STOP-ACEi

CRF01 - RANDOMISATION NOTEPAD

Name of person that completed CRF, please print: This person must be listed on the STOP-ACEi delegation log.	……
Date CRF completed:	D D / M M M / Y Y Y Y

Part A: Participant Details

Investigator: ……	Centre: ……..……
Date of Birth: D D / M M M / Y Y Y Y	Sex: Female ☐ Male ☐
First Name:	Surname:
NHS number: ☐☐☐☐☐☐☐☐☐☐	
And for Scottish participants, CHI number: ☐☐☐☐☐☐☐☐☐☐	
Participant ethnicity code (Please use coded list at the end of this document): ☐☐	

Part B: Eligibility checklist

Eligibility must be assessed by medically qualified personnel. To be eligible, no shaded boxes can be ticked.

	No	Yes
Is the potential participant aged 18 years or over (male or female)?		☐
Does the potential participant have stage 4 or 5 CKD? eGFR of <30 mL/min/1.73m^2 confirmed using 4 variable MDRD equation.		☐
Does the potential participant have progressive deterioration in renal function as confirmed by the spreadsheet tool provided? Progressive deterioration is defined as a fall in eGFR of >2mL/min/year over the previous 24 months. A minimum of 3 eGFR measurements from the last 24 months are required. One must be from within the last 3 months.		☐
Has the potential participant been on treatment with an ACEi or ARB, or combination of both, for more than 6 months?		☐
Is the potential participant currently on at least 25% of the maximum recommended daily dose of ACEi or ARB?		☐
Has the potential participant had at least 3 months of specialist renal follow-up at the time of entry into the trial?		☐
Is the potential participant's resting blood pressure lower than or equal to 160/90 mmHg when measured in accordance with British Hypertension Society guidelines? Clinic readings or home readings from within the last month or a 24 hour ambulatory blood pressure measurement within the last 3 months are acceptable.		☐
Does the potential participant have a blood pressure of more than 160/90 mmHg or require 5 or more agents to control blood pressure?	☐	
Is the potential participant undergoing dialysis therapy?	☐	
Has the potential participant had a kidney transplant?	☐	
Does the potential participant have any condition which, in the opinion of the investigator, makes them unsuitable for trial entry due to prognosis or a terminal illness with a projected survival of less than 12 months?	☐	

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	No	Yes
Does the potential participant have a history of myocardial infarction or stroke in the preceding 3 months?	☐	☐
Does the potential participant have an immune-mediated renal disease that requires disease-specific treatment?	☐	☐
Is the potential participant pregnant or breastfeeding?	☐	☐
Does the potential participant have a known drug or alcohol abuse problem?	☐	☐
Has the potential participant taken part in another interventional research study within the last 6 weeks?	☐	☐
Is the potential participant able to comply with the trial schedule and follow-up?	☐	☐
Is the potential participant able to provide informed consent?	☐	☐
Eligibility assessed by (name): Must be a clinician named on delegation log.	…….	

Part C: Confirmation of eligibility

Progressive decline in renal function

To be eligible for the study, the participant must have progressive deterioration in renal function which is defined as a fall in eGFR of more than 2 mL/min/1.73m^2 per year. To confirm this, a minimum of 3 eGFR measurements from the last 24 months are required. At least one must be from within the last 3 months. Please record the creatinine readings used to determine eligibility here (please list measurements in chronological order, with the oldest listed first):

Creatinine 1: ☐☐☐☐ µmol/L	Date:	D D / M M M / Y Y Y Y
Creatinine 2: ☐☐☐☐ µmol/L	Date:	D D / M M M / Y Y Y Y
Creatinine 3: ☐☐☐☐ µmol/L	Date:	D D / M M M / Y Y Y Y
Creatinine 4: ☐☐☐☐ µmol/L	Date:	D D / M M M / Y Y Y Y
Creatinine 5: ☐☐☐☐ µmol/L	Date:	D D / M M M / Y Y Y Y
Creatinine 6: ☐☐☐☐ µmol/L	Date:	D D / M M M / Y Y Y Y

Stage 4 or 5 CKD

To be eligible for the study, the participant must have stage 4 or 5 CKD, that is an eGFR of less than 30 mL/min/1.73m^2 confirmed using the 4 variable MDRD equation. Please record the reading used to determine eligibility here:

eGFR: ☐☐ mL/min/1.73m^2	Date: D D / M M M / Y Y Y Y

Controlled blood pressure

To be eligible for the study, the participant must have controlled blood pressure of less than or equal to 160/90 mmHg. This can be determined from clinic readings or home readings from within the last month, or a 24 hour ambulatory blood pressure measurement within the last 3 months. Blood pressure should be measured according to current BHS guidelines. Please record the reading and method used to determine eligibility here:

Method: Clinic reading ☐ Home reading ☐ 24 hr ambulatory ☐

BP: ☐☐☐ / ☐☐☐ mmHg	Date: D D / M M M / Y Y Y Y

Part D: Minimisation variables

Urinary PCR **or** ACR by early morning spot urine

Please provide the most recent protein:creatine ratio or albumin:creatinine ratio.

