Standard Operating Procedure for Archiving

SOP name: NWORTH07/19 archiving Version 2

Authorship Team: Angela Gliddon & Rhiannon Whitaker

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Designated NWORTH member (DNM) approval:

Name___Ceri Bray_____

Signature_____Date_____

1st Author approval

Name_Angela_Gliddon_____

Signature_Anglea_Gliddon_____Date____01/08/08_____

NWORTH trial unit manager approval: Name _____

Signature _____ Date of Approval_____

Authorised for implementation by: the Director of NWORTH

Signature __Ian Russell_____ Date of Approval__16/04/08_____

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1		
2	16 April 2008	updates

Section 1: Table of Contents

Section 2: Glossary of Terms

CI **C**hief **I**nvestigator

The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI.

CT **C**linical **T**rial

Any investigation in human subjects intended to discover the efficacy or tolerability or cost-effectiveness of an intervention, whether a procedure, a device, a technology or a medicinal product.

CTIMP **C**linical **T**rial of an **I**nvestigational **M**edicinal **P**roduct

Any investigation in human subjects, other than a non-interventional trial, intended:

a. To discover or verify the clinical, pharmacodynamic effects of one or more medicinal products;
b. To identify any adverse reactions to one or more such products;
c. To study absorption, distribution, metabolism and excretion of one or more such products with object of ascertaining the safety or efficacy of those products.

CTP **C**linical **T**rial **P**ractitioner

A person at the local site with that title, a research nurse or data manager, who is responsible for collecting trial data and shares responsibility with the PI for patient recruitment.

Database Closure Date

The date agreed by CI and management team for "locking" or closure of the trial database after data queries and cleaning are complete.

DNM **D**esignated **N**WORTH **M**ember

A member of NWORTH who has been designated to review an NWORTH SOP and make recommendations to a NWORTH meeting on acceptance.

End of Trial

The date, specified in the Trial protocol, of the last follow-up visit of the last patient or the last receipt of data direct from the last patient. This date triggers reporting dates of 90 days to notification of end of trial for CTIMP.

GCP **G**ood **C**linical **P**ractice

as defined by the ICH, see www.emea.europa.eu/pdfs/human/ich/013595en.pdf

ISF **I**nvestigator **S**ite **F**ile – the file in which all trial documents in accordance with ICH GCP are kept at each site

NWORTH North Wales Organisation for Randomised Trials in Health (and Social Care)

PI **P**rinciple **I**nvestigator

The investigator responsible for the research site where the study involves specific procedures requiring site-specific assessment. There should be one PI for each research site. In the case of a single-site study, the CI and PI will normally be the same person.

SOP **S**tandard **O**perating **P**rocedure

The written instructions and records of procedures agreed and adopted as standard practice.

TMF **T**rial **M**aster **F**ile

File kept at NWORTH for each trial containing essential documents for that trial, as defined for CTIMP in section 8 of ICH GCP (www.emea.europa.eu/pdfs/human/ich/013595en.pdf) and following the MRC GCP

Trial Site

A hospital, local government office, GP surgery etc with approval to participate in a trial. The site from which local trial activities are co-ordinated.

Section 3: Introduction

This document forms part of the set of standard operating procedures of the North Wales Organisation for Randomised Trials in Health (and Social Care) NWORTH. It identifies the roles, responsibilities and actions of the individuals involved in the preparation, issue, control, review and approval of standard operating procedures. (see NWORTH07/1 SOPonSOPs)

NWORTH SOPs are written in compliance with regulatory requirements - The Research Governance Framework, EU Clinical Trial Directive, ICH Good Clinical Practice and Internal Guidelines – NHS guidelines NHS guidelines/policies/clinical governance

All SOPs will distinguish regulatory requirements between Clinical Trials Involving Medicinal Products (CTIMPs) and "other research" (non drug trials).

This SOP considers archives of source data documents e.g. patients' hospital notes at local Trial sites, regulatory documents at local Trial sites and at NWORTH and archiving of electronic datafiles by local Trial sites and at NWORTH.

The essential documents for a trial, as stored in the TMF at NWORTH (see NWORTH07/6 Trialmasterfile) or the ISF (Investigator's Site File) at trial sites, should be filed and archived in a way that facilitates management, monitoring, audit and inspection of the Trial. Archived hard copy and electronic documents should be readily retrievable and available for audit and inspection upon request. These documents individually and collectively permit evaluation of the conduct of the Trial and the quality of the data produced.

