NHS
Health Research Authority

London - South East Research Ethics Committee

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

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.

10 April 2018

Mr Oliver Schofield
Haematology Trials Group. CR-UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London
W1T 4TJ

Dear Mr Schofield

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 1**
Amendment date:	**13 February 2018**
IRAS project ID:	**216147**

This amendment consisted of an update to the Protocol as originally the MHRA rejected the application for Clinical Trial Authorisation and requested the protocol be amended to include rationale for the dose and regimen of nivolumab.

The above amendment was reviewed by the Sub-Committee held by 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.

The members of the Sub-Committee raised no ethical concerns regarding this amendment and were content to issue a Favourable opinion.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper		13 March 2018
Notice of Substantial Amendment (CTIMP)	Substantial Amendment 1	13 February 2018
Other [CTA notice of non-acceptance]		09 February 2018
Other [MHRA approval letter]		27 February 2018
Research protocol or project proposal [clean]	1.1	21 February 2018
Research protocol or project proposal [tracked]	1.1	21 February 2018

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.

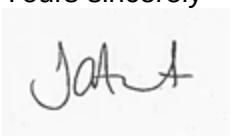
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

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

Yours sincerely



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Ms Stephanie Cooper
Chair

E-mail: nrescommittee.london-southeast@nhs.net

Enclosures:	*List of names and professions of members who took part in the review*
Copy to:	*Mrs Heather House* *Graham Collins, Churchill Hospital*

London - South East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 01 April 2018

Committee Members:

Name	*Profession*	*Present*	*Notes*
Professor Anthony Fox	Pharmaceutical Medicine	Yes	Vice Chair
Professor Zahur Zaman	Retired Clinical Pathologist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Julie Acourt	REC Assistant