



# Health Research Authority

## South Central - Berkshire Research Ethics Committee

Bristol REC Centre  
Whitefriars  
Level 3, Block B  
Lewins Mead  
Bristol  
BS1 2NT

Tel: 0117 342 1387

12 November 2015

Ms Heather House  
Oxford University Hospitals NHS Trust  
R&D Office, Joint Research Office  
Block 60, Churchill Hospital, Headington  
Oxford  
OX3 7JX

Dear Ms House

**Study title:** An assessment of the effects of pressors on graft blood flow after free tissue transfer surgery: A randomised study – Part II

**REC reference:** 09/H0505/121

**EudraCT number:** 2009-015533-79

**Amendment number:** 6

**Amendment date:** 23 October 2015

**IRAS project ID:** 29908

The above amendment was reviewed by the Sub-Committee in correspondence.

### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

### Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Transfer Sponsorship Cover letter Ethics 23.10.2015]		23 August 2015
Letter from sponsor [Full sponsorship letter]		17 December 2014
Letter from sponsor [Transfer of Sponsorship Letter Free4Flow]		26 August 2014
Notice of Substantial Amendment (CTIMP) [AmendmentFormMHRAEudract_ReadyForSubmission SIGNED]		23 October 2015

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>09/H0505/121:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**PP Mr David Carpenter**  
**Chair**

E-mail: [nrescommittee.southcentral-berkshire@nhs.net](mailto:nrescommittee.southcentral-berkshire@nhs.net)

*Enclosures:*                      *List of names and professions of members who took part in the review*

*Copy to:*                              *Mr SR Watt-Smith, Oxford Radcliffe Hospitals NHS Trust*

**South Central - Berkshire Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting in correspondence**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr David Carpenter [chair]	Social Scientist	Yes	
Dr Mike Proven	Coordinator for QA in Research	Yes	