

North West Research Ethics Committee

NHS North West
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30 January 2007

Professor A Silman
ARC Epidemiology Unit
The University of Manchester
Stopford Building
Oxford Road
MANCHESTER M13 9PT

Dear Professor Silman

Full title of study:	Prospective observational study of the long term hazards of anti-TNF therapy in rheumatoid arthritis
REC reference number:	MREC 00/8/053
Protocol number:	N/A
Eudract number:	N/A
Amendment number:	N/A
Amendment date:	14 December 2006

The above amendment was reviewed at the meeting of the Committee held on 16 January 2007.

Ethical opinion

The amendment sought approval to extend recruitment of the British Society for Rheumatology Biologics Register (BSRBR) to patients who had been treated with rituximab. It was proposed to recruit 1100 patients receiving rituximab over a three year period. Baseline and follow-up data collection would be the same as current anti-TNF therapy patients. However, as this group of patients may have tried and failed on previous anti-TNF therapies, it was proposed to collect data on previous exposure at registration and also for those patients who had received anti-TNF therapy and subsequently switched to rituximab, further data on disease measures and medication at the time of the switch.

In support of the amendment a well written and clear rationale, including a sample size calculation, had been provided by the applicant. Supporting documentation in the form of a rituximab specific protocol, consultant baseline and follow-up questionnaires, and data collection forms had also been submitted to the MREC for review.

The Sub-Committee agreed that the inclusion of patients receiving rituximab was highly appropriate and 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:

Document	Version	Date
Covering Letter	From Dr Kath Watson	19 December 2006
Notice of Substantial Amendment (non-CTIMPs)		14 December 2006
Protocol	1	01 September 2006
BSRBR Rituximab		
Questionnaire: Consultant 6 Monthly Follow-up Questionnaire	6	14 December 2006
Questionnaire: Consultant Baseline Questionnaire	6	14 December 2006
Prior Biologic Therapy Form	1	14 December 2006
BSRBR Rituximab Supplementary Switch Form	1	14 December 2006

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Research governance approval

All investigators and research collaborators in the NHS should notify the R&D Department for the relevant NHS care organisation of this amendment and check whether it affects research governance approval of the research.

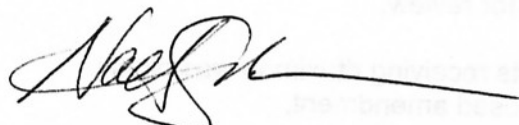
Statement of compliance

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



Noel Graham
Deputy Committee Co-ordinator

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Copy to: Dr Karen Shaw
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Oxford Road
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Enclosures: List of names and professions of members who were present at the meeting
and those who submitted written comments

North West Research Ethics Committee

Members Attendance Sheet – 16 January 2007

Member	Profession	In attendance	Written comments submitted
Professor Hazel Biggs	Professor of Medical Law		
Mrs Arlene Blanchard	Lay Member	✓	
Mr James Bruce	Consultant Surgeon	✓	
Ms Chris Burgess	Lay Member	✓	
Dr Brian Faragher	Medical Statistician	✓	
Professor Sally Furnish	Professor of Mental Health		
Dr Ravi Gulati	Consultant Physician		
Dr Donal Manning	Chairman Consultant Paediatrician	✓	
Mrs Margaret Norval	Chief Pharmacist		
Dr Jane Pearson	Vice-Chair Research & Development Manager	✓	
Professor Elizabeth Perkins	Lay Member	✓	
Mr Alan Rigby	Medical Statistician		
Mrs Jane Rowe	Lay Member	✓	
Dr Tim Sprosen	Medical Researcher / Epidemiologist	✓	
Mr Robert Woodward	Consultant Oral & Maxillofacial Surgeon	✓	