Section 4: Purpose

To define the process of Archiving of trials managed by or adopted by NWORTH.

Section 5: Users

The Trial's Sponsor has overall responsibility for the integrity of a trial.If the Sponsor is Bangor University and the trial is managed by NWORTH, responsibility may be delegated to the Director of NWORTH.

The personnel responsible for utilising and implementing this SOP are as follows:

The NWORTH Manager has responsibility of ensuring that archiving is in keeping with the principles of GCP.

Trial Managers (aka **Trial Co-ordinators)** in conjunction with data managers are responsible for archiving specific trials**.**

Trial Managers, if not personally responsible for the Trial databases, are responsible for requesting copies of final raw and cleaned up databases from the data manager and the statistics files required for archive – (Master sets and other syntax and analysis files, see NWORTH08/15statistics) from the trial statistician for storage in the NWORTH archive. They are also responsible for passing documents, information about computer archives and CDs to the NWORTH Administrator for storage in the NWORTH archive.

Data managers are responsible for locking the final databases (see NWORTH07/10 datamanagement) compacting, repairing and storing them on CD-RWs. They are responsible for supplying data files and CDs to the Trial Managers.

CIs are responsible for signing off the completed Trial archive at NWORTH**.**

The NWORTH Administrator should manage the Archive Logs and hold the key to the archive room.

Site archives

NWORTH Trial Managers are responsible during site set-up for ensuring that PIs are aware of the need for archiving and that resources are available for local archiving (see NWORTH07/09 sitesetup). They are responsible both for liaising with PIs and CTPs about archiving at local trial sites and for collecting details of the location of those site archives. They will pass on all documents about site archives to the NWORTH Administrator for storage in the NWORTH archive.

PIs at trial sites are responsible for archiving of their site documents and electronic data, logging the location and the person to contact for retrieval in case of audit and for notifying the Trial Manager at NWORTH of these details and of any subsequent changes. PIs are also responsible for signing off the site archive log.

The NWORTH Manager, on behalf of the **Sponsor,** is responsible for instructing PIs to destroy archives at the defined time and to send a record of destruction to NWORTH that should be kept for 5 years.

Section 6: Procedure

Archiving should be completed as soon as possible after the database closure date.

Duration of archive:
1. Patient Consent forms - or records that consent forms had been checked – will be kept for 25 years.
2(i). All other hard copy documentation and electronic data files relating to a CT managed by NWORTH will be kept for five years after the end of the trial. (See Glossary for definition and NWORTH07/17 trialclosure) unless 1(ii) applies or the sponsor or regulatory authorities require longer. Electronic data files should be stored on CD-RWs in a fire-proof box and on the BU server.
2(ii). In the case of a CTIMP leading to a marketing application, the duration of archive will be until at least two years after the last approval of a marketing application in the EU.

