TO BE PRINTED ON LOCAL TRUST HEADED PAPER



<Participant Name>

<Participant Address1>

<Participant Address2>

<City>

<Postcode>

<Date>

Dear <Participant name>,

# Re: STOP-ACEi Trial Information Letter – Experimental Arm

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

# Participant Name: ………………………………………………………………………………………………………..….

# Participant DoB: iDi iDi / Mi iMi iMi / Yii iYii iYii iYii

# Participant Trial No: ii I ii I ii I ii

Date of randomisation to the STOP-ACEi trial: iDi iDi / Mi iMi iMi / Yii iYii iYii iYii

Participant Trial Treatment Allocation**: Experimental Arm – Discontinue Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB)**

Thank you for agreeing to participate in the STOP-ACEi trial. You have been randomised to the **experimental arm** of the trial which means that you will now **discontinue** the Angiotensin Converting Enzyme inhibitor (ACEi) and/or Angiotensin Receptor Blocker (ARB) medication that you were previously taking. Examples of the names of the ACEi and ARB medication that you may have been taking are given below:

**ARBs**: Candesartan, Irbesartan, Telmisartan, Eprosartan, Losartan, Olmesartan, Valsartan and Azilsartan

**ACEi:** Lisinopril, Enalapril Maleate, Ramipril, Captopril, Cilazopril, Fosinopril Sodium, Moexipril Hydrochloride, Perindopril Erbumine, Perindopril Arginine, Quinapril, Trandolapril and Imidapril Hydrochloride

**You should discontinue taking any ACEi and/or ARB medication as of today.**

Your clinician will arrange for you to be reviewed on a regular basis at out-patient clinic visits every 3 months for the next 3 years. This means that all assessments for the STOP-ACEi trial are timed to fit in with your routine clinic follow-up visits. At these clinic visits please ask any questions or queries that you may have about the trial or your treatment, and please understand that you may withdraw from the trial at any time without your clinical care being affected.

At these clinic visits you will be asked to:

* Provide blood and urine samples for various tests
* Have a 12 lead ECG which will be performed annually
* Complete a quality of life questionnaire annually
* Have your physical function measured using the 6–minute walk test annually
* Provide blood pressure measurements
* Be weighed annually
* Provide information about any medication you are taking, any symptoms you may have experienced and whether you have been seen by a doctor, nurse or other healthcare professional because of any illness.

Detailed information about what you are required to do as part of the trial is contained within your Participant Information Sheet.

At the end of the 3 year trial period your clinician will decide your future treatment after discussion with you.

Please contact your local hospital to inform your doctor or research nurse of any symptoms or events that may be of concern to you once you have discontinued your ACEi and or ARB medication.

Name of contact: ................................................................................................................

Contact telephone number: ................................................................................................

If you become ill once you have discontinued your ACEi and or ARB medication, please tell your doctor that you are taking part in this trial. If your doctor has any urgent queries about your participation in the trial please give them the following contact details – Professor Sunil Bhandari, Telephone 01482 674566, STOP-ACEi Chief Investigator.

**Study diary**

A study diary has been provided. Please use this to record when you are seen by a doctor, nurse or other healthcare professional because of any illness along with any medicines prescribed or purchased by yourself.

**Trial contact details and information**

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| --- | --- |
| **STOP-ACEi Chief Investigator** | Prof Sunil Bhandari, Consultant Nephrologist/Honorary Clinical Professor, Hull Royal Infirmary, Hull and East Yorkshire Hospitals NHS Trust, Tel: 01482 674566, Fax: 01482 674998 Email: Sunil.bhandari@hey.nhs.uk. |
| **STOP-ACEi Local Principal Investigator** | <insert Local Principal Investigator name and contact details> |
| **STOP-ACEi Funding body** | 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: 11/30/07. |
| **STOP-ACEi Sponsor** | Hull and East Yorkshire Hospitals NHS Trust |
| **STOP-ACEi EudraCT No.:** | 2013-003798-82 |
| **STOP-ACEi Co-ordinating Centre**: | STOP-ACEi Trial Office, University of Birmingham Clinical Trials Unit (BCTU), College of Medical & Dental Sciences, Robert Aitken Institute, University of Birmingham, Edgbaston, Birmingham, B15 2TT. Web address: [www.birmingham.ac.uk/stopacei](http://www.birmingham.ac.uk/stopacei), Email address: [stopacei@trials.bham.ac.uk](mailto:stopacei@trials.bham.ac.uk), Tel 0121 415 9130, Fax: 0121 415 9135. |

If you have any queries please don’t hesitate to contact me.

Yours sincerely,

*<insert local clinician name>*

*<insert local clinician contact details>*