

# National Research Ethics Service

## North West Research Ethics Committee

NHS North West  
Room 155 - Gateway House  
Piccadilly South  
Manchester  
M60 7LP

Tel: (0161) 237 2394 / 2152  
Fax: (0161) 237 2383

21 September 2007

**Dr K D Watson**  
**BSRBR Study Co-ordinator**  
**ARC Epidemiology Unit**  
**The University of Manchester**  
**Stopford Building**  
**Oxford Road**  
**MANCHESTER M13 9PT**

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:** Not stated  
**Amendment date:** 17 August 2007

The above amendment was reviewed at the meeting of the Sub-Committee held on 11 September 2007.

### Ethical opinion

The amendment sought approval for a couple of changes to the original approved application, as follows: -

1. The introduction of a Comparison Cohort Comparability Questionnaire to be completed by rheumatologists/nurses. The purpose of the short questionnaire was to attempt to determine why patients submitted to the control cohort of the study were not current receiving anti-TNF therapy. This information could help in gaining a better understanding of the potential difficulties involved in a lack of comparability between the exposed and non-exposed RA cohorts in relation to their underlying risk of endpoint development and the fact that the comparison cohort were somewhat different to those in the biologic cohort.

The questionnaire would be sent out to rheumatology departments for completion once a new control patient was registered (and would also be available to download from the BSRBR website). There would also be a one-off mailing to rheumatology departments to ask them to complete a form for each patient already recruited to the study.

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*

2. A pilot source verification audit to gain an understanding of the quality and completeness of the clinical data submitted to the British Society for Rheumatology Biologics Register (BSRBR). The audit would compare information in patient medical records to the information submitted on the BSRBR Consultant Baseline and Follow-up questionnaires in 10 hospital centres that had registered patients. The 10 centres would be randomly chosen and 5 patients per hospital would be randomly chosen for the audit. It was recognised that the BSRBR would need to gain approval from each Trust and Consultant for access to patient medical records.

The Sub-Committee had no ethical difficulties with the proposed amendment.

**The members of the Committee present 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: -

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		07 August 2007
Notice of Substantial Amendment (non-CTIMPs)		17 August 2007
BSRBR Patient History Summary Statement		
Comparison Cohort Comparability Questionnaire	1	01 June 2007

### **Membership of the Committee**

The members of the Committee who were present at the meeting 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.

**MREC 00/8/053:**

**Please quote this number on all correspondence**

Yours sincerely

*CAS Stokes*

**Cathie Stokes**  
**Committee Co-ordinator**

**E-mail:** - northwest.mrec@northwest.nhs.uk

**Enclosure:** - List of names and professions of members who were present at the meeting and those who submitted written comments

**Copy to:** - Professor D Symmons  
ARC Epidemiology Unit  
Stopford Building  
The University of Manchester  
Oxford Road  
MANCHESTER  
M13 9PT

R&D office for NHS care organisation at lead site: -

Dr K Shaw  
Head of University Research Office  
The University of Manchester  
Oxford Road  
MANCHESTER  
M13 9PL

## North West Research Ethics Committee

### Attendance at Sub-Committee of the North West REC meeting on 11 September 2007

<b>Name</b>	<b>Profession</b>	<b>Capacity</b>
Dr Jane Pearson – in the Chair	R&D Manager + Nurse Representative	Expert
Ms Chris Burgess	Lay Member	Lay
Mr Barry Clift	Senior Occupational Therapist	Expert
Dr Ravi Gulati	Consultant Physician	Expert
Dr Cameron Munro	General Practitioner	Expert
Professor Elizabeth Perkins	Director: Health and Community Care Research	Lay
Dr Tim Sprosen	Medical Researcher / Epidemiologist	Expert
Mr Ric Swindell	Medical Statistician	Expert
Mr Robert Woodwards	Consultant Oral & Maxillofacial Surgeon	Expert

#### **Also in attendance:**

<b>Name</b>	<b>Position (or reason for attending)</b>
Cathie Stokes	Committee Co-ordinator
Noel Graham	Deputy Committee Co-ordinator