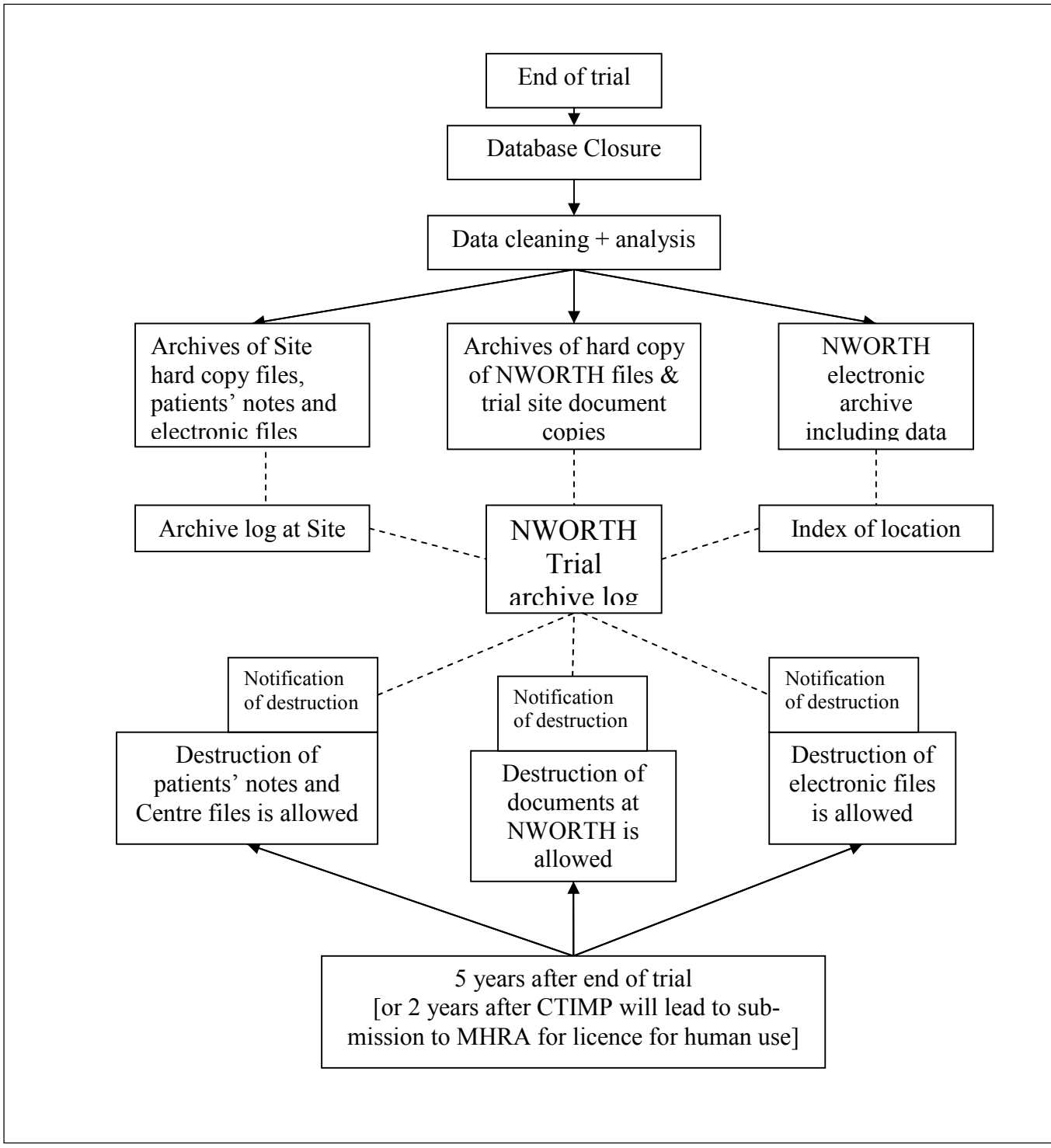
At Trial Sites;
Investigator Site Files (ISFs, see NWORTH 07/6TRIALMASTERFILE SOP) must be stored for the appropriate period defined in 1(i) or 1(ii). Patients' hospital notes should be labelled in some way to identify that the patient is taking part in a CT and that notes should not be destroyed until that period has elapsed after the date of the end of that trial, which should be specified on the label. Trial data from patients at that site will be stored on CD or as hard copy. A detailed archive log should be prepared and stored ready for possible audit or inspection. A copy must be sent to the Trial Manager at NWORTH.

At NWORTH;
All regulatory documents relating to a CT and local site assessments and copies of local regulatory agreements should be stored, together with financial agreements between NWORTH and partners. These will be contained in the TMF. (see 07/6TRIALMASTERFILE SOP)
Paper documents are to be stored in a sealed container in a locked, dry environment. The location and access arrangements will be noted in an Archive Log in the NWORTH office. Details of location and access arrangements at all local trial sites should also be noted in this log.
The archive index/log should record all essential documents (see NWORTH07/6Trialmasterfile) that have been entered into the archive. An archive retrieval log should also be maintained to track and retrieve documents on loan from the archive. If a request is made to access archived material, an entry must be made on the archive retrieval log to ensure accurate recording of this process.
Internal audits may be carried out by NWORTH staff with the authorisation of the NWORTH Director (see NWORTH07/13 QA system).
The sponsor or regulatory authorities may request retrieval in order to conduct an external inspection (see NWORTH07/26 Preparation for audit and inspection).
Regulatory authorities who wish to carry out an inspection of the site files for a

particular trial shall be given details of access to local site archives that are listed in the NWORTH archive log.

