Scanning.

National Research Ethics Service
North West Research Ethics Committee
NHS North West
Room 155 - Gateway House
Piccadilly South
Manchester
M60 7LP

Telephone: (0161) 237 2394 / 2152
Facsimile: (0161) 237 2383

21 July 2008

Professor D Symmons
arc Epidemiology Unit
School of Medicine – Stopford Building
The University of Manchester
Oxford Road
MANCHESTER
M13 9PT

Dear Professor Symmons

Study title:	**Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatiod arthritis**
REC reference:	**00/8/053**
Amendment number:	**Not Stated**
Amendment date:	**19 June 2008**

The above amendment was reviewed at the meeting of the Committee held on 08 July 2008.

Ethical opinion

The British Society for Rheumatology Biologics Register (BSRBR) had recruited approximately 400 patients whose juvenile idiopathic arthritis (JIA) began prior to the age of 16 years and who had been prescribed with anti-TNF drugs during routine clinical use. The research team now wished to study outcomes (i.e. treatment response, drug survival and safety) in this group of patients. The majority of data required for this analysis already existed on the database from ongoing data collection. However, as the register had been primarily established to study outcomes in rheumatoid arthritis (RA) rather than juvenile idiopathic arthritis (JIA), the baseline questionnaire had omitted questions specifically related to JIA and in particular, details to help classify the study participants into one of seven JIA sub-types. Without this data it would be difficult to establish whether certain JIA sub-types might respond better to anti-TNF therapy, or be more prone to side effects. Such data might help to direct therapy, given the increasing choice of biologic agents available to patients with the condition.

The proposed amendment thus sought approval for a number of changes, as follows: -

1. To identify patients with disease onset prior to their 16th birthday, using data already collected as part of the BSRBR.

2. To introduce a supplementary questionnaire (Version 1, dated June 2008) to be sent to the Consultant Rheumatologist (already participating in the study) in order to collect further details of rheumatic disease onset to help classify patients into one of seven juvenile idiopathic arthritis (JIA) sub-types.

It was noted that patients had already consented to the collection of further clinical information from their medical records and that no additional investigations would be required as a result of this change.

The 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:

Document	*Version*	*Date*
Covering Letter - from Dr Kath Watson, BSRBR Study Co-ordinator, ARC Epidemiology Unit, The University of Manchester		19 June 2008
Notice of Substantial Amendment (non-CTIMPs)	Not stated	19 June 2008
Letter to Consultants re JIA Biologics data	V1	June 2008
JIA Biologics Data Questionnaire		

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.

00/8/053:	**Please quote this number on all correspondence**

Yours sincerely

Noel Graham
Deputy Committee Co-ordinator

E-mail: noel.graham@northwest.nhs.uk