



National Research Ethics Service

North West 9 Research Ethics Committee – Greater Manchester West

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21 January 2011

Dr Emily Sutton
BILAG Biologics Register Study Co-ordinator
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The University of Manchester
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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

Amendment number: 7

Amendment date: 17 January 2011

Thank you for your letter of 17 January 2011, notifying the Committee of the above amendment.

The amendment has been considered by the Chair.

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
BILAG Biologics Register: Consultant Registration Form	1	13 January 2011
BILAG Biologics Register: Sample Collection	1.0	15 December 2010
Notification of a Minor Amendment	7	17 January 2011

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

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