procedures must be followed for the formal, written notification of the end of a trial (including premature end).

End of Trial Notification:

For trials involving an investigational medicinal product(s) (CTIMPs) conducted within The European Union (EU), the European Clinical Trials Directive 2001/20/EC (EUCTD) requires the sponsor to notify relevant CAs and ECs in writing that the trial has ended, within 90 days of the defined end of trial. If the trial is terminated early, the deadline for notification is within 15 days of the trial ending. **(References 4, 5 and 6).**

For non-CTIMPs notification is made to the relevant EC(s) only.

For trials involving international sites, notifications to EC, and CA where applicable, outside the UK at the end of a trial may be undertaken (if delegated in written agreement) by the Country Coordinating Centre (CCC)/Country Lead Site (CLS)).

SCOPE OF THIS SOP

The end of trial notification process commences when the trial ends, either per protocol definition or prematurely, and finishes when the required notification procedures to relevant CAs and ECs and follow up actions are complete. This SOP also covers the procedures for;

- a temporary halt in a trial
- the closure of a site that did not open to recruitment
- the closure of recruitment within a trial before full trial closure.

The procedure for site close-out commences with the notification of site closure and ends when all follow up activities that render the site closed are resolved and a formal site closure letter is issued, which advises on archiving activities.

RESPONSIBLE PERSONNEL

It is the responsibility of the Senior Trial Coordinator (STC) and/or Trial Coordinator (TC) to ensure that the appropriate CAs and ECs are informed of the end of a trial and that site close-outs are undertaken. Additional responsibilities are outlined in the procedure section.

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PROCEDURE

1. Closing a Trial to Recruitment

The decision to close a trial to recruitment will be taken in discussion with the Chief Investigator and/or Trial Management Group. Planning should start as protocol recruitment targets are close to being achieved. Recruitment closure may also be required before recruitment targets are met, see sections 1.2 & 1.3 below.

Section no	Procedure	Responsibility
1.1	**UCL Sponsored Trial:** Discuss arrangements for planned recruitment closure of a trial with the Chief Investigator (CI)/Trial Management Group (TMG), including the trial statistician. **Non UCL Sponsored Trial:** Receive instructions form Sponsor and discuss arrangements for planned recruitment closure with relevant individuals (depending on CTC's delegated role in the trial).	TGL STC/TC
1.2	Notify all trial sites of planned recruitment closure via email using formal letter, and requesting acknowledgment of receipt. Letter should include (where relevant): • Date of closure to recruitment • Actions regarding approaching remaining patients and/or patients that may already have been approached • Requirements for follow-up • Anticipated trial closure date • Instruction to sites to forward letter appropriately within the site (e.g. to local R&D department)	TGL/STC/TC
1.3	Notify all other relevant organisations involved in the trial of planned recruitment closure (sponsor, funder(s), drug supplier(s), drug distributer(s) etc).	STC/TC
1.4	Inform all contacts for relevant websites (ISRCTN, Cancer Help, UKCRN etc.) of status change to ensure details of trial are current.	STC/TC

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Section no	Procedure	Responsibility
1.5	Develop a tracking system that is maintained until all acknowledgements of receipt are received.	STC/TC
1.6	The status of the trial on the CTC trials database should be updated.	STC/TC
1.7	Ensure that all correspondence is filed in the trial closure section of the eTMF/TMF as per CTC/05/T03 Standard Operating Procedure for CTC Trial Master Files **(Referenced SOP 3)**.	STC/TC
1.8	When a trial closes to recruitment, update the details on the CTC website and remove any trial documents that are no longer needed by sites. Please refer to the UCL CTC policy on uploading information to the CTC website for details **(Referenced CTC Policy 1)**	STC/TC

2. Closing a Trial to Recruitment – temporary halt

Section no	Procedure	Responsibility
2.1	**For the temporary halt of a trial:** In the event of a decision to temporarily halt recruitment to a trial (e.g. by the TMG/IDMC), document the decision fully in the eTMF/TMF. Prepare documentation to be sent to sites/patients (if applicable) and notify the MHRA and REC of a temporary halt in recruitment by submitting a substantial amendment (see CTC/12/T71 Standard Operating Procedure for Preparing, Submitting, Processing and Disseminating Amendments **(Referenced SOP 4)**). This must be done immediately, and at the latest within 15 days of the halt. If the trial is re-opened a further amendment must be submitted and approval received before re-opening the trial. If the decision is made not to recommence the trial, document the decision and notify the MHRA and REC within 15 days of the decision using the end of trial declaration form. Follow relevant instructions from **section 3**.	TGL/STC/TC

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NB: For trials not involving an IMP, all of the following procedures apply with the exception of informing the CA and IMP return/destruction

3. Prior to Notification of the End of a Trial

The decision to end the trial (and cease all follow up) will be taken in discussion with the Chief Investigator and/or Trial Management Group (and/or with the sponsor for non UCL sponsored trials), and in line with protocol requirements.

