



Central Office for Research Ethics Committees (COREC)

NOTICE OF SUBSTANTIAL AMENDMENT

For use in the case of all research other than clinical trials of investigational medicinal products (CTIMPs). For substantial amendments to CTIMPs, please use the EU-approved notice of amendment form (Annex 2 to ENTR/CT1) at <http://eudract.emea.eu.int/document.html#guidance>.

To be completed in typescript by the Chief Investigator in language comprehensible to a lay person and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC"). In the case of multi-site studies, there is no need to send copies to other RECs unless specifically required by the main REC.

Further guidance is available at <http://www.corec.org.uk/applicants/apply/amendments.htm>.

Details of Chief Investigator:	
<i>Name:</i>	Professor Alan Silman
<i>Address:</i>	arc Epidemiology Unit, The University of Manchester, Stopford Building, Oxford Road, Manchester, M13 9PT
<i>Telephone:</i>	0161 275 5041
<i>E-mail:</i>	alan.silman@manchester.ac.uk
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Full title of study:	Prospective Observational Study of the long term hazards of anti-TNF therapy in rheumatoid arthritis
Name of main REC:	North West MREC
REC reference number:	MREC 00/8/53
Date study commenced:	October 2001
Protocol reference (if applicable), current version and date:	Protocol dated 06/10/2003

Amendment number and date:	
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Type of amendment (indicate all that apply in bold)

(a) *Amendment to information previously given on the REC application form*

Yes *No*

If yes, please refer to relevant sections of the REC application in the “summary of changes” below.

(b) *Amendment to the protocol*

Yes *No*

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) *Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study*

Yes *No*

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified to the REC and given an unfavourable opinion?

Yes **No**

Summary of changes

Briefly summarise the main changes proposed in this amendment using language comprehensible to a lay person. Explain the purpose of the changes and their significance for the study. In the case of a modified amendment, highlight the modifications that have been made.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

The BSRBR would like to update the Chief Investigator details relating to this study. Professor Alan Silman has now left the arc Epidemiology Unit and is no longer involved in this study. We would like to remove Alan as Chief Investigator and replace him with Professor Deborah Symmons (c.v. enclosed). We would also like to add Dr Kimme Hyrich as a Principle Investigator (c.v. enclosed).

Any other relevant information

Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the REC is sought.

List of enclosed documents		
<i>Document</i>	<i>Version</i>	<i>Date</i>
Professor Deborah Symmons CV	n/a	
Dr Kimme Hyrich CV	n/a	
MREC application form pages 24 signed by Prof Deborah Symmons	n/a	

Declaration

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment to be implemented.

Signature of Chief Investigator:

Print name:

Date of submission: