



Health Research Authority

NRES Committee South Central - Berkshire

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Bristol BS1 2NT

Telephone: 0117 342 1330

22 December 2014

Professor Freddie Hamdy
Nuffield Professor of Surgery
University of Oxford
Old Road Campus Research Building (off Roosevelt Drive)
Headington
Oxford
OX3 7DQ

Dear Professor Hamdy

Study title: A randomised controlled trial of Partial prostate Ablation versus Radical prostatectomy (PART) in intermediate risk unilateral clinically localised prostate cancer.

REC reference: 14/SC/1376

IRAS project ID: 159568

Thank you for your email of 16th December 2014. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 01 December 2014.

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Non-validated questionnaire [Resource Utilisation Diary]	2.0	08 December 2014

Non-validated questionnaire [Resource Utilisation Diary tracked]	2.0	08 December 2014
Participant consent form [PART ICF tracked]	2.0	08 December 2014
Participant consent form [PART QRI ICF tracked]	2.0	08 December 2014
Participant consent form [Staff QRI ICF tracked]	2.0	08 December 2014
Participant consent form [PART ICF]	2.0	08 December 2014
Participant consent form [PART QRI ICF]	2.0	08 December 2014
Participant consent form [Staff QRI ICF]	2.0	08 December 2014
Participant information sheet (PIS) [PART PIL tracked]	2.0	08 December 2014
Participant information sheet (PIS) [PART QRI PIL tracked]	2.0	08 December 2014

A Research Ethics Committee established by the Health Research Authority

Participant information sheet (PIS) [PART QRI Info for Staff tracked]	2.0	08 December 2014
Participant information sheet (PIS) [PART PIL]	2.0	08 December 2014
Participant information sheet (PIS) [PART QRI Info for Staff]	2.0	08 December 2014
Research protocol or project proposal [PART Protocol]	2.0	08 December 2014
Research protocol or project proposal [PART Protocol tracked]	2.0	08 December 2014

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 on headed paper [PART REC Cover Letter]		31 October 2014
GP/consultant information sheets or letters [PART GP Letter]	1.0	31 October 2014
Interview schedules or topic guides for participants [PART QRI schedule for patients]	1.0	31 October 2014
IRAS Checklist XML [Checklist_11122014]		11 December 2014
IRAS Checklist XML [Checklist_16122014]		16 December 2014
Letter from sponsor [PART Letter from Sponsor]		31 October 2014
Non-validated questionnaire [Resource Utilisation Diary]	2.0	08 December 2014
Non-validated questionnaire [Resource Utilisation Diary tracked]	2.0	08 December 2014
Participant consent form [PART ICF]	2.0	08 December 2014
Participant consent form [PART QRI ICF]	2.0	08 December 2014
Participant consent form [Staff QRI ICF]	2.0	08 December 2014
Participant consent form [PART ICF tracked]	2.0	08 December 2014
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Participant information sheet (PIS) [PART PIL tracked]	2.0	08 December 2014
Participant information sheet (PIS) [PART QRI PIL tracked]	2.0	08 December 2014
Participant information sheet (PIS) [PART QRI Info for Staff tracked]	2.0	08 December 2014
REC Application Form [REC_Form_31102014]		31 October 2014
Research protocol or project proposal [Pa]	2.0	08 December 2014
Research protocol or project proposal [PART Protocol tracked]	2.0	08 December 2014
Summary CV for Chief Investigator (CI) [CI Short CV]		31 October 2014
Validated questionnaire [EPIC 2]		
Validated questionnaire [FACT-P]		
Validated questionnaire [iief-15]		
Validated questionnaire [ipss]		
Validated questionnaire [The Modified 18-Item Memorial Anxiety Scale for Prostate Cancer]		
Validated questionnaire [EQ-5D-5L]		

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.

14/SC/1376

Please quote this number on all correspondence

Yours sincerely



Charlotte Allen Deputy HRA Improvement & Support Manager

E-mail: nrescommittee.southcentral-berkshire@nhs.net

Copy to: *Ms Heather House*
Dr Glenn Wells, Oxford University Hospitals NHS Trust R&D Department
Steffi Le Conte, PART Trial Manager

