UPSTREAM – Phase II: 5-Year Follow Up of the UPSTREAM study.

*UPSTREAM: The **U**rodynamics for **P**rostate **S**urgery **T**rial; **R**andomised **E**valuation of **A**ssessment **M**ethods for diagnosis and management of bladder outlet obstruction in men.*

Participant Information Sheet: "UPSTREAM – Phase II"

We invite you to take part in the 5-year follow up of the UPSTREAM study

- You previously took part in the UPSTREAM study *("UPSTREAM – Phase I")* because you had urinary problems such as difficulty passing urine, or frequent and urgent need to pass urine (lower urinary tract symptoms (LUTS)). We monitored your symptoms and the treatment you received for 18-months. You agreed to be contacted about a longer term follow up.
- We now want to establish the longer term (5-year) results of any treatment that you received for your LUTS, and what extra treatment may have been needed after the initial 18-months *("UPSTREAM – Phase II")*.
- In taking part in "UPSTREAM - Phase II", you do *not* need to return to hospital for any clinical assessments. Instead we will ask you to **complete one questionnaire booklet** about your urinary symptoms, their effect on your everyday life, and your general state of health. To thank you for your time we will offer you a £20.00 gift voucher upon receipt of your completed questionnaire.
- We will also securely collect information relevant to this study from central NHS records. For example, information about relevant inpatient stays and outpatient attendances.
- By taking part in this study, you will be providing evidence for future men with bothersome LUTS who may be faced with similar decisions you and your urologist have had about assessing and treating your condition.
- You can stop taking part in this study at any time.

***Please note:** for the purpose of this information sheet, any reference to 'we' means the study sponsor.*

Important things that you need to know

- Before you decide to take part, it is important that you understand what the study is about, why it is being done and what will be involved.
- Please take time to read this Participant Information Sheet:
  - PART A: explains why this study is being done;
  - PART B: describes what taking part involves; and
  - PART C: provides further general information about the study and information about what will happen to your data if you decide to take part.
- Feel free to talk to family members or others if you wish.
- Please contact a member of the UPSTREAM Study Office using the details below if there are any parts of this information sheet that you do not understand, or you would like further information on.

Contact details - UPSTREAM Study Office

- **Email:** upstream-trial@bristol.ac.uk
- **Tel:** 0117 331 3907 | 0117 928 7276
- **Website:** http://www.bristol.ac.uk/population-health-sciences/projects/upstream/

University of BRISTOL | BRISTOL TRIALS CENTRE | FUNDED BY NIHR National Institute for Health Research | NHS North Bristol NHS Trust

Contents

PART A: Why is the study being done?

1. Why are we doing a longer term (5-year) follow up study?

Between 2014 and 2016 you took part (enrolled) in Phase I of the UPSTREAM study because you had bothersome lower urinary tract symptoms (LUTS). To recap; when referred to hospital, men with bothersome LUTS are assessed with a set of standard assessments (tests). UPSTREAM set out to see whether including an extra assessment called "urodynamics" helps when considering treatment options.

Men who took part ("you") were split into two groups to receive either standard assessments (routine care) or routine care plus urodynamics. All men then discussed the results of the tests with their urologist and decided what treatment to have. 18-months after you agreed to take part in the study, you completed a questionnaire booklet about your urinary symptoms, their effect on your everyday life, and your general state of health, and identified what treatment you received. The study aimed to provide evidence to help doctors and the National Health Service (NHS) decide whether urodynamics should be more widely used for the assessment of men with LUTS who are seeking further treatment, such as surgery.

During the first phase of the UPSTREAM study, however, we identified that there is significant variation in the assessment pathway in 26 hospitals across England, including duration, as well as in patient factors. We identified that several patients had not fully completed their LUTS treatment when they reached the 18-month follow up, or had completed it less than 6-months beforehand. From a clinical perspective, a 12-month timeframe is appropriate to show the immediate impact of surgery.

