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Study Information Sheet -
Consent to interview for Health Care Practitioner (HCP)

A new urinary catheter designed to improve bladder drainage: first-in-human testing of the Flume catheter
Stage 2, in patients requiring an indwelling catheter

Permission to take part in a recorded discussion about your experiences of using indwelling catheters during the treatment of patients

We would like to invite you take part in a short interview about your experiences on using the Flume catheter. Please take some time to read this information carefully before deciding whether or not you would like to take part in the interview.

1. Why are you conducting interviews with trial participants?

By conducting interviews with Healthcare Practitioners we are hoping to learn more about their experience of using the Flume Catheter. Understanding more about these aspects may help us to improve care in the future.

2. Do I have to have an interview?

No. It is entirely up to you to decide if you want to participate or not.

3. When and where will the interview take place?

If you agree to take part in the interview a member of the research team will contact you to arrange a convenient time for this to take place. You will be able to choose whether the interview takes place face to face at the hospital, via telephone or via web conference (eg Teams or Skype), depending on your preference. The interview will be conducted by Dr Nikki Cotterill or one of her colleagues. Dr Cotterill is an Associate Professor at the Bristol Urological Institute and a visiting fellow at the University of Southampton. Dr Cotterill is very familiar with conducting interviews of this type. The interview is expected to take about 30 minutes. During the interview we would like to ask you some questions about how the catheter used in the

study (Flume catheter) compares with the Foley catheter. This will include whether the placement and removal of the Flume catheter was easy or difficult, whether there are positive or negative aspects of the Flume catheter and if you have any comments on how the catheter could be improved.

4. What will I have to do if I decide to take part?

If you agree in principle to have an interview, you will be contacted by a member of the trial team from Bristol. They will discuss the interview with you in more detail and answer any questions you have. If you are still willing to help, they will arrange a date and time for the interview that suits you.

On the day of the interview, the researcher will ask you to give your agreement (consent) to speak with them and for us to audio-record the interview. The interview should not be longer than 30 minutes. We will be asking the same basic questions to everyone, but we are also interested in anything you feel would be helpful or important to discuss.

During the interview the conversation between you and the interviewer will be recorded using an audio tape recorder and the interviewer may also make notes during the discussion. The purpose of the recording is to allow the researcher to capture all the information discussed during the interview, which is important for later analysis. The recording will also be transcribed so that a text version is available. The recording will be transcribed by an NBT member of staff. The recording of the interview will be kept in a secure location at the Bristol Urological Institute until the end of the study. Dr Cotterill or a nominated member of the study team will analyse the interview to see what we can learn from them. Findings from the interview will provide information about the catheter that may help in the future design and development of the catheter.

With your consent, we may use some anonymised quotations from the interview in the final published results of the study.

Only Dr Cotterill or a nominated member of the research team will have access to the recording and transcription. Official bodies such as Notified Bodies or Competent Authorities may also

need to look at the text of your interview. If this happens, they will treat your data with the same level of confidentiality as the researchers.

5. How will you ensure my details are kept confidential?

Ensuring your data is kept safe is an important priority for the research team. Your interview recordings will be stored on a password-protected computer network at the University of the West of England and North Bristol NHS Trust. The interview recording will be transcribed by a nominated person employed by the North Bristol NHS Trust before being anonymised (removing anything that could identify you such as anyone's names, places, or dates) and analysed by the researcher.

North Bristol NHS Trust is the sponsor for this study. We will be using information from you in order to undertake this study and will act as the data controller. This means that we are responsible for looking after your information and using it properly.
study.

6. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/

- our leaflet available from www.nbt.nhs.uk/PatientResearchdata
- by asking one of the research team
- by contacting Helen Williamson (Head of Information Governance)

at helen.e.williamson@nbt.nhs.uk or by ringing 0117 41 44767.

7. What should I do if there are any problems or I would like to make an independent complaint?

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In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the North Bristol NHS Trust but you may have to pay your legal costs. NHS-sponsored research studies such as this one are covered by NHS indemnity (the same indemnity that applies to any patient in the NHS). In the unlikely event that you feel that you have been adversely affected by participating in this study, you should contact the research team as soon as possible. The team will arrange to meet you as soon as possible to discuss your concerns. Should you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms will be available to you. Please visit www.nbt.nhs.uk/patients-carers/feedback for further information about how to make a complaint or contact the North Bristol Trust Hospital Patient Advice and Liaison Service (PALS) on **0117 414 4569**. PALS can also provide confidential advice and support to patients, families and their carers.

If you need any further information you can contact ??? at:

XXXXXX

Contact name: (*To be inserted)*

Role: (*To be inserted)*

Contact telephone number: (*To be inserted)*

Thank you for taking the time to read this information, and for considering taking part in the interview.