TO BE PRINTED ON LOCAL TRUST HEADED PAPER

GDPR Addendum to the
PATIENT (16-18 years) INFORMATION SHEET
Version 1.0, 6th August 2018

Study Title
Short course daily prednisolone therapy at the time of upper respiratory tract infection in children with relapsing steroid sensitive nephrotic syndrome; the PREDNOS 2 study

Study IRAS Number: 111990

Introduction

This Addendum to the PREDNOS 2 Patient (16-18 years) Information Sheet which you have already received provides new information following the introduction of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 on 25 May 2018. The new information is as follows.

Additional Information

The University of Birmingham and Manchester University NHS Foundation Trust are the co-sponsors for this study based in the United Kingdom. The co-sponsors will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that the co-sponsors are responsible for looking after your information and using it properly. The co-sponsors will keep identifiable information about you from this study for up to 25 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.

Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to know what information the study coordinating office has recorded about you. If you wish to view this information, or find more about how we use this information, please contact Legal Services at Legal Services, University of Birmingham, Edgbaston, Birmingham B15 2TT. Please note that a small fee may be payable to retrieve this information.

More information on how the University of Birmingham processes personal data can be found on the University of Birmingham's website on the page called 'Data Protection - How the University Uses Your Data'.

<Insert Trust name> will collect information from you and your medical records for this research study in accordance with our instructions.

<Insert Trust name> will keep your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

The information that will be provided to the co-sponsors and other organisations involved in this research is specified in the Patient (16-18 years) Information Sheet.

<Insert Trust name> will keep identifiable information about you from this study for up to 25 years after the study has finished.

All other aspects of the Patient (16-18 years) Information Sheet, which you have already consented to, will remain in effect.

Where can I get further information?
For queries about the study or for further information please contact:

Dr Martin Christian Telephone: 0115 924 9924 x63832 PREDNOS 2 Chief Investigator

<Insert Local PI Name>, Telephone <Insert Local PI Tel. No.>, PREDNOS 2 Principal Local Investigator

The PREDNOS 2 study co-ordinating centre is located at the Birmingham Clinical Trials Unit, Institute of Applied Health Research, Public Health Building, , University of Birmingham, Edgbaston, Birmingham B15 2TT. Tel 0121 415 9132, Fax: 0121 415 9135, Web address: www.birmingham.ac.uk/PREDNOS2.

Please keep a copy of this addendum with the Parent Information Sheet and the signed consent form for the study.