

National Research Ethics Service

North West 9 Research Ethics Committee - Greater Manchester West

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12 May 2010

Dr Emily Pattison
BILAG Biologics Register Study Coordinator
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The University of Manchester
Rutherford House
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40 Pencroft Way
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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

Protocol number: 1.3

Amendment number: Minor 2

Amendment date: 07 May 2010

Thank you for your letter of 07 May 2010, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Participant Consent Form: Participant Consent Form	3	08 February 2010
Participant Consent Form: Participant Assent Form	3	06 May 2010
Participant Consent Form: Parental Consent Form	3	08 February 2010
Covering Letter		07 May 2010
Notification of a Minor Amendment		07 May 2010

This Research Ethics Committee is an advisory committee to North West Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

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



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Committee Co-ordinator

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