APPENDIX 5 INVESTIGATOR STUDY ARCHIVE FORM

Please complete this form, give the original to the clinical trial archivist and enter this study onto your archive log

SHORT TITLE	CI/PI NAME			R&D NUMBER.
INCLUDED FOR ARCHIVING		**Y**	**N**	
(Tick one box on each line)				**COMMENTS**
REGULATORY				
Investigator Brochure		☐	☐	
Summary of product characteristics		☐	☐	
All versions of the signed protocol and amendments		☐	☐	
Case report forms (CRFs) , please state how many are being archived in the comments sect.		☐	☐	No. archived:
Insurance Statement (RD&E Sponsored trials only)		☐	☐	
All appropriate Ethics Committee(s) documentation		☐	☐	
General communications with sponsor		☐	☐	
Site specific communications with sponsor (letters, Site selection/ initiation meeting notes, notes of telephone calls)		☐	☐	
All appropriate Regulatory Authority authorisation/approvals documentation		☐	☐	
Sample Patient Information Sheets, Consent Form on site headed paper (all versions)		☐	☐	
CVs of Investigators and Sub-Investigators, including CVs which were superseded during the trial period		☐	☐	
GCP certificates of Investigators and Sub-Investigators, including certificates which were superseded during the trial period		☐	☐	
Training log/s, if applicable		☐	☐	
IMP				
Pharmacy File (Obtain from Clinical Trials Pharmacy Manager)		☐	☐	
Signature of Clinical Trials Pharmacy Manager :				
Signature sheets and Delegation logs		☐	☐	
Subject screening and enrolment log, and identification code list/randomisation log if appropriate		☐	☐	
CLINICAL				
Signed informed consent forms		☐	☐	
SAE notifications, and safety information		☐	☐	
Source documents (if appropriate)		☐	☐	
Signed Registration and Randomisation Confirmations or IVRS		☐	☐	
Medical/laboratory/ technical procedure(s) and/or test results		☐	☐	
Record of tissue samples released *(Copies of correspondence with pathology departments regarding the retrieval of tissue)*		☐	☐	
Fridge/ Freezer temperature Logs		☐	☐	
Confirmation of shipping/disposal of all study related samples		☐	☐	
MONITORING				
Monitoring log and reports		☐	☐	
R&D/Sponsor File if appropriate (ask archivist)		☐	☐	
Supplementary Information		☐	☐	
ADDITIONAL DOCUMENTS:				

I confirm that the above documents have been submitted for archiving and electronic records have been reviewed and deleted as necessary *e.g. copy GP letters, logs containing patient identifiers.

Name:	**Signature:**	**Date:**	
Print Name & job title:			