Participant Study No

STUDY CONSENT FORM
eTHoS: either Traditional Haemorrhoidectomy or Stapled Haemorrhoidopexy for Haemorrhoidal Disease

Please tick ALL boxes

By signing this form and ticking each box I agree that I have:

- been given the Information Sheet about the study (Version 2.1, dated Dec 2011) ☐
- had the opportunity to discuss the study ☐
- received satisfactory answers to questions ☐
- been given enough information about the study ☐

I understand that:

- my participation is voluntary and taking part in the study may not benefit my own health ☐
- I am free to withdraw from the study at any time without having to give a reason ☐
- if I withdraw, this will not affect my medical care or legal rights ☐
- I may be contacted in the future for long term follow-up ☐

I agree that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of Aberdeen, from regulatory authorities or from the NHS Board or Trust, where it is relevant to my taking part in this research. Information relevant to the eTHoS study may be collected from my hospital and NHS records, including Office of National Statistics (ONS) and NHS central registers. ☐

I agree that relevant data and my contact details will be held confidentially and securely by the study office in Aberdeen, and may be subject to audit and monitoring by regulatory authorities, without breaching data confidentiality ☐

I agree that my family doctor (GP) and my hospital consultant may be told that I am taking part in this study ☐

I agree to take part in the eTHoS study ☐

Your signature (participant) _____

Your name in block capitals _____

Date _____

For office use only

I confirm that I have explained to the person named above, the nature and purpose of the eTHoS study and the procedures involved

Signature Date

eTHoS Study Office, Centre for Healthcare Randomised Trials (CHaRT),
Health Services Research Unit, University of Aberdeen, Foresterhill, Aberdeen AB25 2ZD
Tel [redacted] Fax [redacted] Email: [redacted]

Copies: White sent to researchers in Aberdeen; pink to participant, green to site file and yellow to be filed with hospital notes.

PROJECT SUMMARY

Title of project

Clinical and cost-effectiveness of two main treatment options for the surgical management of Haemorrhoids grade II, III and IV.

Background

Haemorrhoids are common in all age groups from mid-teens onwards. In England in 2006/2007 approximately 25,000 haemorrhoidal procedures were performed as hospital day-case or inpatient admissions, resulting in significant calls on health service resources. The treatment of haemorrhoidal disease is directed at relieving its related symptoms.

There are two major surgical treatments for haemorrhoids: the conventional excisional haemorroidectomy (traditional surgery) and the stapled haemorrhoidopexy. Improved understanding of the pathogenesis of haemorrhoids, increasing belief in the importance of preserving the anal cushions and greater awareness of the high incidence of complications associated with excisional haemorrhoidectomy led to the invention of the stapled haemorrhoidopexy.

Two recent systematic reviews and an HTA monograph compared the two main procedures revealing 95% of patients who received stapled surgery had less pain in the immediate post-operative period compared with the traditional surgery but equivalent complication and pain rates occurred with both procedures at day 21. Other potential advantages of stapled over conventional surgery include a reduction of operating time, hospital stay, time to return to work. However, uncertainties around complication rates, recurrence of symptoms and costs, precludes its widespread use across the NHS. Over the long term there was a significant increase rate of residual prolapse requiring re-intervention with stapled haemorrhoidopexy. eTHoS is therefore investigating what is the best surgical treatment for patients who have haemorrhoids grade II (with two episodes of rubber band ligation), III and IV that require surgery.

Brief outline of the study

Ethical approval has been obtained for this study Written consent has been obtained from participants. Participants will be reviewed in outpatients approximately six weeks after their surgery. Participants are sent postal questionnaires at approximately 1, 3 and 6 weeks and 12 and 24 months after their operation. Our main interest is in the improvement of haemorrhoidal symptoms, as reported by the patients themselves.