Appendix 2 PATIENT INFORMATION SHEET

Study Title: Urinary Biomarker URO17™ Study
Sponsor: Cardiff University
Chief Investigator: Prof Howard Kynaston

Version 1.

You are being invited to take part in a research study called the Urinary Biomarker URO17 study. Before you decide, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Take time to decide whether or not you wish to participate. If you would like to participate the research team will go through the information sheet with you, please ask the team if there is anything that is not clear or if you would like more information.

1. What is the purpose of the study?

The purpose of this study is to see if testing urine with different laboratory tests can provide a better understand of bladder health.

2. Why have I been asked to take part?

You have been chosen to participate as you are due to attend a Urology appointment for further investigation into bladder health. We need urine samples from a wide range of patients for our study and this invitation does not imply that there is anything wrong with your bladder.

3. What will happen if I agree to take part?

If you agree to take part, you will need to sign a consent form.

During your clinic appointment you will be asked to provide a urine sample, if your doctor requires a urine sample as part of your clinic appointment we will use this sample to collect a sample for the research study. You will also asked if you will complete a questionnaire about the study being done about how you feel having the tests done in clinic.

4. Optional Questionnaire sub-study

We are giving 250 our participants the option to participate in an additional questionnaire sub-study. The sub-study is looking to find out patients' thoughts on using a non-invasive test instead of Cystoscopy.

If you choose to participate in the sub-study you will be asked to complete a questionnaire before and after your cystoscopy examination

5. Do I have to take part?

Taking part in the study is voluntary, and it is up to you to decide whether or not to take part. If you decide not to take part, you do not have to explain your reasons and it will not affect any future medical treatment or legal rights. You are free to withdraw from the study at any time, without giving a reason, even after signing the consent form. However, we may need to keep any data you provided up until the point you chose to leave the study and this may be included in the data analyses.

6. What will happen with my urine sample

Your urine will be sent to the laboratory at University Hospital of Wales and analysed for any abnormal cells using 2 different techniques. Any remaining urine sample not used as part of the two tests will be destroyed according to the local rules for disposal of clinical material.

Your sample(s) will be assigned a unique identification code, and the link between this code and your name will only be accessible by researchers named on the project.

As clinical material, material used in the tests will be stored for up 30 years after the end of the study. After this time, the samples will be destroyed.

It is hoped that special labelling of proteins in the cells contained in the urine will be able to differentiate between cancerous and non-cancerous conditions.

7. Will I benefit from taking part in this study?

Taking part in this study will not be of any direct benefit to you and the study will not alter your treatment in any way, although we hope the information will help us in the future to better diagnose patients with bladder problems.

There is no payment for taking part in the study.

8. What are the possible disadvantages?

There are no expected disadvantages or side-effects from taking part in the study as it will only involve you providing a urine sample during your clinic appointment. However, if you are worried about any issues, please feel free to discuss them by contacting us using the email or telephone number at the bottom of the leaflet.

9. Will my details be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Your data will be anonymised and will be stored on a secure server at Cardiff & Vale University Health Board on a password protected computer and only the research team will be able to access it. Identifiable information (e.g. contact details) will not be shared outside the research team and will be kept separate to the study data. Anonymised data will be transferred to researchers at Cardiff University.

Should you wish to withdraw from the study, you are free to do so but data collected will be retained. At the end of the study, your data will be archived for 15 years in accordance with good research practice and Cardiff University / Cardiff & Vale University Health Board data protection regulations and archiving procedure.

10. How will information about you be used?

We will need to use information from you for this research project.

This information will include your initials, name, contact details. People in Cardiff &Vale University Health Board 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 the data for 15 years, as this is the policy for research data at Cardiff University. We will write our reports in a way that no-one can work out that you took part in the study.

Anonymised data (including data collected through NHS information systems) will be transferred to Cardiff University for data analysis. The anonymised data may be used for future research and this may be carried out by researchers other than CU. Studies using such data collected in the study will only take place after scientific and ethical review.

11. 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.

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, your anonymised data may be used for future research.

12. 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 GDPR generic leaflet available from: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
- by asking one of the research team.

You can find out more about Data Protection, including information on:

- your rights
- the legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- how to contact the Cardiff University Data Protection Officer
- how to contact the Information Commissioner's Office

which may be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection

13. What will happen to the study results?

It is intended that the results of the study will be presented at conferences and published in medical journals so we can explain to the medical community what our research results have shown. Your name will *never* appear in any report or publication arising from this study. The results of this study will also help us to design future research projects.

14. Who has approved the study?

The study has been reviewed and approved by Cardiff University as well as a National Research Ethics Committee.

15. Who is funding the study?

This research is supported and funded by the Accelerate programme which is co-funded by the Welsh European Funding Office, European Regional Development Fund and Welsh Government's Health and Social Services Group. Two companies, KDx diagnostics, an American company and CellPath Ltd, a Welsh company, are supporting the study by providing staff time and consumables.

16. What if I do not wish to take part or change my mind?

Participation for the study is completely voluntary and as such you may withdraw from the study at any point without the need to give a reason. This will not affect your routine care or any care that you would receive at any point.

In case of your withdrawal from the study, the data collected from your sample will be used in the study unless you specifically ask for it to be removed.

17. What if something goes wrong?

Any complaint about the conduct of the study, the way you have been dealt with during the study, or any possible harm you might suffer, will be addressed. If you have a concern about any aspect of the study, you should speak to one of the researchers in the first instance, who will do their best to answer your questions.

If you have any further questions concerning this study, please contact: Professor Howard Kynaston or Mr Jon Featherstone (contact details below).

If you decide to take part you will be given a copy of this information sheet and the signed consent form to keep.

Thank you for taking the time to read this leaflet and to consider the study.

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