Additionally, very little is known about men's attitudes to the long-term experience of LUTS and associated treatments, which has been identified as a research priority.

2. What is the aim of this longer term follow up study?

In this further follow up study ("UPSTREAM – Phase II"), we want to find out the longer term (5-year) results of treatment for your LUTS, and see how many men went on to receive surgery after the initial 18-months (i.e. after the original study, "UPSTREAM - Phase I").

PART B: What does taking part in the study involve?

3. Why have I been invited to take part?

When you took part in the original study ("UPSTREAM - Phase I"), you agreed that we could contact you about a longer term follow up. It is now approaching 5-years since you originally agreed to take part, so we would like to invite you to take part in this study.

4. What is involved in the study?

The diagram on page 4 illustrates what happens during this study. To summarise, you will now be asked to:

- **complete one questionnaire** booklet about your urinary symptoms, their effect on your everyday life, and your general state of health. The questionnaire booklet should take about 20 minutes of your time to complete; a copy is included with this information sheet.
- You then need to **return the booklet** to the UPSTREAM Study Office, using the pre-paid (freepost) envelope provided. Alternatively, you can complete the questionnaire online, or over the telephone with a member of the study team, if preferred.

You do *not* need to return to hospital for any clinical assessments. Instead, we will securely collect information relevant to this study from hospital and/or central NHS records. This will include, for example, information about any relevant inpatient stays and outpatient attendances, including procedures for your LUTS. By using these records, we are using information that has already been collected, saving you, and the NHS, extra time and resources. You agreed for us to collect this information when you enrolled in the original study ("UPSTREAM – Phase I").

5. What are the possible benefits and disadvantages of taking part?

While you may not receive a direct benefit of taking part in this study, you will be providing evidence for future men with bothersome LUTS who may be faced with similar decisions you and your urologist have had about assessing and treating your condition.

We do not anticipate any disadvantages in taking part, although you will need to spend time completing the questionnaire.

6. Do I receive anything for taking part?

To thank you for completing the "5-Year Follow Up" questionnaire booklet, we will offer you a £20.00 gift voucher upon receipt of your completed questionnaire.

7. Do I have to take part?

It is your choice whether you take part in this longer term follow up, or not.

If you decide not to take part, your treatment will not be affected at any point.

If you have any queries, or if there are any parts of this information sheet that you do not understand, please contact us using the details on the front page.

8. Can I stop taking part after I have started?

If you do decide to take part, you are also free to leave the study (withdraw) any time you wish without giving a reason; please contact us using the details on the front page. You do not have to give a reason and your medical care and legal rights will not be affected.

If you do withdraw from the study we would retain, confidentially, the relevant information we had already collected about you. We would continue to collect data from central NHS records unless you request otherwise.

