



Health Research Authority

London - South East Research Ethics Committee

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30 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 - New Sites

Amendment date: 13 April 2018

IRAS project ID: 216147

Thank you for submitting the above amendment, which was received on 13 April 2018.

<i>Research site</i>	<i>Principal Investigator / Local Collaborator</i>
Nottingham University Hospitals NHS Trust, The Centre for Clinical Haematology, Hucknall Road, NG5 1	Andrew McMillan
University Hospital Southampton NHS Foundation Trust, Department of Haematology, Southampton General	Peter Johnson
Royal Marsden Hospital, Downs Road, Sutton, SM2 5PT	David Cunningham

The amendment relates to the addition of new site(s) and/or investigator(s) within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland. Site-specific assessment (SSA) for any site within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland will form part of the nation specific local processes for that site. Guidance on how to work with sites is provided in the IRAS help section at <https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx>

On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and/or investigator(s), subject to management permission being given by the relevant host organisation prior to the study starting at the site.

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.

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

Yours sincerely



Julie Acourt
REC Assistant

Email: nrescommittee.london-southeast@nhs.net

Copy to: *Graham Collins, Churchill Hospital*