

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

North West Centre for Research Ethics Committees
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10 September 2010

Dr Kath Watson
BSR Biologics Register
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 rheumatoid arthritis
REC reference: 00/8/053
Amendment number: 12 July 2010
Amendment date: 20 August 2010

The above amendment was reviewed at the meeting of the Committee held on 07 September 2010.

Ethical opinion

Favourable Opinion

The amendment (dated 12 July 2010) sought approval introduce electronic data collection. A move towards electronic data collection was considered to be vital for the ongoing success of the BSRBR as it was hoped that the comparative ease of the new system would encourage clinicians and research nurses to submit data to the Register in a more efficient way as well as reducing the scope for data entry error, as the information would be entered directly at source in the hospital rather than by a separate data-entry team.

A comprehensive, clear and well written rationale had been provided in support the amendment. In addition, a revised Participant Information Sheet and Consent Form had been submitted for review.

The Committee noted with interest that it was intended to pilot the new system at eight centres across the UK, before extending the system to all centres, and that the issues regarding data protection had been considered.

The 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.

This Research Ethics Committee is an advisory committee to North West Strategic Health Authority

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		20 August 2010
Notice of Substantial Amendment (non-CTIMPs):		20 August 2010
Participant Information Sheet: Tracked Changes	7	23 July 2010
Participant Information Sheet: Clean 12 July 2010	7	23 July 2010
Participant Consent Form: Tracked Changes	7	23 July 2010
Participant Consent Form: Clean	7	23 July 2010
Letter from Sponsor: From Mohammed Zubair, University of Manchester		10 March 2010

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Mr Alan Rigby declared an interest on the basis that he knows Professor Deborah Symmons (Chief investigator) although he is not involved in this study.

Mr Rigby remained in the meeting room and participated in discussion on the application.

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

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Attendance at Committee meeting held on 07 September 2010

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Arlene Blanchard	Retired Lecturer / Patient Representative	Yes	Lay
Mr James Bruce	Consultant Paediatric Surgeon	No	Expert
Professor Caroline Carlisle	Visiting Professor to the Department of General Practice and Primary Care – The University of Glasgow	Yes	Expert
Mr Stephen Edgar	Designer	Yes	Lay
Dr Michael U Eshiett	Consultant Physician in Neurological Rehabilitation	No	Expert
Professor Ravi S Gulati	Consultant Physician	Yes	Expert
Ms Pat Harvey	Hospital Chaplain	No	Lay
Mrs Chris Haywood	Nurse and Head of Hospice Services	Yes	Expert
Dr Ben Johnson	Consultant Psychiatrist	Yes	Expert
Dr Donal Manning	Consultant Paediatrician	Yes	Expert
Mrs Margaret Norval	Chief Pharmacist	No	Expert
Professor Elizabeth Perkins	Director	Yes	Lay
Mr Alan Rigby	Medical Statistician	Yes	Expert
Dr Valerie E Siddall	Retired Senior Manager - Pharmaceutical Industry	No	Lay
Dr Tim S Sprosen	Chief Scientific Officer	Yes	Expert
Mr Ric Swindell	Medical Statistician	No	Expert

In attendance:

<i>Name</i>	
Noel Graham	Committee Co-ordinator
Miss Helen Penistone	Assistant Committee Co-ordinator