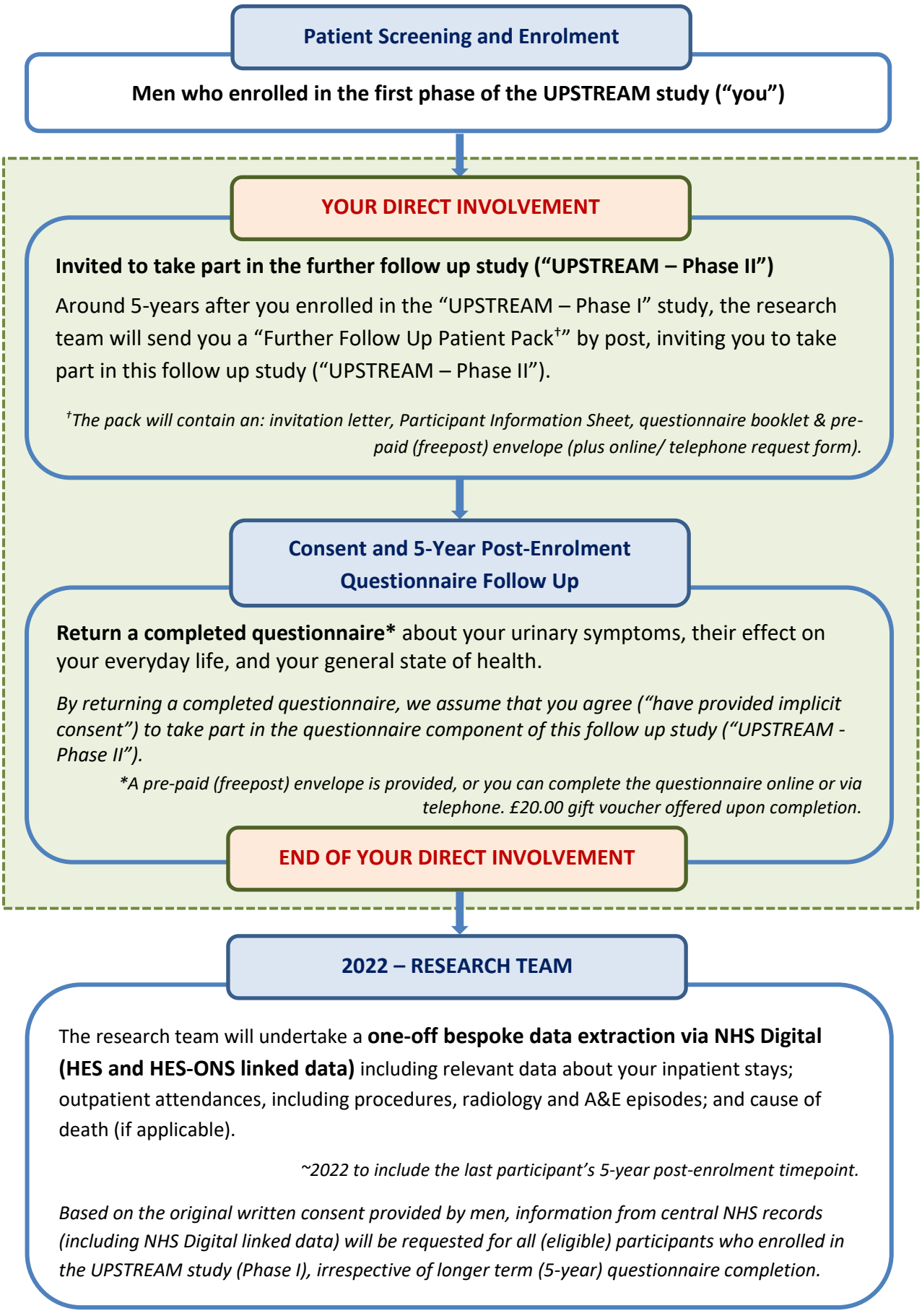
9. How long does the study last and what happens when it is finished?

Once you have returned your "5-Year Follow Up" questionnaire booklet, your *direct* involvement in this study is complete.

This study will run through to June 2022. Once completed, the overall results will be published in medical journals and shared with other healthcare professionals interested in this topic at conferences. No one will be able to identify you from any of the study reports/ publications.

Men who take part will also be sent the results via a study newsletter, which is expected in 2023. Results will also be made available via the study website.

10. Diagram about "UPSTREAM - Phase II"



PART C: Further information about the study and what will happen to your data if you decide to take part

11. Who funded this study, who is the sponsor, and who is managing this study?

This study is funded by the National Institute for Health Research (NIHR), which is the research arm of the NHS (reference 12/140/01). The study is sponsored by North Bristol NHS Trust (reference 4560), and the Bristol Randomised Trials Collaboration (part of the Bristol Trials Centre), University of Bristol, are responsible for managing the study.

12. Will the information I provide be kept confidential?

Yes, we are committed to handling the information (data) used in the UPSTREAM study securely and confidentially. North Bristol NHS Trust is the sponsor for this study based in the United Kingdom (UK). The Bristol Randomised Trials Collaboration (BRTC), as part of the Bristol Trials Centre (BTC), University of Bristol (UK), are responsible for managing the study. North Bristol NHS Trust and the University of Bristol act as joint data controllers for this study. This means that we are responsible for looking after your information and using it properly.