Section No	Procedure	Responsibility
3.1	Obtain confirmation and/or approval from the Chief Investigator (CI)/Trial Management Group (TMG), including the trial statistician, that the trial can be closed.	TGL/STC/TC
3.2	**For premature/early termination:** Ensure any additional information relating to the rationale for early termination including statements from the IDMC/Trial Steering Committee (TSC), where applicable, is obtained and filed. • Obtain information and advice regarding future management of trial patients following early termination (when required). • Prepare documentation to be sent to sites/patients following early termination of a trial and obtain any relevant approval/favourable opinion(s) from the CAs (CTIMPs only) and ECs. If the trial has been terminated prematurely due to an Urgent Safety Measure, please also refer to SOP CTC/08/T60 Standard Operating Procedure for Reporting Urgent Safety Measures **(Referenced SOP 5)**.	TGL/STC/TC
3.3	**For trials involving international sites**: Compile information on all international/national requirements for the notification of the end of a trial, identifying details of all CAs and ECs, timelines and documentation requirements. Develop a tracking system that is maintained until all notifications are submitted and accepted.	TGL/STC/TC
3.4	Notify relevant drug suppliers (if applicable) when drug supply is to end.	TGL/STC/TC

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Section No	Procedure	Responsibility
	Notify all involved third party organisations of planned trial closure. Ensure all contractual obligations are met.	
3.5	Prepare the **end of trial notification documentation** in accordance with international and/or local requirements. Arrange for the documentation to be reviewed and approved by the STC/TGL. For end of trial notification for CTIMPs within the EU, the notification form is available on the HRA website **(Reference 7)**. In the UK the completed form should be submitted to the REC and MHRA within 90 days of the end of the CTIMP. In the UK, for non-CTIMPs the 'declaration of the end of a study' form is available on the HRA website, and should be emailed to REC within 90 days of the end of the non-CTIMP **(Reference 7)**.	TGL/STC/TC
3.6	Ensure all outstanding data are collected. See sections 8.1 and 8.2.	TGL/STC/TC

4. Submission of the Notification of the End of a Trial to Relevant Authorities

Section No	Procedure	Responsibility
4.1	For EU trials, submit the end of trial notification **(see section 2.5)** and required documents to all relevant ECs and/or CAs	TGL/STC/TC
4.2	**For trials with international sites**: Distribute the end of trial notification documents to the respective CCCs/CLSs and provide any specific instructions and timelines for submission to CAs and ECs (where this has been delegated in the relevant agreements). Maintain tracking system of submissions & approvals, and follow up with CCCs/CLSs on a regular basis until process complete.	TGL/STC/TC
4.3	The CTC trials database should be updated.	STC/TC

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5. Completion of the Notification of the End of Trial Activities

Section No	Procedure	Responsibility
5.1	Ensure that all submission and acceptance and/or approval documentation is received from relevant RAs and/or ECs, and filed in the CTC Trial Master File (TMF).	STC/TC
5.2	Inform the sponsor that all the end of trial notification activities are complete (for UCL sponsored trials see JRO/SPON/S04 Standard Operating Procedure for UCL Sponsorship of Clinical Trials and Studies managed by UCL affiliated CTUs for details **(Referenced SOP 6)**). Copy the email to the CTC regulatory team (ctc.regulatory@ucl.ac.uk) and the CTC Pharmacovigilance team (ctc.pharmacovigilance@ucl.ac.uk). If applicable, the CI/trial statistician preparing the clinical trial report should also be notified that all the end of trial notification activities are complete.	STC/TC
5.3	Inform all contacts for relevant websites (ISRCTN, Cancer Help, UKCRN, UCL CTC etc.) to ensure details of end of trial are added.	STC/TC
5.4	Ensure all CTC databases are updated with the information that the trial is closed.	STC/TC

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6. End of Trial Reporting

End of trial reports should be produced within 6 months of the declaration of End of Trial for paediatric clinical trials and within one year for non-paediatric clinical trials.

