



Health Research Authority

National Research Ethics Service

NRES Committee Northwest – Greater Manchester West

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

Telephone: 0161 625 7434

14 September 2015

Dr Emily Sutton
BSPAR ETN / BILAG BR Study Coordinator
Biologic Studies Group
Arthritis Research UK Centre For Epidemiology
The University of Manchester
Unit 4 Rutherford House
Manchester Science Park
40 Pencroft Way
Manchester, M15 6SZ

Dear Dr Sutton

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

EudraCT number: N/A

Amendment number: Three

Amendment date: 10 July 2015

IRAS project ID: 24407

The Substantial Amendment proposes to:

- Extend the study end date until 01 December 2018 and increase the sample size
- Add SLICC SLE criteria
- Add prescribing reason for registration therapy
- Amend registration sheet to include registration therapy and clarify date field
- Addition of an invitation leaflet to allow nurses to post out the PIS and ICFs in advance
- Add quality of life questionnaire suitable for children recruited

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
Letters of invitation to participant [Study Invitation Letter]	1.0	10 July 2015

Notice of Substantial Amendment (non-CTIMP)	Three	10 July 2015
Other [Funding letter from Lupus UK]		10 July 2015
Other [Clinician Baseline form]	4.0- Tracked	10 July 2015
Other [Patient Registration form]	3.0- Tracked	10 July 2015
Other [Child Health Utility 9D]		18 January 2008
Research protocol or project proposal [Protocol]	1.6- Tracked	10 July 2015

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



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*
 Prof Ian Bruce, The University of Manchester

NRES Committee North West - Greater Manchester West

Attendance at Sub-Committee of the REC meeting on 04 September 2015

Committee Members:

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

Also in attendance:

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