Urinary PCR: ☐☐☐☐ mg/mmol	Urinary ACR: ☐☐☐☐.☐ mg/mmol

Diabetes

Please select one option: Type 1 diabetic ☐ Type 2 diabetic ☐ Non-diabetic ☐

Type 2 diabetes includes non-insulin dependent diabetes and insulin-treated type 2 diabetes.

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Part E: Informed consent

If participant fulfils all the eligibility criteria, please proceed to informed consent.

Consent for main study	
Has the participant given informed consent for the main study?	No ☐ Yes ☐
Version of informed consent form used:	☐☐.☐
Optional consents	
Has the participant given consent for serum and urine samples to be taken, stored and used for future analysis of biomarkers both within this study and in future related studies?	No ☐ Yes ☐
Has the participant consented to allow information held and maintained by The Health and Social Care Information Centre and current and future UK NHS bodies being used in the future to provide information about their long-term health status and health care, and for BCTU to hold their name, gender, date of birth and NHS number for this purpose?	No ☐ Yes ☐

Part F: Randomisation

Thank you for completing the STOP-ACEi CRF01: Randomisation Notepad

STOP-ACEi Online Randomisation and Data Entry: https://www.trials.bham.ac.uk/STOPACEi (24hrs)
STOP-ACEi Telephone Randomisation: 0800 953 0274 (UK toll free), 9am to 5pm Mon-Fri.

STOP-ACEi Study Office, Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, University of Birmingham, Edgbaston, Birmingham, B15 2TT.
Tel: 0121 415 9130, Fax: 0121 415 9135, E-mail: STOPACEi@trials.bham.ac.uk

STOP-ACEi website: www.birmingham.ac.uk/STOPACEi

Date of Randomisation:	D D/M M/Y Y Y Y
Arm participant randomised to:	Continue ACEi/ARBs ☐ Discontinue ACEi/ARBs ☐
Participant trial ID number:	☐☐☐☐

Following Randomisation

- Please fax a copy of the participant's signed consent form to the STOP-ACEi trial office (0121 415 9135). Remember to add the participant trial ID number to the top of the consent form before sending.
- Please give the participant the following documents:
  - A copy of the appropriate Participant Advice Letter for treatment continuation or discontinuation
  - A blank copy of the Participant Diary. This should be completed by the participant between trial visits and collected at each visit.
  - A copy of the signed Consent Form
  - A copy of the Participant Information Sheet
- Please send a copy of the appropriate GP letter for treatment continuation or discontinuation to the participant's GP.
- Please save a copy of the Confirmation of Randomisation e-mail in the participant's case notes and a copy in the local Site File.
- Please keep a copy of the Consent Form and Participant Information Sheet in the participant's case notes and file the original in the local Site File.
- Please ensure that the participant's details are listed with the participant trial ID number in the Participant Identification Log in the Site File.

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Ethnicity Codes

31	White - English / Welsh / Scottish / Northern Irish / British
32	White - Irish
33	White - Gypsy or Irish Traveller
34	White - Any Other White background
35	Mixed / Multiple ethnic group - White and Black Caribbean
36	Mixed / Multiple ethnic group - White and Black African
37	Mixed / Multiple ethnic group - White and Asian
38	Mixed / Multiple ethnic group - Any Other Mixed / multiple ethnic background
39	Asian / Asian British – Indian
40	Asian / Asian British – Pakistani
41	Asian / Asian British – Bangladeshi
42	Asian / Asian British – Chinese
43	Asian / Asian British - Any other Asian background
44	Black / African / Caribbean / Black British – African
45	Black / African / Caribbean / Black British – Caribbean
46	Black / African / Caribbean / Black British – Any other Black / African / Caribbean background
47	Other ethnic group – Arab
48	Other ethnic group – Any other ethnic group
98	Any other
99	Not known/not provided