Section No	Procedure	Responsibility
6.1	**End of Trial reporting - CTIMPS** Posting and publishing of clinical trial results in EudraCT **(see section 7)** is considered as the submission of the clinical trial summary report as part of the end of trial declaration to CAs and ECs. **Note**: In the UK, a download of this report should also be emailed to the REC. **(Reference 7).** The MHRA also request you send a short confirmatory email to CT.Submission@mhra.gov.uk once the result-related information has been uploaded to EudraCT, with 'End of trial: result-related information: EudraCT XXXX-XXXXXX-XX' as the subject line. You will not get an acknowledgment email or letter Requirements for trial results for trials involving international sites outside the EU should be clarified with the CCCs/CLSs.	STC/TC
6.2	**End of Trial reporting - Non- CTIMPs** In the UK, a report should be emailed to the REC. **(Reference 7).** Requirements for reporting results for studies involving international sites should be clarified with the CCCs/CLSs.	STC/TC
6.3	In the event of a likely delay in the reporting of trial results must be communicated in writing to the CA and EC. In the UK the MHRA have requested that a courtesy email is sent in instances where posting of results will be delayed. The courtesy email should be sent to clintrialhelpline@mhra.gsi.gov.uk. A second email should be sent to ct.submission@mhra.gsi.gov.uk.	STC/TC

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	These emails should be forwarded to ctc.regulatory@ucl.ac.uk	
6.4	If applicable, provide reports/research findings/data to relevant third parties, where contractually agreed (e.g. drug supplier(s) where agreed in the drug supply agreement).	STC/TC
6.5	Summarise and relay findings to sites for patients where applicable. In the UK the HRA require that copies of the end of study information sheets which have been provided to participants should be included with the final report sent to REC.	STC/TC

7. Submission of Clinical Trial Results in EudraCT (CTIMPS only)

As of 21st July 2014, it became mandatory for sponsors of CTIMPs to post clinical trial results in the European Clinical Trials Database (EudraCT). Summary results will become available to the public **(Reference 8).**

Sponsors are now obliged to post results in EudraCT for any interventional trials registered in EudraCT **within 6 months of the declaration of End of Trial for paediatric clinical trials and within one year for non-paediatric clinical trials.** For details on how to register a trial on EudraCT and to prepare and post results refer to the 'Getting started with EudraCT to prepare and post results' training slides on the EudraCT Training webpage **(Reference 9)**.

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Section No	Procedure	Responsibility
7.1	Register on EudraCT to post results (see above)	TC/STC
7.2	The data must be uploaded by the trial statistician or delegate and TC/STC following a pre-determined dataset that has been compiled by the EMA and is detailed in the Technical Guidance on the Format of the Data Fields of Result-related Information on Clinical Trials **(Reference 10 and 11)**.	TC/STC/Trial Statistician
7.3	The full dataset contains information regarding the number of participants, the study design, endpoints, adverse event (AE) information, and the statistical findings. Details of any substantial amendments submitted in the trial will also need to be included.	TC/STC/Trial Statistician

Section No	Procedure	Responsibility
7.4	In addition, a summary report can be added (for extra detail) as a PDF; this will also be made available to the public.	TC/STC/Trial Statistician
7.5	Once the data are uploaded it must be validated. Validating will ensure that all information has been completed accurately and all mandatory information included **(Reference 12)**.	TC/STC/Trial Statistician
7.6	Once the data are validated the TGL/STC should be notified. The validated information should be reviewed by the TGL/STC and once they are satisfied with the information the results should be posted to EudraCT.	TC/STC/Trial Statistician/TGL
7.7	The TGL/STC/TC should print the proof of upload and file in the TMF/eTMF alongside the PDF copy of the report which can be saved and printed from EudraCT.	TC/STC/TC, Trial Statistician
7.8	The CTC trials database should be updated.	STC/TC

8. Site Close Out

Site close-out is performed upon completion, premature termination (for example, due to Independent Data Monitoring Committee (IDMC) decision or an Urgent Safety Measure), or cancellation of a trial.

Additionally, an individual investigational site may be closed before the completion of a trial for example for one or more of the following reasons:

- No patients have been, or will be, recruited;
- All patients enrolled at the investigational site have completed participation in the trial (for example, all patients at the trial site are deceased so there will be no further safety data to collect at the site) but, due to the nature of the trial, the defined end of trial may not be reached for a significant period of time.

