RAMPART (MRC RE06)

PRINCIPAL INVESTIGATOR STATEMENT

Please complete this form, keep the original in your site file and email a copy to:
RAMPART Trial Management Team mrcctu.rampart@ucl.ac.uk

Institution: _____

I, the undersigned, declare that:

1. I have read the final protocol, version 1.0 dated 22-Nov-2017, for RAMPART (Renal Adjuvant MultiPle Arm Randomised Trial). Updated versions of the protocol will be provided and will not require modification of this document.
2. I agree to conduct the study in accordance with the current protocol and will only depart from the protocol when necessary to protect the safety, rights or welfare of patients.
3. I understand that as Principal Investigator I am responsible for the conduct of the trial at this site and will ensure that all colleagues and supporting staff assisting with the trial are adequately informed about the protocol, the investigational products and their trial related duties.
4. I will ensure that any information provided under a condition of confidentiality will be kept confidential by all staff working on this trial at this site.
5. I have obtained appropriate trial site approvals including any local approvals as required

I agree to comply with the obligations below:

a) To conduct the trial in compliance with the protocol, the principles of ICH GCP and applicable regulatory requirements.
b) To report any serious breach of the trial protocol or the principles of ICH GCP to the Trials Centre as soon as identified.
c) To submit all trial data in a timely manner and as described in the protocol. Individual institutions may be suspended if data returns are poor or if trial conduct is violated in other ways.
d) Record and report all Serious Adverse Events/Reactions including SUSARs and notable events to the Trials Centre, and according to the procedure outlined in the study Manual of Operations and using the study forms. Supply any additional information required for expedited reporting in a timely manner.
e) To report to the Trials Centre immediately any Urgent Safety Measures taken by the investigator to protect subjects.
f) Ensure that patients in the trial have contact information for the trial for any clinical queries or emergencies that occur out of hours.
g) Cooperate with monitoring and auditing undertaken by the host institution, the Sponsor, local co-ordinator and regulatory authorities, including but not limited to the MHRA, as required
h) Document, with the Pharmacy Department, the supply, handling, labelling and accountability of Investigational Medicinal Products
i) Maintain and keep up to date a Site Investigator File (SIF) containing the essential documents and making this Site Investigator File available for inspection if requested by the Sponsor or regulatory authorities

j) Not to disclose, present or publish any trial data without the approval of the Trial Steering Committee.
k) To retain all trial related documents for 25 years after the completion of the trial.

□ **I have no potential conflict of interest,** e.g. a professional interest, a proprietary interest or any other conflict of interest.
□ **YES, I have a potential conflict of interest** (If you have a potential conflict of interest, we will send you an appropriate form).

Name of Principal Investigator:
(Print name in Capitals) _____

Signature: _____

Date: _____