

# National Research Ethics Service

## North West 5 Research Ethics Committee - Haydock Park

NHS North West  
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04 September 2009

**Professor Deborah Symmons  
The University of Manchester  
arc Epidemiology Unit  
School of Medicine  
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:** 14 August 2009

The above amendment was reviewed at the meeting of the Sub-Committee held on 25 August 2009.

### Ethical opinion

RECEIVED

The British Society for Rheumatology Biologics Register (BSRBR) has been collecting data on patients receiving biologic therapy (including the anti-TNF drugs etanercept, infliximab and adalimumab) for rheumatoid arthritis (RA) during routine clinical care since 2001. One of the main reasons for setting up the study was to determine whether or not treatment with these drugs increased the risk of cancer, and in particular lymphoproliferative cancers including lymphoma. The amendment (dated 14 August 2009) sought approval for a number of changes to the current approved study protocol, as follows: -

1. To ascertain the prevalence and incidence rates of patients with lymphoma who are already taking part in the BSRBR.
2. To determine the subtypes of lymphoma in the biologics cohort by reclassifying them in accordance with the World Health Organisation classification.
3. To examine the factors predicting development and outcome of lymphoma in the biologics treated cohort, and in particular the influence of disease activity.

There are currently 49 patients registered with the BSRBR, who have been treated with biologic drugs for RA and had been diagnosed with lymphoma during the course of the study. It was anticipated that this number would increase as patients continued to be followed via the registry.

A comprehensive, clear and well written rationale had been submitted in support of the amendment.

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*

The Sub-Committee had no ethical difficulties 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 Kimme Hyrich	1	14 August 2009
Notice of Substantial Amendment (non-CTIMPs)		14 August 2009
Appendix A: Letter to Consultant	1	10 August 2009
Appendix B: Letter to Patient	1	10 August 2009
Appendix C: Letter to Pathologist	1	10 August 2009
Appendix D: Patient Information Sheet	1	10 August 2009
Appendix E: Patient Consent Form	1	10 August 2009

#### **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 on 25 August 2009

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Tim Sprosen	Medical Researcher / Epidemiologist	Expert
Professor Caroline Carlisle	Professor of Education in Nursing and Midwifery – The University of Manchester	Expert

#### Written comments received from:

<i>Name</i>	<i>Position</i>
Mr Alan Rigby	Medical Statistician

#### In attendance:

<i>Name</i>	<i>Position</i>
Mr Noel Graham	REC Co-ordinator

**Copy to:**

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