Dr Murali
Copy
20/1/09

National Research Ethics Service
South Yorkshire Research Ethics Committee
1st Floor Vickers Corridor
Northern General Hospital
Herries Road
Sheffield
S5 7AU

Telephone: 0114 226 9153
Facsimile: 0114 256 2469
Email: joan.brown@sth.nhs.uk

08 December 2008

Professor T H Jones
Consultant Physician and Endocrinologist and Hon. Professor of Andrology
Barnsley Hospital NHS Foundation Trust
Gawber Road
Barnsley
S75 2EP

Dear Professor Jones

Full title of study: **Longitudinal follow up study on the effect of Testosterone status on Mortality, Cardiovascular Events and risk factors in Men with Type 2 Diabetes Mellitus.**

REC reference number: **08/H1310/112**

The Research Ethics Committee reviewed the above application at the meeting held on the 27 November 2008. Dr Muraleedharan attended the meeting to discuss the study on your behalf.

Discussion

Dr Muraleedharan confirmed that participants would have their medical history taken, and be given a blood test and an ultrasound scan. He explained there were clear guidelines available for the treatment of these patients and it was normal clinical practice if a patient was found who required any additional treatment that the patient would be referred for appropriate management to either their GP or their consultant. The committee accepted this clarification

Dr Muraleedharan clarified that the rectal examination was not part of this study and further clarified that he would be performing the ultrasound examinations himself and had received the appropriate training. The committee accepted these clarifications.

There were a couple of minor additions required to the Participant Information Sheet (PIS)

Ethical opinion

Members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, **subject to the conditions specified below.**

Ethical review of research sites

The Committee agreed that all sites in this study should be exempt from site-specific assessment (SSA). There is no need to submit the Site-Specific Information Form to any Research Ethics Committee. The favourable opinion for the study applies to all sites involved in the research.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

- Submit copy of final revised Participant Information Sheet (Version 1.2) to also include the following details:
  - Contact details for PALs
  - Under a heading "Who has reviewed the study" insert "The South Yorkshire Research Ethics Committee has reviewed and approved this study"

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Investigator CV		
Peer Review		
Participant Consent Form	1	
Participant Information Sheet (awaiting Version 1.2	1	
GP/Consultant Information Sheets	1	
Letter of invitation to participant	1	
Peer Review		04 November 2008
Letter from Sponsor		
Covering Letter		
Protocol	1.1	31 October 2008
Application		07 November 2008

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

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.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/H1310/112	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

pp **Jo Abbott**
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers" SL-AR2

Copy to: Research Governance Co-ordinator, Barnsley Health & Social Care Research Alliance R & D Department, Block 12, Barnsley NHS Foundation Trust, Gawber Road, Barnsley, S75 2EP

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11 February 2009

Professor T H Jones
Consultant Physician and Endocrinologist and Hon. Professor of Andrology
Barnsley Hospital NHS Foundation Trust
Gawber Road
Barnsley
S75 2EP

Dear Professor Jones

Full title of study:	**Longitudinal follow up study on the effect of Testosterone status on Mortality, Cardiovascular Events and risk factors in Men with Type 2 Diabetes Mellitus.**
REC reference number:	**08/H1310/112**
Protocol number:	**1.1**

Thank you for your letter of 29 January 2009. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 8 December 2008. Please note these documents are for information only and have not been reviewed by the committee.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant Consent Form	1.2	29 January 2009

08/H1310/112 **Please quote this number on all correspondence**

Yours sincerely

Mrs Joan Brown
Committee Co-ordinator

Copy to: Research Governance Co-ordinator, R & D Dept, Barnsley NHS FT

Dr V Muraleedharan, Clinical Research Fellow, Diabetes & Endocrinology, Barnsley Hospital NHS FT, Gawber Road, Barnsley, S75 2EP