RECAST-3 – Working Practice Document

Title: Site Closedown, No. 010

Introduction

To ensure that the RECAST-3 trial is closed down in accordance with Good Clinical Practice (GCP) and regulatory requirements, it is mandatory for each centre to follow the closedown procedures as described in this document. The Sponsor of RECAST-3 (University of Nottingham) has agreed a procedure to allow the closedown of RECAST-3 centres remotely, using the RECAST-3 Closedown Checklist (see Appendix 1 for an example).

Purpose of this document

To define the procedure for closing out centres participating in the RECAST-3 trial and ensure all essential documentation for RECAST-3 is complete and archived to demonstrate compliance with GCP. To outline the responsibilities of the PI to ensure the requirements have been met.

Scope of this document

This document is applicable to all PIs, research team members and staff from the coordinating centre delegated the responsibility of ensuring that the closedown procedures outlined in this document are carried out in accordance with Sponsor requirements and GCP.

Essential documentation and archiving

It is a GCP requirement that the essential documentation is reviewed prior to the closedown visit (where appropriate);

"trial master files should be established at the beginning of the trial, both at the investigator/institution site and at the sponsor's office" ICH-GCP-E6

The trial Sponsor Standard Operating Procedure (SOP QA005 Archiving) defines that for a multi-centre trial "documents and electronic data should be retained locally to allow reconstruction of the trial at that site. Only one copy of each document needs to be retained. Electronic documents and databases should be transferred onto a suitable storage medium and archived as for paper documents".

Archiving

The trial Sponsor Standard Operating Procedure (SOP QA005 Archiving) states that "archiving of research data shall be for a **minimum of seven years after the date of any publication that is based on them**". The publication date will be confirmed at the end of the trial and the coordinating centre will inform sites when archiving should be undertaken in accordance with local archiving protocols. note that the PI at each hospital site will need to ensure that responsibility for archiving is delegated to a named individual. The PI is also obliged to notify R&D of any change of ownership of the Investigator Site File (ISF). Audits by trial sponsors, competent authorities or local boards can occur for this trial for the duration of the archiving period.

End of randomisation

A trial centre will not be closed until all trial data is complete and any queries have been resolved for all patients randomised into the trial.

Return of RIC/Sham devices
RIC/sham devices used for the RECAST-3 trial must be removed from clinical areas following the end of trial recruitment and returned to the co-ordinating centre in Nottingham.

Payments
Any centre payments due will only be paid once all documentation is received. Sites will be informed of the end of trial date and invoices should be sent no later than 3 months before.

Closedown procedure
The RECAST-3 Closedown Monitoring Checklist (see appendix 1 for an example) must be completed, signed and returned to the Trial Coordinating Centre (RECAST-3@nottingham.ac.uk) to confirm that all the essential documentation is present and ready to be archived at your site.

The PI is responsible for all patient related data, regulatory and trial correspondence and patient records being archived appropriately. The responsibility may be delegated but the list must be checked and signed off by the PI.

Every attempt should be made to ensure that all missing documents are found and present in the file before archiving. If a document is deemed to be unrecoverable a file note should be added to the appropriate section and noted on this document.

Once the end point of the trial has been reached, the PI must notify R&D or any other appropriate bodies.

Please note that whilst we intend to ensure that all data checks are complete prior to closedown, please be aware that there may still be some outstanding queries that will require your attention after the closedown paperwork has been submitted. We will do our best to ensure that these are, if any, kept to a minimum.

Appendix 1

RECAST-3 Closedown Monitoring Checklist (Example)

This checklist must be completed by a person delegated this role on the RECAST-3 trial delegation log. The PI (or a responsible person in R&D if no PI remains) must countersign the form and return it to the Trial Coordinating Centre (RECAST-3@nottingham.ac.uk) in order to complete closedown for your site. Each item must be initialled. Once completed and signed, this checklist provides documented proof that all activities required for your centre closedown are completed and copies of all essential documents are held in the appropriate files in accordance with Good Clinical Practice and sponsor requirements.

Centre Name: …… **Centre Number: C……** **Name of PI: …….**	**Number of RECAST-3 Patients recruited** **_____** **(See online recruitment list)**

Reason for closedown:				
		Initials		
Essential documentation required for closedown and archiving		YES	NO	N/A
INVESTIGATOR SITE FILE (ISF) contains:				
• Latest contact details of trial office & emergency numbers.				
• Latest Trial delegation log • All previous versions of delegation log				
• Signed & dated CVs (for everyone listed on the delegation log)				
• GCP certificates for all investigators on the delegation log. (These must cover the duration of each investigator's role in the trial)				
• Signed & dated current protocol				

• Superseded protocols (since commencing the trial)	List:			
• All current approved information sheets • All current approved consent forms (on hospital headed paper):				
• Relevant superseded information sheets: • Relevant superseded consent forms:				
• Current approved GP letter				
• Local R&D approval letters (from initial approval to take part and for all subsequent substantial amendments approved).				
• Copies of correspondence with Ethics (commencing with initial approval letter for trial, approval for site and all subsequent substantial amendments relating to changes of protocol, consent forms, information sheets and GP letters).				
• MHRA approval and amendments (As ethics above)				
• Sponsor letters				
• Insurance letters (to cover the duration of your site taking part in the trial).				
• Signed contract (between University of Nottingham as Sponsor and your hospital)				
• Completed Trial Dose Accountability log(s)				
• Device documentation: Technical dossier				
• Screening log(s)				
• File note stating where CRFs can be found.				

• SAE reports signed/dated by PI (or designated medic)				
• Protocol deviation & violation forms (where applicable)				
• Data correction forms (where applicable)				
• Monitoring reports				
• Patient contact details (may be stored separately, from the ISF) **Patient contact details must be kept until all the trial paperwork is actually archived, then they must be destroyed as per protocol.**	If stored, separately, where…… …… …… …			
• Source documents (medical records for all trial patients have been labelled that the patient is in the specific trial and will be required to be archived until 7 years after closedown)				
• Master signed consent forms (must be stored in the ISF or if stored separately, file note to document location)	If stored, separately, where…… ……			
• RECAST-3 Trial Final Report	The report will be available on our investigator website, to be downloaded and filed prior to archiving trial documents.			
CLOSEDOWN DOCUMENTS **HRA/Ethics/MHRA** and signed/completed closedown checklist				

DATA ENTRY is completed for all:		**Initials**		
		YES	NO	N/A
• Randomisation				
• Day 1				
• Day 2				
• Day 4				
• Discharge/death				
• SAE/SADE/Outcome events				
• All scans have been uploaded to the website				

MISCELLANEOUS		**Initials**		
		YES	NO	N/A
Any other documentation/queries/issues (e.g. temperature excursions): • • •				

I can confirm that all queries relating to any trial participant involvement have been resolved and all essential documentation is in place before archiving.

Principal Investigator Signature: ……

Name (block capitals): ……..

Signature of those who have initialled work as completed:

Name Signature Initials Date

…… …… …… ……

…… …… …… ……

Please note that archiving of all the documents cannot take place until after the publication of results.