

SUBJECT – FOCUS Study Closeout Final Checklist

Dear <PI> < coordinator> < pharmacy contact> <R&D contact>,

Thank you for returning the initial FOCUS checklist, confirming all trial documentation is in place in the ISF and the IMP has been destroyed. We are now in a position to begin the final closeout process for your site. A link to the sponsor SOP CR009 is available at: <http://accord.scot/research-access/resources-researchers/sop> should you require this.

To assist with this process, please find enclosed:

- The FOCUS Site Closedown Final Checklist
- A copy of the Lancet paper – please file in section 10 of the ISF
- A copy of the end trial notification – please file in section 10 of the ISF

If you could review the enclosed Checklist, complete it and the PI sign that you are happy with the content and return this to FOCUS (pdf and scan to focus.trial@ed.ac.uk) Once complete, the original should be retained in section 8 of your site file (Monitoring). Note we are looking for the final stop date for all staff on the delegation log.

Once you have returned this form and the final copy of the closed delegation log you have permission from sponsor to archive the FOCUS ISF and PSF. Note this is for 15 years from now, i.e **January 2034**

- If there is no PI or delegated physician on site, R&D retain the responsibility for the ISF and closeout so this can be signed off by R&D.

If the trust/health board merges with another during the 15 years of archiving, the sponsor should be notified if the responsibility for patient data has moved from the original trust named in the site agreement.

To expedite this process please complete and return this form before 31st January 2019 and contact the FOCUS team if you have any questions.

Many thanks for your support for FOCUS.

Sent on behalf of

Prof Dennis

Chief Investigator