Note: In these instances the end of trial declaration would not have been submitted, therefore notification for site closure must be sent to HRA as a non-substantial amendment **(Reference 6)**. Where a site is closed before the end of the trial, the site must be notified when the trial ends and the archiving period begins.

Generally, site close-out is coordinated remotely by the CTC. For early phase trials an on-site closure visit may be undertaken, if considered necessary and/or required by the trial monitoring plan. The site close-out arrangements are based on the trial Monitoring Plan and any applicable contract/agreement(s) with the local institution/Country Coordinating Centre/Country Lead Site (CCC/CLS).

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8.1 Safety Reporting Reconciliation and Key Data Collection

Section No	Procedure	Responsibility
8.1.1	Follow up any outstanding questions or information for Serious Adverse Events (SAEs), pregnancies and confirm that the relevant authorities and sponsor have been notified, where required. If trial is just closing to recruitment, continue to follow up data from all active patients as well as those in follow up.	STC/TC/ Monitor
8.1.2	Check all site incidents in the incident database are closed and a corresponding incident report is provided where necessary. See CTC/10/T69 – Standard Operating Procedure for Incident Reporting (**Referenced SOP 8**).	
8.1.3	Remind the Principal Investigators that follow-up queries for SAEs, pregnancies and incidents may still be generated and will require prompt resolution when received.	
8.1.4	Collect, review and resolve all outstanding patient data queries with sites that are required for the main trial analyses. If it is not possible to fully resolve an issue, discuss with the TGL/STC/Trial Statistician and, if appropriate, produce a file note to explain why the query has been left unresolved.	STC/TC/ Monitor/TGL

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8.2 Investigational Medicinal Product (IMP) Return/Destruction (CTIMPS only)

Section No	Procedure	Responsibility
8.2.1	Obtain the final drug accountability log(s) from all sites. Confirm that supplied drugs were dispensed only to trial patients.	STC/TC/ Monitor
8.2.2	Ensure any drug accountability/reconciliation discrepancies identified are clearly documented.	STC/TC/ Monitor
8.2.3	If applicable, arrange for all supplied IMP remaining at site – both used and unused – to be returned to the drug supplier or destroyed, in accordance with the trial protocol and/or drug supply agreement.	STC/TC/ Monitor

Section No	Procedure	Responsibility
8.2.4	Obtain a copy of the drug destruction records for supplied IMPs if destruction is performed at site.	STC/TC/ Monitor
8.2.5	Provide IMP reconciliation updates/destruction confirmations to relevant drug supplier, where contractually agreed in drug supply agreement.	STC/TC

8.3 Other Trial Supplies, Laboratory Samples and Materials

Section No	Procedure	Responsibility
8.3.1	Retrieve, arrange for return, or authorise destruction of any unused trial-related supplies and materials (not including IMP), as appropriate.	STC/TC/ Monitor
8.3.2	Ensure any biological samples remaining on site are shipped to the appropriate laboratory/designated destination (if applicable).	STC/TC/ Monitor
8.3.3	If samples are to be disposed of on site, ensure that this is undertaken as per protocol requirements.	STC/TC/ Monitor
8.3.4	Verify that final transmissions have occurred for all central data reviews e.g. pathology reviews, PET scans etc. (if applicable).	STC/TC/ Monitor

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8.4 Site Closure Documents

Section No	Procedure	Responsibility
8.4.1	Conduct site Close-out visit(s) where required by the trial Monitoring Plan **(Referenced SOP 2).**	STC/TC/ Monitor
8.4.2	Prepare Site Closure Documents, which includes: • Trial Site Closure Notification Letter **(Associated Template 1)** • Relevant site checklists adapted from *Investigator/Pharmacy/ATIMP Management Site File Checklist* **(associated template to Referenced SOP 2)**	STC/TC/ Monitor

Section No	Procedure	Responsibility
8.4.3	Review the last on-site monitoring report or site close out visit report (if applicable) and other site correspondence with outstanding issues or follow up actions identified and ensure these are addressed during or prior to close out.	STC/TC/ Monitor
8.4.4	Submit Site Closure Documents to contacts (main trial contact and pharmacy contact) at relevant site(s). Develop a tracking system for the receipt of the accountability log, delegation log, and any other trial specific document/equipment required by the CTC, that is maintained until all sites are closed **(Associated Template 2).** **For international trials,** submit closure pack and any other supporting documents to CCCs/CLSs for coordination of activities.	STC/TC
8.4.5	Check the status of trial-related payments to sites and arrange for any outstanding invoices to be processed in a timely manner as per contract (if applicable).	STC/TC
8.4.6	Inform other relevant parties of the scheduled close-out, for example central laboratories, drug suppliers, etc. **Note:** Closure of central laboratories should be discussed with the regulatory team.	STC/TC