6.1 Procedure Flow Chart

Hatched area to be achieved before the end of funding. Lines with arrows show time-relation. Dotted lines indicate the transfer of information.



Section 7. Training plan for SOP implementation

1. Training in principal is conducted through the SOP approval process in NWORTH SOP meetings. Once an SOP is approved at the SOP meeting, staff attending meeting will be deemed trained in principal and sign the" training in principal log". The SOP will then become effective.

2. Training in practice will be effective once a staff member has completed the SOP task. The staff member will sign the "training in practice log".

Section 8. References

International Conference on Harmonisation Good Clinical Practice as interpreted by Directive 2001/20/EC of the European Parliament and Council
www.emea.europa.eu/pdfs/human/ich/013595en.pdf

MRC GCP guidelines for non CTIMP trials
www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416

EU draft guidance for non-commercial trials – TMF and archiving
http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-10/v10_chap5.pdf
(-not yet finalised)

www.shef.ac.uk/content/1/c6/05/38/55/ArchiveSOP.pdf

Section 9. Referenced SOPs

NWORTH07/1 SOPonSOPs

NWORTH07/6 Trialmasterfile

NWORTH07/9 Sitesetup

NWORTH07/10 Datamanagement

NWORTH07/13 QA system

NWORTH08/15statistics

NWORTH07/17 TrialClosure

NWORTH07/26 Preparation for audit and inspection

Section 10 Appendices

a) A model Archive Log for Sites
b) A model Archive Log for NWORTH
c) A model Archive Retrieval Log
d) Training for this SOP

Appendix a Site Archive Record of a Clinical Trial managed by NWORTH

When asked by the NWORTH Trial manager, after the end of a trial, please complete this form and retain one copy in the archived Investigator Site File, keep a copy in your Department and send one copy to the Trial Manager at NWORTH.

When informed by the NWORTH manager that documents and CDs may be destroyed, please arrange for destruction, sign final column and send a copy to the NWORTH Manager.
When consent forms have been destroyed, send the final copy of this form to the NWORTH Manager.

ISRCTN	
Local reference	
Title	
Sponsor	
Investigator	

Document	location	date archived	planned destruction date	date destroyed
ISF, incl R&D and ethics docs				
Patients' consent forms				
CRFs (hard copy or CD)				
hospital notes of trial patients				

I confirm that the above documents have been archived in accordance with all applicable regulations.

Signed …… (Investigator) date ……..

I confirm that the above archive components have been destroyed in accordance with all applicable regulations.

Signed ……..……. (Investigator) date ……

return this form, when completed or amended to:

Appendix b NWORTH Archive Record of a Clinical Trial

ISRCTN	
Sponsor	
Title	
Trial Manager	
Chief Investigator(s)	

Document	location	date archived	planned destruction date	date destroyed
TMF, incl R&D and ethics docs				
Minutes of TMG				
Minutes of DMEC and TSC				
CRFs (hard copy or CD)				
Details and location of Trial Site archives				

I confirm that the above documents have been archived in accordance with all applicable regulations.

Signed …… (Chief Investigator) date ……..

I confirm that the above archive components have been destroyed in accordance with all applicable regulations.

Signed ……..……. (Chief Investigator) date ……

One copy of this form, and amended later forms, to be stored in the archive. One copy to be filed in the NWORTH Office.

Appendix c Archive Retrieval Log

A copy of this form should be completed for each request to review an archive.

Archive Retrieval Log

Trial name: ISRCTN:……..

Data archive material requested: …

Documentary material requested: …

Date retrieval requested: …

Box(es) to be retrieved: …

Date box(es) were retrieved: …

Name and signature of retriever: …

Temporary location of box(es): …

Date box(es) were returned: …

Name and signature of returner: …

Name and signature of individual who is responsible for archiving:

……

Appendix d). Training for Archiving SOP

Name of SOP user	Name of Trainer	Date of training (principles)	Date of training (practical)	Duration of training	Location/type of training *i.e. ethical submission, randomisation*	User signature	Trainer signature

Name of SOP user	Name of Trainer	Date of training (principles)	Date of training (practical)	Duration of training	Location/type of training	User signature	Trainer signature