the CATHETER trial

Participant Study No: | | | | | | |

CONSENT FORM

Types of Urethral Catheter for Reducing Symptomatic Urinary Tract Infections

(The **CATHETER** Trial)

Chief Investigator: **Professor James N'Dow** (Consultant Urological Surgeon)

Attach catheter sticker here

Please tick boxes

1. I confirm that I have read and understand the information sheet (Version 4 121007) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals directly involved in this study or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree that my personal contact details can be kept confidentially and securely by the study office in Aberdeen. I agree that the study co-ordinators can use my contact details to send me follow study questionnaires and to contact me by telephone or post. ☐
5. I agree to my GP being informed of my participation in the study ☐
6. I agree to take part in the above study ☐

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

4 copies: Top copy for Study Office in Aberdeen; 1 for patient; 1 to be filed with hospital notes and 1 for recruitment officer.

CATHETER is funded by the NHS Research and Development Health Technology Assessment Programme.

It is being organised by The **CATHETER** Trial office at the Academic Urology Unit, and The Centre for Healthcare Randomised Trials, Health Services Research Unit, Health Sciences Building, University of Aberdeen.

~ INFORMATION SHEET ~

Types of urethral catheter for reducing symptomatic urinary tract infections in hospitalised adults requiring short-term catheterisation (The Catheter Trial)

Title of project
Types of urethral catheter for reducing symptomatic urinary tract infections in hospitalised adults requiring short-term catheterisation: multicentre randomised controlled trial of antibiotic and antiseptic impregnated urethral catheters (The Catheter Trial)

Background
25% of patients admitted to hospital will require urethral catheterisation at some stage during their stay and the risk of developing bacteriuria in catheterised patients is approximately 5% per day. It has been estimated that symptomatic urinary tract infection occurs in approximately 20% of patients with bacteriuria, the presence of bacteria in urine, whilst bacteraemia occurs in up to 4% of these patients. Catheter-associated symptomatic urinary tract infections are the leading cause of hospital acquired infections, accounting for between 23% and 40% of all cases.

A recent Cochrane review of randomised controlled trials concluded that the silver alloy impregnated catheter (an antiseptic impregnated catheter) has the most evidence of benefit out of the antibiotic/ antiseptic impregnated urethral catheters available. However, the included trials were small and of poor or moderate quality.

Aim of trial
The trial is investigating the clinical benefit and cost-effectiveness of using antibiotic- or antiseptic-impregnated urethral catheters over standard urethral catheters in hospitalised adults requiring short-term catheterisation. Two pragmatic comparisons will be made comparing catheters, as they would be used in the NHS:

1. Antibiotic-impregnated (nitrofurazone) catheter versus 'standard' PTFE (PolyTetraFluoro-Ethylene)-coated latex catheter
2. Antiseptic-impregnated (silver alloy) catheter versus 'standard' PTFE (PolyTetraFluoro-Ethylene)-coated latex catheter

Brief outline of the study
Following enrolment in the trial, a mid-stream specimen of urine will be sent for microbiological analysis immediately prior to catheterisation, if one has not been sent within the preceding 48 hours (baseline sample). Where this is not possible, a specimen of urine will be obtained during catheterisation (i.e. catheter-specimen of urine) using standard aseptic techniques. Urine will also be sent for microbiological analysis at 3 days after catheter removal. If patients are discharged home prior to the third post-catheter removal day, they will be provided with sterile urine collection bottles that would be filled and submitted by post on the third post-catheter removal day. If a clinical diagnosis of symptomatic UTI is made at any stage, either a catheter-specimen or mid-stream specimen of urine will be obtained by ward staff or the patient's GP as is normal clinical practice.

Participants are asked to complete questionnaires 3 days, and 1 and 2 weeks, following catheter removal and again at 6 weeks following randomisation.

The Researchers
The trial is being co-ordinated at the Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit, University of Aberdeen. If you have any questions about this study or the inclusion of your patient in it, please contact the study trial manager on 01224 559043.