



# Health Research Authority

## London - Riverside Research Ethics Committee

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**Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.**

06 January 2020

James Larkin  
Royal Marsden Hospital  
Downs Road  
Sutton  
SM2 5PT

Dear James Larkin

**Study title:** Renal Adjuvant MultiPle Arm Randomised Trial (RAMPART): An international investigator-led phase III multi-arm multi-stage randomised controlled platform trial of adjuvant therapy in patients with resected primary renal cell carcinoma (RCC) at high or intermediate risk of relapse

**REC reference:** 17/LO/1875

**Protocol number:** RE06

**EudraCT number:** 2017-002329-39

**Amendment number:** 12

**Amendment date:** 28 November 2019

**IRAS project ID:** 219487

The above amendment was reviewed by the Sub-Committee in correspondence.

### **Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

### **Approved documents**

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper	n/a	03 December 2019
Investigator's brochure / IMP Dossier [(tracked).]	v15.0	08 October 2019
Investigator's brochure / IMP Dossier [(clean)]	v15.0	08 October 2019
Notice of Substantial Amendment (CTIMP)	12	28 November 2019
Other [Summary of Changes from RAMPART Participant Information Sheet v2.0 to v3.0 ]	n/a	03 December 2019
Participant information sheet (PIS) [ (clean).]	v3.0	03 December 2019
Participant information sheet (PIS) [(tracked).]	v3.0	03 December 2019
Research protocol or project proposal [(tracked).]	v3.0	28 November 2019
Research protocol or project proposal [ (clean).]	v3.0	28 November 2019
Summary, synopsis or diagram (flowchart) of protocol in non technical language [ v2.0 to v3.0]	n/a	28 November 2019

### **Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

### **Working with NHS Care Organisations**

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

### **Statement of compliance**

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### **HRA Learning**

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

<b>17/LO/1875:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely

A handwritten signature in cursive script, appearing to read 'Margaret Jones', enclosed in a light grey rectangular box.

pp

**Dr Margaret Jones**  
**Chair**

E-mail: [nrescommittee.london-riverside@nhs.net](mailto:nrescommittee.london-riverside@nhs.net)

Copy to: *RAMPART Trial Management Team*



**Health Research  
Authority**

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**Attendance at Sub-Committee of the REC meeting on 13 December 2019**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Nuria Gonzalez-Cinca	Clinical Study Manager	Yes	
Dr Margaret Jones	Retired General Practitioner	Yes	Chaired the meeting

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Mia Cooper	Approvals Administrator