



National Research Ethics Service
NRES Committee West Midlands - Edgbaston

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Co-ordinator: Nicola Murphy

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19 September 2011

Professor Nicholas James
C/O Karen Saunders
MRC Clinical Trials Unit
4th Floor Aviator House
125 Kingsway
London
WC2B 6NH

Dear Professor James,

Study title: Systemic Therapy in Advancing or Metastatic Prostate cancer: Evaluation of Drug Efficacy
REC reference: 04/MRE07/35
EudraCT number: 2004-000193-31
Amendment number: AM75 (our ref)
Amendment date: 02 September 2011

The above amendment was reviewed at the meeting of the Sub-Committee held on 19 September 2011 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:

Document	Version	Date
MHRA Cross Reference Letter		25 August 2011
Distribution Authorisation (B&C Group)		
Abiraterone Manufacturing Licence (Janssen Research & Development)		
IRAS minimal dataset		02 September 2011
Correspondence related to non-substantial amendment		
Investigator's Brochure	8.0	04 April 2011

Protocol	8.0	02 September 2011
European Commission Notification of Substantial Amendment Form	AM75 (our ref)	02 September 2011
Covering Letter		02 September 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

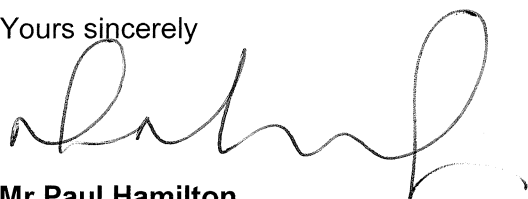
This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

04/MRE07/35:	Please quote this number on all correspondence
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Yours sincerely



PP

Mr Paul Hamilton
Chair

E-mail: nikki.murphy@westmidlands.nhs.uk

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

NRES Committee West Midlands - Edgbaston

Attendance at Sub-Committee of the REC meeting on 19 September 2011

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mr Paul Hamilton	Local Government Officer (Chair)	Lay
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert