NHS
National Research Ethics Service
North West 5 Research Ethics Committee – Haydock Park
North West Centre for Research Ethics Committees
3rd Floor - Barlow House
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7819/7832
Fax: 0161 237 9427

20 December 2010

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 rheumatiod arthritis**
REC reference:	**00/8/053**
Amendment number:	**23 November 2010**
Amendment date:	**29 November 2010**

The above amendment was reviewed at the meeting of the Sub-Committee held on 14 December 2010.

Ethical opinion

The amendment (dated 23 November 2010) requested approval for the addition of a further biologic drug to the Register – certolizumab pegol – and to introduce a new anti-TNF comparison cohort.

A new anti-TNF drug – certolizumab pegol – has been approved for use in rheumatoid arthritis in the UK. The BSRBR intends to recruit 2000 patients who are receiving certolizumab pegol over a three year period and to collect follow-up data for a minimum of five years. Baseline data collection and follow-up will be the same as for the current biologic therapy cohorts.

A high proportion of patients who are eligible to start certolizumab pegol in routine clinical care will have already been exposed to other biologic therapies (unless contraindicated) and therefore it is proposed that the certolizumab pegol cohort is compared with two non-certolizumab pegol reference cohorts.

A comprehensive rationale and justification had been submitted in support of the amendment. In addition, a specific certolizumab pegol Protocol, DAS23 3 Months Form, Consultant Baseline and Follow-up Questionnaires, an Extension Follow-up Form and Short Baseline Form had been submitted for ethical review.

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 Co-ordinator and Manager of Pharmacoviglance Studies		30 November 2010
Notice of Substantial Amendment (non-CTIMPs): 23 November 2010		29 November 2010
Protocol: BSRBR Certolizumab substudy	3	15 November 2010
DAS 28 collection- 3 months after drug start	1	22 October 2010
Short Baseline Form	1	04 November 2010
Questionnaire: Consultant Baseline Questionnaire	8	23 November 2010
Questionnaire: Extended Follow-Up Questionnaire	3	04 November 2010
Questionnaire: Consultant 6 monthly follow-up questionnaire	8	23 November 2010
NICE quick reference guide - Certolizumab pegol for the treatment of rheumatoid arthritis		01 February 2010

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**

Yours sincerely

Noel Graham
Committee Co-ordinator

E-mail: noel.graham@northwest.nhs.uk

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

Copy to:

Professor Deborah Symmons
Arthritis Research UK Epidemiology Unit
The University of Manchester
Stopford Building
Oxford Road
Manchester
M13 9PT

Dr Karen Shaw
Head of University Research Office
University of Manchester
Oxford Road
Manchester
M13 9PL

North West 5 Research Ethics Committee – Haydock Park

Attendance at Sub-Committee meeting held on 14 December 2010

Present:

Name	*Profession*	*Capacity*
Professor Caroline Carlisle	Visiting Professor to the Department of General Practice and Primary Care– The University of Glasgow	Expert
Mr Stephen Edgar	Designer	Lay
Dr Michael U Eshiett	Consultant Physician	Expert
Professor Ravi S Gulati - Chair	Consultant Physician	Expert
Mrs Chris Haywood	Nurse and Head of Hospice Services	Expert
Dr Ben Johnson	Consultant Psychiatrist	Expert
Mr Charles Otim	Research Support Officer	Lay
Mr Alan Rigby	Medical Statistician	Expert
Dr Valerie E Siddall	Retired Senior Manager - Pharmaceutical Industry	Lay
Dr Tim S Sprosen – Vice Chair	Chief Scientific Officer – UK Biobank	Expert

Also in attendance:

Name	***Position (or reason for attending)***
Mr Noel Graham	Committee Co-ordinator
Miss Helen Penistone	Assistant Committee Co-ordinator