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<HOSPITAL LOGO>

**PARTICIPANT INFORMATION SHEET (FOR ADULTS)**

**SUPPLEMENTARY INFORMATION – KIDNEY SAMPLE**

**The BILAG Biologics Prospective Cohort: Long-term Safety of New Treatments in the**

**Management of SLE**

**Thank you for taking part in BILAG BR. We would like to ask for**

**your consent to further help us in our research aims.**

**Update regarding the BILAG BR study**

The BILAG BR study has received ethical approval to request kidney samples from clinical biopsies currently stored by your hospital in paraffin blocks. We would like to find out whether the way genetic material (RNA) works in your kidneys affects how well you respond to your lupus treatment.

**Why we are writing to you.**

We are writing to you to ask for your consent to use your left over 'excess' kidney tissue stored at the hospital. We ask you to gift your tissue for research.

**What will happen to my kidney tissue?**

With your permission we will ask your hospital to allow us to collect your left over kidney tissue already stored at the hospital to analyse in our study. This does not interfere with the results of the biopsy for your clinical assessment as once all histology tests have been completed the tissue is simply routinely stored in paraffin blocks. We will also seek your permission to allow us optionally to collect left over kidney tissue from future kidney biopsies you may have up to the end of the BILAG-BR study.

We will use this excess tissue to try and see what is happening to your genes during kidney inflammation in lupus. We may publish this research in academic books and journals. If we do this, any information about you will be anonymised. We may also share anonymised information about your kidney sample with other collaborators (academic institutions or commercial organisations worldwide) to perform research that will lead to a greater understanding of the causes and processes involved in lupus.

**How do I know my information is safe?**

It is very important to us to handle your paraffin blocks securely and confidentially. Paraffin blocks containing your kidney tissue are routinely marked with information identifying you to the hospital, including your name or initials.

Blocks will be transferred securely from the hospital to a researcher at Imperial College London, e.g. by using a trackable courier service. The researcher fully understands the need for confidentiality, as she has undergone training and has a certificate in safe and confidential handling of personal and clinical information. The small piece of your kidney tissue taken for research will no longer have your name or other details, and will be identified by a unique code. The paraffin block will then be transferred securely back to the hospital.

**What do I do now?**

Your participation is entirely voluntary so you don’t have to take part if you do not want to – you can refuse permission for this if you want and still take part in the rest of the BILAG BR study. You are free to withdraw at any time without giving any reason; this will not affect your medical care or your legal rights. If you withdraw, any paraffin block containing your kidney tissue will be returned to your hospital.

Please ask a member of the research team if there is anything that is not clear, or you would like more information.

If you feel you are happy to take part please sign and date the consent form attached – and return two copies to us using the freepost envelope enclosed. Please keep one copy for yourself so you can refer to it.

**Who can I contact to talk about this?**

**Who has reviewed these changes?**

These changes have been reviewed and given favourable opinion by Northwest 9 – GM West Research Ethics Committee.

Thank you for reading this information and taking the time to consider donating your tissue samples.