NHS

National Research Ethics Service

County Durham & Tees Valley Research Ethics Committee

Room 002
TEDCO Business Centre
Viking Industrial Park
Rolling Mill Road
Jarrow
Tyne & Wear
NE32 3DT

Telephone: 0114 226 9153
Facsimile: 0114 256 2469

Research & Development
- 7 JAN 2011
CDDFT

04 January 2011

Dr Anjan Dhar
Consultant Gastroenterologist
County Durham & Darlington NHS Foundation Trust
Department of Gastroenterology
Cockton Hill Road
Co. Durham
DL14 6AD

Dear Dr Dhar

Study Title:	**Biodegradable stent in benign oesophageal stricture compared to standard balloon dilatation treatment - a pilot study**
REC reference number:	**10/H0908/54**
Protocol number:	**BESST**

Thank you for your letter of 20 December 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

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.

For NHS research sites only, management permission for research ("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 for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Protocol	2.0	16 December 2010
GP/Consultant Information Sheets	1	11 August 2010
Response to Request for Further Information		20 December 2010
Investigator CV		
Letter from funder (NIHR)	1	06 August 2010
Covering letter addressing points raised in provisional opinion letter		16 December 2010
Participant Information Sheet	2.0	08 December 2010
Letter from Sponsor	1	03 September 2010
Evidence of CE Marking		
Letter of support for stent procedures		31 March 2010
Evidence of insurance or indemnity		15 November 2010
Letter from Statistician	1	
Referees or other scientific critique report		
REC application	IRAS 3.0	31 August 2010
Participant Consent Form	2.0	16 December 2010

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 Service 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
- Adding new sites and investigators
- 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.

10/H0908/54	**Please quote this number on all correspondence**

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

Yours sincerely

J Brown

pp **Dr John Drury**
Chair

Email: joan.brown@sotw.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Dr Helen Close, School of Medicine & Health, Queen's Campus, Durham University, Stockton-on-Tees, TS17 6BH*

R&D Office, Darlington Memorial Hospital, Pierremont Unit, Darlington, DL3 6HX ✓