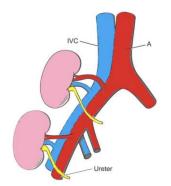
## How might PITHIA change the day of your transplant?

The biggest changes will happen 'behind the scenes' - we will be training doctors and support staff to provide the service. However, you may be called to hospital whilst your team are still waiting for a PITHIA biopsy result. In that case, your doctor will tell you how the biopsy result will affect their plans for your operation. In some cases, he/she may suggest that a dual kidney transplant (where two kidneys are transplanted together, diagram below) should be performed, to provide you with the best possible kidney function after the operation.

PITHIA will employ a team of specialist doctors to analyse the biopsy test at any time of day, or night. We will also be installing 6 high-tech digital scanners at several locations across the country to ensure the process is as fast as possible.

#### **Dual kidney transplant:**



### **Contact Us**

[insert local Trust contact details]

@PITHIA\_trial

- -

PITHIA@nhsbt.nhs.uk

www.pithia.org.uk

[insert Trust logo]



<u>Pre-Implantation Trial of</u> <u>H</u>istopathology <u>In renal Allografts</u>

> BETTER QUALITY ASSESSMENT IN TRANSPLANTATION



#### **About the PITHIA trial**

All kidney transplants have some risk of not working, and we know that kidneys from older donors are more likely to fail than kidneys from younger donors. However, many potential kidney transplants are from donors aged over 60 years, and so the risk of not using these kidneys has to be balanced against the risk of continuing to wait for a transplant.

Age alone is not a good predictor of kidney health, and many people live into very old age with excellent kidney function. To assess long-term kidney damage, we can perform a biopsy (remove a sample of kidney, then look at it under a microscope) before the organ is transplanted to help identify healthier kidneys. Performing a biopsy is however not without risk. It may cause bleeding, delay transplantation, and it may increase the chance that the kidney cannot be used for a transplant. For these reasons it is important to assess whether the benefits of performing biopsies outweigh the potential risks.

The PITHIA trial will see every transplant centre in the UK being given access to the national biopsy service. The trial will monitor how effective the biopsy service is in increasing the number and quality of kidney transplants performed in the UK.

## How might PITHIA change UK practice?

We expect that PITHIA will allow doctors to perform higher numbers of good quality transplants using organs from older donors. We think that this will be because the biopsy will enable them to be more confident that they are able to pick out the healthy donors from the unhealthy ones. Another possibility is that transplant centres which do not currently perform dual transplants, will begin to do so by using the biopsy result to guide their planning.

Only some kidneys will be biopsied for the PITHIA trial, and the decision to biopsy will be made on a case by case basis. We will not seek your consent to perform the biopsy, because this will generally happen before you're called to hospital. However, if your doctor or surgeon has requested a biopsy, this will be discussed with you when you are called into the hospital. The results of the biopsy will also be explained to you. This trial does not affect your right to decline any organ which you feel is inappropriate.

### www.pithia.org.uk

# How will your data be used?

Cambridge University Hospitals and the University of Cambridge are the Sponsor for this study based in the United Kingdom. We will be using information from your transplant records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Cambridge University Hospitals / the University of Cambridge will keep identifiable information about you for 30 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at <u>www.hra.nhs.uk/information-about-patients</u> or by contacting PITHIA@nhsbt.nhs.uk.

Cambridge University Hospitals / the University of Cambridge will collect information about you for this research study from the 'UK Transplant Registry' (held by NHS Blood and Transplant). NHS Blood and Transplant will not provide any identifying information about you to the Sponsor. We will use this information to analyse the effectiveness of the national biopsy service.