TO BE PRINTED ON LOCAL TRUST HEADED PAPER



<Doctor>

<Practice>

<Street>

<City>

<Postcode>

<Date>

Dear Dr <GP name>,

# Re: Name: …………………………………………………………………………………………………………….

# DoB: ……………………………………………………………………………………………………………….

# NHS No: …………………………………………………………………………………………………………

**The STOP-ACEi Trial: A multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease.**

I am writing to inform you that your patient, named above, has consented to take part in the STOP-ACEi trial. This investigator led multi-centre open-label, randomised controlled clinical trial will test the hypothesis: Does a strategy of discontinuing angiotensin converting enzyme inhibitors (ACEi) or angiotensin receptor blockers (ARBs) or combination of both in patients with advanced (stage 4 or 5) progressive chronic kidney disease (CKD) lead to the stabilisation of, or improvement in, renal function over a 3 year follow-up period, provided good blood pressure control is maintained with other agents, compared to a strategy of continuing ACEi and / or ARB.

The trial will recruit 410 people aged 18 and over with advanced (stage 4 or 5) progressive CKD receiving either ACEi or ARBs or a combination of both. All standard measures will be assessed at three monthly intervals from baseline to 3 years in the standard follow-up clinic consistent with the recommendation of the NICE CKD guideline for routine clinical practice. All patients are reviewed on a regular basis at out-patient clinic visits every 3 months, thus all assessments are timed to fit in with routine clinic follow-up visits.

**This patient has been randomised to the experimental arm – STOP ACEi and/or ARB**

Under the experimental arm, the patient has stopped their current treatment with ACEi and/or ARB therapy. In order to compensate for the loss of antihypertensive activity, additional antihypertensive treatment has been commenced. Any antihypertensives other than ACEi/ARBs are permitted to control blood pressure throughout trial participation. The normal contraindications and safety precautions for use of these treatments should be adhered to, as per routine care. Please notify me of any changes to this patient’s care during trial participation using the contact details listed below.

If at any point during trial participation, you feel that the participant’s blood pressure is not adequately controlled, any of the following alternative blood pressure medications can be prescribed: calcium channel blockers, alpha- and beta-adrenoreceptor antagonists, hydralazine, minoxidil and thiazides. We recommend that the Renal Pharmacy Handbook is consulted in combination with the British National Formulary due to the complex prescribing needs of patients with Chronic Kidney Disease. In all cases, it is best to commence treatment at low doses and then increase to a therapeutic level. If you have any concerns or queries, please do not hesitate to contact me using the details listed below.

STOP-ACEi is being coordinated by the University of Birmingham Clinical Trials Unit (address below), and is being funded by the Efficacy and Mechanism Evaluation (EME) programme (part of the National Institute for Health Research (NIHR) and the Medical Research Council (MRC) coordinated strategy for clinical trials) Ref. No.: 11/30/07. The trial has been approved by the Yorkshire and The Humber (Leeds East) Research Ethics Committee (Ref: 13/YH/0394). STOP-ACEi is sponsored by Hull and East Yorkshire Hospitals NHS Trust. The Chief Investigator is Prof Sunil Bhandari, Consultant Nephrologist/Honorary Clinical Professor at Hull and East Yorkshire Hospitals NHS Trust and the trial EudraCT No. is 2013-003798-82.

If you have cause to see your patient during the course of the trial 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 over the next three year trial period.

If you have any questions or would like any more information please contact *<insert responsible clinician name>* on *<insert responsible clinician telephone number>*.

Yours sincerely,

*<insert responsible clinician name>*

STOP-ACEi Study Office, The University of Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, Robert Aitken Institute, University of Birmingham, Edgbaston, Birmingham, B15 2TT.

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