

FOCUS Remote close out visit checklist Part 2 PI still on site

FOCUS has now closed and the results have been published. Please complete this form, sign and return it to the FOCUS Trial Co-ordinating Centre along with a copy of your final closed delegation log to focus.trial@ed.ac.uk.

The Clinical Trial Report (trial results and notification - enclosed) should be added to your ISF for completeness. Once this form is returned, with that delegation log, you should archive the trial materials for **15 years (January 2034)** as stipulated in the site agreement.

Site Number:	Site Name:
---------------------	-------------------

Delegation of Responsibilities	Yes	Comments
Have the final dates been added to the delegation log for each researcher?		
Has the log been signed as closed by the PI?		
Has a copy of the log signed by the PI been sent to the TCC		
Archiving		
Where will the ISF be archived? Please provide address		
Who will serve as the named contact for archived trial documentation throughout the archiving period (15 years)?	Name: Address: Email: Telephone number:	

Checklist Completed By:

Name: _____ Designation: _____

Signature: _____ Date: _____

PI Statement

I confirm that all site close out actions have been completed as outlined above, all essential documentation is present in the ISF as recorded in the attached checklist and the ISF is now ready for archive.

PI name: _____

PI Signature: _____ Date: _____

Thank You

Please email to: focus.trial@ed.ac.uk

Enc: Lancet paper & end of trial notification