



CENTRE CLOSE OUT FORM & ARCHIVE CHECKLIST FOR CLOTS 3 CENTRES

CENTRE DETAILS

Centre Number / Name	
Principal Investigator (PI)	
Hospital Co-ordinator (HC)	
Number of patients recruited	
All data in and verified	YES, Thank you!

I CAN CONFIRM THAT:

Please tick

1. ESSENTIAL DOCUMENTATION

- all documents that were needed for the site set up are in the Site File (any approvals, etc are available via CSP)
- the PI has signed that the site file is complete
- copies of site specific patient informed consent forms are present

2. AUDIT AND INSPECTIONS

- the local study team is aware that inspections and audits may still be carried out after the end of the trial

3. DELEGATION LOG TASKS

- final dates to be added for each researcher
- log signed and dated as closed by the PI

4. COLLECTION OF PUMPS AND SLEEVES

- pumps have been returned to Covidien using the freepost labels provided
- full boxes of sleeves have been returned to Covidien using the freepost labels provided

5. ACKNOWLEDGMENTS

Centres who have randomised one or more patients (see page 1 for recruitment at your centre) will be acknowledged in all future publications (as per protocol).

- acknowledgements have been completed via the CLOTS website

6. ARCHIVING

- our local R&D department has been notified to the close out of CLOTS 3 at our site
- all relevant information relating to CLOTS 3 patients recruited at our site has been filed as per our Trust's policy on archiving

Signature of Principal Investigator: _____

Date: _____

**Please return to the CLOTS Trial Co-ordinating Centre
by email (XXXX) or fax on (XXXX XXX XXXX)**

Thank you for supporting the CLOTS 3 Trial