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8.5 Site Personnel and Facilities

Section No	Procedure	Responsibility
8.5.1	Collect a copy of the local R&D notification and confirmation email/letter of site closure (if available).	STC/TC/ Monitor
8.5.2	Obtain the final version of the site delegation log (and pharmacy log if separate).	STC/TC/ Monitor
8.5.3	Obtain written confirmation from sites that documents held in their ISF/PSF are up-to-date according to the document version checklists provided, or, if completed checklists are returned	STC/TC/ Monitor

Section No	Procedure	Responsibility
	ensure that any required documents are provided to the site. If necessary to send missing documents to sites, ensure that the site confirms receipt.	
8.5.4	Once any outstanding issues are resolved, send Formal Site Closure Letter **(Associated Template 3)** to the Investigator to confirm: • that the site is closed • when trial related documents can be archived, and any trial-specific requirements for archiving • that post-trial audits and/or regulatory inspections may be conducted • that the Investigator should notify the Sponsor immediately if notified of a forthcoming inspection by a CA NB: If sites are closed before the End of Trial declaration, they will need to be notified at End of Trial to allow for correct archiving timelines.	STC/TC
8.5.5	Following closure of all sites all trial documents should be removed from CTC website and the details updated **(Referenced CTC Policy 1).**	STC/TC

9. Archiving

Section No	Procedure	Responsibility
9.1	Archive all CTC essential documents related to the procedure according to CTC/07/T18 Standard Operating Procedure for Archiving **(Referenced SOP 7)**.	STC/TC

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REFERENCES

1. The Medicines for Human Use (Clinical Trials) Regulations 2004 http://www.legislation.gov.uk/uksi/2004/1031/contents/made

2. ICH Topic (E6) guideline for Good Clinical Practice http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf

3. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC http://ec.europa.eu/health/human-use/clinical-trials/regulation/index_en.htm

4. Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1) http://ec.europa.eu/health/files/eudralex/vol-10/2010_c82_01/2010_c82_01_en.pdf

5. HRA website http://www.hra.nhs.uk/

6. NRES Standard Operating Procedures for Research Ethics Committees http://www.hra.nhs.uk/resources/research-legislation-and-governance/standard-operating-procedures/

7. HRA website – Ending your project https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/

8. Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf

9. Training on EudraCT results https://eudract.ema.europa.eu/training.html

10. Validation rules for posting result related information https://eudract.ema.europa.eu/docs/userGuides/EudraCT%20V9%20Results%20Validation%20Rules%20Supplementary%20Specification.pdf

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11. Technical Guidance on the Format of the Data Fields of Result-related Information on Clinical Trials
http://ec.europa.eu/health/files/eudralex/vol-10/2013_01_22_tg_en.pdf

12. EudraCT Result Related Information: Validate results
https://eudract.ema.europa.eu/result.html

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REFERENCED SOPs

1. CTC/04/T01 Standard Operating Procedure for the Preparation, Review, Approval and Release of Central CTC Standard Operating Procedures

2. CTC/10/T13 Standard Operating Procedure for Monitoring and Oversight of Clinical Studies

3. CTC/05/T03 Standard Operating Procedure for CTC Trial Master Files

4. CTC/12/T71/01 Standard Operating Procedure for submitting, processing and disseminating amendments

5. CTC/08/T60 Standard Operating Procedure for Reporting Urgent Safety Measures

6. JRO/SPON/S04 Standard Operating Procedure for UCL Sponsorship of Clinical Trials and Studies managed by UCL affiliated CTUs

7. CTC/07/T18 Standard Operating Procedure for Archiving

8. CTC/10/T69 – Standard Operating Procedure for Incident Reporting

REFERENCED POLICIES

1. CR UK & UCL Cancer Trials Centre (CTC) policy: Uploading Information to the CTC Website

ASSOCIATED TEMPLATES

1. Trial Site Closure Notification Letter

2. Site Closure Tracking Log

3. Formal Site Closure Letter

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Author: Nicole Gower – Regulatory Manager

Signature: Nicole Gower.

Date: 12/11/2018

Authorised by: Roisin Beehag – Regulatory Manager- Quality

Signature: R Beehag

Date: 12/11/18

[Must be signed and dated by both parties before the SOP can be made effective.]

CONTACT LIST

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