(To be printed on local headed paper)

REC Number: 22/SS/0094
IRAS ID: 316986
SPONSOR'S Number: RHM GSU0281

INFORMED CONSENT FORM

CaDeT: Multicentre trial of the clinical and cost effectiveness of a novel urinary catheter design in reducing catheter-associated urinary tract infection compared with the traditional Foley design for adults requiring long-term catheterisation

Participant Identification Number for this trial:

C	**D**	**T**	**-**							

Name of Researcher: _____

Please write your initials in each box to confirm that you have read and agree to the following statements	Please initial box
1. I confirm that I have read and understand the information sheet (version 4, dated 22 Feb 2024) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	INITIAL
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being adversely affected.	INITIAL
3. I give permission for a copy of my consent form to be sent to the Southampton Clinical Trials Unit (where it will be stored securely), to allow confirmation of my consent.	INITIAL
4. I consent to the collection and use of information about me in accordance with the participant information sheet.	INITIAL
5. I consent to the storage of my contact details onto a secure trial contacts database for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication.	INITIAL
6. I give permission for my GP to be notified of my participation within the CADET Trial	INITIAL
7. I give permission for information from my GP medical notes (including serious adverse events) to be collected from my GP by delegated site study staff if applicable.	INITIAL

8. I am happy for my contact details (name and address) to be provided to a courier in the instance that necessary study materials need to be delivered to me.	INITIAL	
9. I agree to my pseudo-anonymised research data being held on servers located in the EU and USA. Pseudo-anonymised means that the research data will not contain any personal information that could identify me. Access to data managed by the Southampton CTU will be strictly controlled. Applicable Data Legislation will be abided by.	INITIAL	
10. I understand that relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from the research team at the University of Southampton or by the Sponsor (University Hospital Southampton NHS Foundation Trust) for the purpose of this research. I give permission for these people to look at my medical records.	INITIAL	
11. I understand that if I withdraw from the study my pseudonymised data that has been collected will be used for analysis.	INITIAL	
12. I understand that the information collected about me may be used to support other research in the future, and de-identified information may be shared with other researchers.	INITIAL	
13. **If a WOMAN OF CHILD-BEARING POTENTIAL:** I agree to inform the trial team if I am/become pregnant, as detailed in the patient information sheet for the CaDeT study. **If not applicable, please tick the N/A box on the right.**	INITIAL	**N/A** ☐
14. **I agree to take part in the CaDeT study.**	INITIAL	

	Yes	No
15. **OPTIONAL:** I would consider being interviewed for the CaDeT study and I agree for my contact details (email address, phone number, postal address) to be shared with the interviewer.	INITIAL	INITIAL
16. **OPTIONAL**: I agree to being informed of the results of the CaDeT study.	INITIAL	INITIAL
17. **OPTIONAL:** I would consider being interviewed for the separate study EQUATE to discuss my thoughts and views on the use of digital technology in research and I agree for my contact details (email address, phone number, postal address) to be shared with the interviewer based at University of Southampton.		

Name of Patient	Signature	Date (DD-MMM-YYYY)
Name of researcher taking consent	Signature	Date (DD-MMM-YYYY)

Reminder for Research Team if paper consent:
1 (original) signed consent form to be kept in Investigator Site File;
1 copy for the participant
1 copy to be kept in Medical Notes with a copy of the PIS
1 copy to be sent to cadet@soton.ac.uk using SafeSend, for central monitoring purposes