All information collected for the study at any time will be stored using a 'study identity number' for confidentiality and will be kept secure using passwords on a University of Bristol server. The information will be handled in line with data protection requirements and will only be available to those responsible for maintaining research standards. Your doctor (GP) will be informed of your participation in the study.

We will retain your data for at least 5-years after the study ends, which is considered good practice for clinical trials. After that period, the data will be securely destroyed.

When taking part in the original study ("UPSTREAM – Phase I") you agreed that we can access relevant information from hospital and/or central NHS records (such as NHS Central Registers, or other registries including those managed by NHS Digital (formerly Health and Social Care Information Centre), including Hospital Episode Statistics (HES) and Office for National Statistics (ONS)). NHS Digital handles information from healthcare organisations in England and Wales, including dates and details for hospital admission/ attendance and where applicable, cause of death. This information will be kept secure and confidential. To access this information, we will securely share some identifiable information with NHS Digital, such as your study number, NHS number, date of birth and gender.

It is a requirement that your records in this research, together with any relevant medical records, can be looked at by authorised staff working for the sponsor or the Regulatory Authorities. Their job is to check that research is properly conducted and the interests of those taking part are adequately protected.

Other researchers may wish to access data from this study in the future. Unless you advise otherwise, anonymous data collected in this study may be used in future ethically approved studies; this will not include names, addresses or dates of birth, and it will not be possible to identify participants in any way. If anonymised data from the study is shared, the consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

13. How will we use information about you?

We will need to use information from you and/or from your medical records for this research project. This information will include your:

- Initials
- NHS number
- Name
- Gender
- Date of birth
- Contact details (for example: postcode, telephone number, email address)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

14. 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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and/or your hospital. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

15. 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 http://bristol.ac.uk/population-health-sciences/projects/upstream/
- at the University of Bristol website, www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
- at North Bristol NHS Trust website, www.nbt.nhs.uk/research-innovation/our-research/patient-information-health-care-research
- by sending an email to upstream-trial@bristol.ac.uk, or
- by ringing us on 0117 331 3907 | 0117 928 7276.

16. Who has reviewed this study?

This study has been reviewed by North Bristol NHS Trust, the Health Research Authority and NHS Research Ethics Committee (South Central – Berkshire Research Ethics Committee, reference 19/SC/0578) who have provided approval for this study to be conducted. An independent Trial Steering Committee will monitor the study to ensure it is conducted according to good research practice.

17. What if there is a problem?

Taking part in this study does not affect your normal legal rights. Whether or not you do take part, you will retain the same legal rights as any other patient in the NHS (which includes professional indemnity insurance for negligence).

If you wish to complain about your health care or any aspects of this study, the normal NHS mechanisms will be available to you. We do not expect participation to affect private medical insurance, but please check with your insurers before agreeing to take part in the study.

In the unlikely event that something does go wrong, and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against North Bristol NHS Trust but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

If you become unable or unwilling to continue in this study, we would withdraw you from it.

18. How do I make a complaint?

If you have a concern about any aspect of the study, please contact the UPSTREAM Trial Manager who will do their best to answer your questions (phone: 0117 331 3907, email: upstream-trial@bristol.ac.uk). If you remain unhappy with any aspect of the study, please email the sponsor (researchsponsor@nbt.nhs.uk).

If you are still concerned and wish to complain formally, you can do this through the NHS Complaints Procedure, either by post, email or by telephone.

By post: NHS England, PO Box 16738, Redditch, B97 9PT. By email: england.contactus@nhs.net *(Please state: 'For the attention of the complaints team' in the subject line).* By telephone: 0300 311 22 33.

You can visit their website for further information: https://www.england.nhs.uk/contact-us/complaint/complaining-to-nhse/

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION.
PLEASE KEEP A COPY FOR YOUR RECORDS.