



Health Research Authority

National Research Ethics Service

NRES Committee North West –Greater Manchester West

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03 December 2013

Prof Ian Bruce
Professor of Rheumatology
The University of Manchester
Arthritis Research UK Epidemiology Unit
School of Translational Medicine, Musculoskeletal Research Group
Stopford Building, Oxford Road
M13 9PT

Dear Prof Bruce

Study title: BILAG Biologics Prospective Cohort: The Use of Novel Biological Therapies in the Treatment of Systemic Lupus Erythematosus (SLE).(Lay title: Long-term Safety of New Biologic Treatments in the Management of SLE)

REC reference: 09/H1014/64

Amendment number: 2

Amendment date: 10 October 2013

IRAS project ID: 24407

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:

Document	Version	Date
BILAG BR ESI Pack	1	01 October 2013
Questionnaire: Consultant Follow-up Questionnaire	3	01 October 2013
Consultant Registration Form	2	10 October 2013
Rituximab funding eligibility checklist	1	17 September 2013
Protocol	1.5	10 October 2013
Control to Biologic switch form	1.2	10 October 2013
Notice of Substantial Amendment (non-CTIMPs)	2	10 October 2013
Retreatment/biologic switch form	1.2	10 October 2013
Questionnaire: Consultant Baseline Questionnaire	3	10 October 2013

Membership of the Committee

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

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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 NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

09/H1014/64:

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink, appearing to read 'L. Lighton', with a stylized flourish at the end.

Dr Lorraine Lighton (Chair)
Chair

E-mail: nrescommittee.northwest-gmwest@nhs.net

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

*Copy to: Dr Lynne Webster, Central Manchester And Manchester Children's University Hospitals NHS Trust
Dr Richard Sherburn*

NRES Committee North West - Greater Manchester West

Attendance at Sub-Committee by correspondence

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mr Jonathan Deans	Consultant in Head & Neck Surgery	Expert
Dr Lorraine Lighton (Chair)	Consultant in Communicable Diseases	Expert

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Anna Bannister	REC Manager