<LOCAL HEADER & TRUST LOGO>

<Insert Patient Address>

<insert date>

Dear <insert patient name>

**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 (CaDeT study)**

**We are writing to inform you of some important changes that we have made to the study.**

Please take some time to read this letter. If you have any questions or concerns about the study, please contact <local investigator name> <contact details>.

**<delete as appropriate**><We recently invited you to take part in the CaDeT study> <You recently consented to take part in the CaDeT study>. You may remember receiving a copy of the Patient Information Sheet, which explained the study objectives, procedures, and the total number of patients that would need to take part in the study, to answer the questions that we wanted to answer. Please find a copy of the Patient Information Sheet, enclosed.

The study has been recruiting patients since January 2023. Unfortunately, the study has not recruited enough participants for us to be certain that we will meet the 310 patients that are needed, to make strong scientific comparisons between the Optitip and the Foley catheter. This means that we are no longer able to effectively answer the question that we initially set out to answer ‘**Does the Optitip catheter reduce the number of urinary Tract Infections (UTIs) and other catheter-related symptoms compared to the Foley catheter**’.

Although we are no longer able to answer the question that we set out to answer, there are still some other important research questions in this area that need answering, which we can achieve even with a smaller number of participants recruited. For example, there is a lack of data on the problems associated with long-term catheters. Specifically, there is considerable uncertainty regarding the incidence of UTI and catheter blockage, which can often lead to the high use of out-of-hours community services. Secondly, there is also a gap in knowledge on catheter-associated healthcare costs. There aren’t currently any research studies that can answer these questions.

**We will continue to recruit eligible and interested patients into the study, because we can still answer the questions above, even with fewer participants.** All the procedures as outlined in the Participant Information Sheet will remain the same. If you decide to <consent to the study> <continue your participation in the study>, we will conduct the <Consent and> Baseline visit with you approximately 4 weeks before your next catheter change. You then will be randomised to the Optitip or Treatment as Usual Arm, approximately 2 weeks before your next planned catheter change. The study will close to recruitment on 31 May 2024. After this time, we won’t be able to randomise any more patients.

**What will happen after I have been randomised?**

1. **After you have been randomised, we will let you know whether you have been randomised to the Optitip Arm or the Treatment as Usual Arm.** If you are randomised to the Optitip Arm, you should have received enough Optitip to last you for the duration of the study. Please note that whilst we will try our best to provide you with enough of the Optitip catheter, the supply may be impacted by the availability from the manufacturer LINC Medical, and supply may decrease beyond our control.
2. **You will still be sent a questionnaire to complete every month, for 12 months from the date that you were randomised to the study.**

**Please read the enclosed participant information sheet, which outlines the study procedures in more detail.**

**What will happen at the end of the study?**

After you have completed your final questionnaire at month 12, you will have finished the

trial. We will collect information from your Community Nursing records and your GP Notes. This will include information about your catheter-related care, and any symptoms or medications you had during the trial that are catheter or bladder-related (including test results for any infections).

The results will be analysed, but this can take a further 6 months. The results will then be submitted for publication in a medical or nursing journal. No directly identifiable personal data will be used in any reports or publications that come from the CaDeT study. We will send you a summary of the study results, unless you have told us that you would prefer not to receive this. The summary will also be available to members of the public on the Southampton Clinical Trials website: www.southampton.ac.uk/ctu/index.page

**If you were randomised to the Optitip Arm and would like to continue to use the Optitip catheter at the end of the 12-month supply, you are advised to speak with the member of your care team responsible for prescribing your catheter.**

We hope you are willing to continue participation in CaDeT, but as we explained at the start of the study, you are free to withdraw at any time, either because of the changes to the study we have detailed in this letter, or for any other reason.

If you have any questions or concerns about the study, please contact <local investigator name> <contact details>.

Thank you for taking the time to read this letter.

Yours sincerely

[Insert name]

Principal Investigator CaDet Trial <insert trust name>