

National Research Ethics Service

North West 9 Research Ethics Committee – Greater Manchester West

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31 March 2011

Dr Emily Pattison
BILAG BR Study Coordinator, BILAG Biologics Register
ARC Epidemiology Unit
The University of Manchester
Rutherford House
Manchester Science Park
40 Pencroft Way
Manchester
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Dear Professor 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: Substantial Amendment 1

Amendment date: 07 March 2011

- The amendment proposes to make the different study documents consistent with regards to follow up visits.
- Additionally, it is proposed that urine samples will be obtained from routine clinical samples, not using a pot sent out to participants.
- The amendment also clarifies that control patients will be commencing standard therapy and will be in the study for at least three years.
- It also proposed that the web-based data collection will no longer use the iBLIPS system but instead use a different secure web-based system.

The above amendment was reviewed 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
Participant Consent Form: Participant Assent Form	4	11 March 2011

Participant Consent Form: Parental Consent Form	4	11 March 2011
Participant Consent Form: Participant Consent Form	4	11 March 2011
Participant Information Sheet: Information for children and young people	4	11 March 2011
Participant Information Sheet: Information Sheet For Parents	4	11 March 2011
Participant Information Sheet: Participant Information Sheet (For Adults)	4	11 March 2011
Protocol	1.4	07 March 2011
Notice of Substantial Amendment (non-CTIMPs)	Substantial Amendment 1	07 March 2011
Covering Letter		24 March 2011

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.

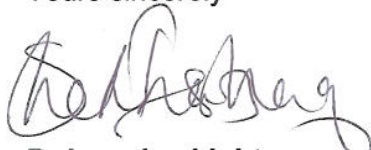
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/H1014/64:

Please quote this number on all correspondence

Yours sincerely



Dr Lorraine Lighton
Chair

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

Copy to: Professor Nalin Thakker, R&D Department - The University of Manchester

Professor Ian Bruce
Professor of Rheumatology
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Stopford Building
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Attendance at Sub-Committee of the REC meeting on 31 March 2011

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Peter Donnelly	Lay Member	Lay Plus
Dr Lorraine Lighton	Consultant in Communicable Diseases	Expert