



**National Research Ethics Service**  
**North West 5 Research Ethics Committee – Haydock Park**

North West Centre for Research Ethics Committees  
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04 August 2010

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

Dear Professor Symmons

**Study title:** Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis  
**REC reference:** 00/8/053  
**Amendment number:** N/A  
**Amendment date:** 12 July 2010

The above amendment was reviewed at the meeting of the Sub-Committee held on 27 July 2010.

**Ethical opinion**

The amendment (12 July 2010: 13 July 2010) requested approval to extend the BSRBR to recruit a cohort of tocilizumab treated patients in order to assess the efficacy and comparative safety outcomes in clinical practice, particularly cardiovascular events, as well as malignancy and serious infection. It is intended to recruit 2600 patient who are receiving tocilizumab over a three-year period. Baseline data collection and follow-up will be the same as the current biologic therapy patients. As patients are likely to have tried and failed on previous anti-TNF therapy, it is proposed to collect further data on their previous exposure at registration. For patients who switch to tocilizumab from other biologic therapies, it is proposed to collect disease measures and medication at the time of switch via a biologic supplementary therapy switch form. In addition, the consultant baseline questionnaire has been modified to include an option to register patients as starting tocilizumab, and the follow-up questionnaire has been adjusted to collect information on when infusions of tocilizumab are given, as well as the dose of the infusion. The approved BSRBR Participant Information Sheet and Consent Form have not been amended as the biologic therapies are not specifically referenced and are simply referred to as "new therapies".

A comprehensive, clear and well written rationale had been provided in support the amendment. In addition, a tocilizumab specific Protocol and had been submitted for review.

**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.**

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*

## 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 Pharmacovigilance Studies		13 July 2010
Notice of Substantial Amendment (non-CTIMPs):12 July 2010		13 July 2010
Protocol: Approved Version		06 October 2003
Protocol: Tocilizumab Protocol	1	20 April 2010
Questionnaire: BSRBR Consultant Baseline Questionnaire	7	08 July 2010
Questionnaire: BSRBR Consultant 6 Monthly Follow-up Questionnaire	7	08 July 2010
BSRBR Biologic Supplementary Switch Form	1	08 July 2010
Prior Biologic Therapy Exposure Form	2	08 July 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

## North West 5 Research Ethics Committee – Haydock Park

Attendance at Sub-Committee meeting of the REC held on 27 July 2010

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Professor Caroline Carlisle	Professor of Education in Nursing and Midwifery	Expert
Dr Michael U Eshiett	Consultant Physician	Expert
Dr Donal Manning (Chair)	Consultant Paediatrician	Expert

**In attendance:**

<i>Name</i>	<i>Capacity</i>
Noel Graham	Committee Co-ordinator

**Copy to:**

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BSRBR Study Co-ordinator and  
Manager of Pharmacovigilance Studies  
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