



Health Research Authority

NRES Committee South West - Central Bristol

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15 August 2013

Re-issued with correct date of approval letter.

Professor Alun H Davies

[Redacted address]

Dear Professor Davies

Study title: A randomized clinical trial to compare early versus delayed endovenous treatment of superficial venous reflux in patients with chronic venous ulceration.
REC reference: 13/SW/0199
IRAS project ID: 131153

Thank you for your letter of 14 August 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 31 July 2013

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		14 August 2013
Other: Covering Letter for Qn	1	14 August 2013
Participant Consent Form	1	14 August 2013
Participant Information Sheet	1	14 August 2013

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		28 June 2013
Covering Letter		14 August 2013
Evidence of insurance or indemnity	Verification of Ins.	30 July 2012
GP/Consultant Information Sheets	1	19 June 2013
Investigator CV	1	19 June 2013
Letter from Sponsor		27 June 2013
Other: Letter from funder		22 May 2013
Other: Flowchart	1	19 June 2013
Other: Covering Letter for Qn	1	14 August 2013
Participant Consent Form	1	14 August 2013
Participant Information Sheet	1	14 August 2013
Protocol	1	19 June 2013
Questionnaire: Aberdeen Varicose Vein Qn		
Questionnaire: EQ-5D		
Questionnaire: SF-36		
REC application	3.5	27 June 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

13/SW/0199

Please quote this number on all correspondence

Yours sincerely



Committee Co-ordinator

Copy to: , Imperial College London