TO BE PRINTED ON LOCAL TRUST HEADED PAPER

<Doctor>

<Practice>

<Street>

<City>

<Postcode>

<Date>

Dear Dr <GP name>,

Re: **Name:** .....

DoB: .....

NHS No: .....

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.

I am writing to inform you that your patient, named above, has agreed to take part in the PREDNOS 2 study. The aim of the study is to evaluate the effectiveness of a six day course of daily prednisolone therapy at the time of URTI in reducing the development of subsequent nephrotic syndrome relapse in children with relapsing SSNS. I am writing to give you some information about the study.

The PREDNOS 2 study will investigate whether the administration of a 6 day course of daily prednisolone at the time of development of URTI will reduce the risk of relapse developing. The study, which will be placebo controlled, will run for 12 months, with visits occurring once every three months (i.e. a total of 5 visits). Parents/the patient will be issued with a supply of either prednisolone or placebo, a card with strict definitions of URTI and instructions regarding what to do once URTI develops. The six day course of prednisolone or placebo will be administered each and every time the patient develops and URTI over the 12 month study period. Follow-up visits will monitor response to study drug, general medical history, adverse effects including behaviour and health economic information. To enter the study, children and young adults (under 19 years of age) need to have suffered two disease relapses in the preceding 12 months. Patients who have participated in PREDNOS will be allowed to enter PREDNOS 2. The study will receive full MCRN support.

Live vaccines can, in some situations, cause severe or fatal infections in immunosuppressed individuals due to extensive replication of the vaccine strain. For this reason, severely immunosuppressed individuals should not be given live vaccines, and vaccination in immunosuppressed individuals should only be conducted in consultation with an appropriate specialist. Inactivated vaccines cannot replicate and so may be administered to immunosuppressed individuals, although they may elicit a lower response than in immunocompetent individuals.

Subjects who receive prednisolone, orally or rectally, at a daily dose (or its equivalent) of 2mg/kg/day for at least one week, or 1 mg/kg/day for one month are classified as a special risk group for being given live vaccines. Administration of live vaccines should be postponed for at least three months after immunosuppressive treatment has stopped, or three months after levels have been reached that are not associated with immunosuppression. Live vaccines include MMR and the BCG vaccine for tuberculosis. Also for parents who may wish to travel with their children other live vaccines include Yellow Fever and oral typhoid.

Where these issues arise with a subject within the trial please seek the advice of an immunologist or specialist within the field. Your patient's varicella immune status will have been checked in hospital as part of the routine investigation of a child with nephrotic syndrome, though until this result is available your patient should avoid contact with such cases: should contact inadvertently occur, then you are advised to contact me <*insert responsible clinician telephone number*>.

PREDNOS 2 is being coordinated by the University of Birmingham Clinical Trials Unit (address below), and is being funded by the National Institute for Health Research Health Technology Assessment programme (NIHR HTA) Ref: 11/129/261. The trial has been approved by North West – GM Central Research Ethics Committee. PREDNOS 2 is co-sponsored by the University of Birmingham and the Manchester University NHS Foundation Trust.

If you have cause to see your patient during the course of the study and want to discuss any aspect of their management e.g. treatment regimen, contra-indications etc., please do not hesitate to contact me on Tel: <*insert responsible clinician telephone number*>. It would be particularly helpful if you could inform me of any adverse events your patient reports to you or any therapy changes you make or wish to make.

Yours sincerely,

<*insert responsible clinician name*>