

National Research Ethics Service

NRES Committee North West - Haydock

North West Centre for Research Ethics Committees
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30 June 2011

Dr Kath Watson
BSRBR Study Co-ordinator and
Manager of Pharmacovigilance Studies
Biologic Studies Group
Unit 4 Rutherford House
Manchester Science Park
Manchester
M15 6SZ

Dear Dr Watson

Study title: Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis
REC reference: 00/8/053
Amendment number: 16 May 2011
Amendment date: 15 June 2011

The above amendment was reviewed at the meeting of the Sub-Committee held on 28 June 2011.

Ethical opinion

The Sub-Committee reviewed the above amendment (16 May 2011: 15 June 2011). Approval was sought for the addition of two questionnaires. The *BSRBR Work Disability Questionnaire* was for participant completion and the *DMARD comparison cohort to biologic cohort switch form* to be completed by clinicians.

The Sub-Committee identified no ethical issues with the proposed amendment.

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
Covering Letter from Dr Kath Watson, BSRBR Study Coordinator and Manager of Pharmacovigilance Studies		17 May 2011
Notice of Substantial Amendment (non-CTIMPs): 16 May 2011		15 June 2011
Questionnaire: BSRBR Work Disability Baseline Questionnaire	1	04 March 2011

Questionnaire: BSRBR Work Disability Follow-Up Questionnaire	1	04 March 2011
Questionnaire: BSRBR Comparison Cohort Switch Form	2	08 February 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.

00/8/053:	Please quote this number on all correspondence
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Yours sincerely



PP

Dr Tim S Sprosen
Chair

E-mail: helen.penistone@northwest.nhs.uk

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

Copy to: Professor Deborah Symmons
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Attendance at Sub-Committee of the REC meeting on 28 June 2011

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mrs Chris Haywood	Head of Hospice Services	Expert
Dr Tim S Sprosen	Chief Scientific Officer	Expert

Also in attendance:

<i>Name</i>	<i>Capacity</i>
Miss Helen Penistone	Assistant Committee Co-ordinator