NHS
Health Research Authority

NRES Committee North West - Haydock
North West Centre for Research Ethics Committees
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14 December 2011

Dr J Armitage
ASCEND
Clinical Trial Service Unit
Richard Doll Building
The University of Oxford
Old Road Campus
Headington
OXFORD
OX3 7LF

Dear Dr Armitage

Study title:	**ASCEND**
REC reference:	**03/8/087**
EudraCT number:	**2004-000991-15**
Amendment number:	**CTSUASCEND7, version 9.0_2011-01-14**
Amendment date:	**06 December 2011**

The above amendment was reviewed at the meeting of the Sub-Committee held on 13 December 2011.

Ethical opinion

The Sub-Committee reviewed the above amendment which sought approval for four new documents which would be used when collecting optional blood and urine samples from participants. These samples would only be collected from a randomly selected sub-set of participants.

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:

Document	Version	Date
Covering Letter from Jane Armitage		01 December 2011
European Commission Notification of Substantial Amendment Form: CTSUASCEND7, version 9.0_2011-01-14		06 December 2011
Summary and rationale for Proposed Amendment		

Participant Information Sheet: Additional Blood & Urine sampling information leaflet	V1.0_2011-12-01	01 December 2011
Participant Consent Form: Additional Blood & Urine sampling consent form	V1.0_2011-12-01	01 December 2011
GP letter for additional blood and urine results	V1.0_2011-12-01	01 December 2011
Additional Blood & Urine sampling instruction	V1.0_2011-12-01	01 December 2011
email from Susan Tonks to evidence Sponsor support for amendment		07 December 2011

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.

03/8/087:	**Please quote this number on all correspondence**

Yours sincerely

H Penistone

pp **Professor Ravi S Gulati**
Chair

E-mail: helen.penistone@northwest.nhs.uk

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

Copy to:

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NRES Committee North West - Haydock

Attendance at Sub-Committee of the REC meeting on 13 December 2011

Name	*Profession*	*Capacity*
Mrs Linda Ashcroft	Senior Statistician	Expert
Professor Caroline Carlisle	Research Nurse, MRC Social and Public Health Sciences Unit, University of Glasgow	Expert
Mr Stephen Edgar	Designer	Lay Plus
Professor Ravi S Gulati	Consultant Physician	Expert
Ms Pat Harvey	Hospital Chaplain	Lay Plus
Mrs Chris Haywood	HEAD of HOSPICE SERVICES	Expert
Dr Simon Marwood	Senior Lecturer in Physiology	Expert
Mr Charles Otim	Research Support Officer	Lay Plus
Dr David Pilling		Expert
Mrs Sandra Reilly		Lay Plus
Mr Alan Rigby	Medical Statistician	Expert
Dr Valerie E Siddall	Retired Senior Manager - Pharmaceutical Industry	Lay Plus

Also in Attendance:

Name	Position (or reason for attending)
Miss Helen Penistone	Acting Committee Co-ordinator
Mr Ashley Totenhofer	Assistant Committee Co-ordinator