

North West 9 Research Ethics Committee – Greater Manchester West

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09 December 2010

Dr Emily Sutton
BILAG Biologics Register Study Co-ordinator
Arthritis Research UK Epidemiology Unit
The University of Manchester
Rutherford House
Manchester Science Park
40 Pencroft Way
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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: Minor Amendment 6

Amendment date: 06 December 2010

- Following on from the stream-lining of the consultant baseline questionnaire (minor amendment 4, 18/06/2010) it has been necessary to update the Consultant Follow-up Questionnaire to reflect the areas that had altered in the baseline questionnaire. The section on Antimalarials has been removed.

Thank you for your letter of 06 December 2010, 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
Questionnaire: Consultant Follow-up Questionnaire	2	24 November 2010
Notification of a Minor Amendment	Minor Amendment 6	06 December 2010

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
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Yours sincerely



Miss Shehnaz Ishaq
Committee Co-ordinator

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