

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.

07 July 2020

Dear Ms Lawrie,

Study title: A phase II study of nivolumab monotherapy in patients with relapsed/refractory Hodgkin lymphoma, fit for autologous stem cell transplant, who fail to reach complete metabolic remission after first or second line salvage therapy

REC reference: 18/LO/0204

Protocol number: UCL/15/0515

EudraCT number: 2017-002544-32

Amendment number: Substantial Amendment 6

Amendment date: 28 May 2020

IRAS project ID: 216147

The above amendment was reviewed at the meeting of the Sub-Committee held 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>
Annex 2: Notification of Amendment	Substantial	28 May 2020

	Amendment 6	
Cover Letter		28 May 2020
MHRA Notice of No Objection Letter (Medical Devices) and relevant correspondence [MHRA Acknowledgement of amendment]		10 June 2020
Other [Updated ARSAC PRA Form]		28 May 2020
Participant consent form [Pregnancy Monitoring Consent Form Tracked Changes]	1.0	28 May 2020
Participant consent form [Pregnancy Monitoring Consent Form Clean]	1.0	28 May 2020
Participant consent form [ANIMATE ICF Clean]	4.1	28 May 2020
Participant consent form [ANIMATE ICF Tracked Changes]	4.1	28 May 2020
Participant information sheet (PIS) [Pregnancy Monitoring Information Sheet Clean]	1.0	28 May 2020
Participant information sheet (PIS) [Pregnancy Monitoring Information Sheet Tracked Changes]	1.0	28 May 2020
Participant information sheet (PIS) [ANIMATE PIS Clean]	5.0	28 May 2020
Participant information sheet (PIS) [ANIMATE PIS Tracked Changes]	5.0	28 May 2020
Research protocol or project proposal [Clean]	4.0	28 May 2020
Research protocol or project proposal [Tracked Changes]	4.0	28 May 2020

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.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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.

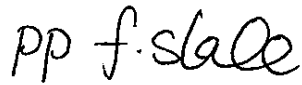
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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/>

18/LO/0204:	Please quote this number on all correspondence
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Yours sincerely



Professor Anthony Fox
Chair

E-mail: londonsoutheast.rec@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the review

*Copy to: Graham Collins, Churchill Hospital
Mr Oliver Schofield*

London - South East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 03 July 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Anthony Fox	Pharmaceutical Medicine	Yes	Chaired the Meeting
Dr Karen Ma	Retired Consultant	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Faye Slade	Approvals Administrator