NHS
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 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 in section 5 of our Standard Operating Procedures available at www.corec.org.uk/applicants/help/docs/SOPs.doc.

Details of Chief Investigator:

Name:	Professor Alan Silman
Address:	ARC Epidemiology Unit The University of Manchester Stopford Building Oxford Road Manchester M13 9PT
Telephone:	0161 275 5037
E-mail:	Alan.silman@manchester.ac.uk
Fax:	0161 275 5040

Full title of study:	Prospective observational study of the long-term hazards of biologic therapy in rheumatic conditions
Name of main REC:	North West MREC
REC reference number:	MREC 00/8/53
Date study commenced:	01/10/2001
Protocol reference *(if applicable)*, current version and date:	
Amendment number and date:	

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

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. Supporting scientific information should be given (or enclosed separately) where the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study.

Questionnaire Changes:

In November 2003, MREC approval was granted to amend this observational study from studying rheumatoid arthritis to cover all rheumatic conditions. The British Society for Rheumatology has recently published guidelines for the use of anti-TNFα in ankylosing spondylitis (AS) and psoriatic arthritis (PsA). We are already collecting the data they suggest for AS but they have suggested that we should collect information on two important risk factors for PsA (alcohol consumption and PUVA exposure).

Increased alcohol intake has been associated with the onset of psoriasis and has also been associated with disease course[1]. It is recognised that psoriasis is associated with an increased risk of non-melanoma skin cancers, most probably a result of enhanced use of psoralen and ultraviolet A (PUVA)[2].

Therefore two questions have been added to the Patient Baseline Questionnaire on PUVA exposure and alcohol intake (page 2)

A question has also been added to the Consultant Baseline Questionnaire on PUVA exposure (page 5), should the patient not know this information.

[1] Naldi L et al. Family history, smoking habits, alcohol consumption and risk of psoriasis. *Br J Dermatology* 1992; **127**: 212-7.
[2] Stern RS et al. Risk of squamous cell carcinoma and methoxsalen (psoralen) and UV-A radiation (PUVA). A meta-analysis. *Arch Dermatol* **134**: 1582-85.

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: Professor Alan Silman

Date of submission: …….

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

Patient Baseline Questionnaire, Version 4, Date 01/11/2004
Consultant Follow-up Questionnaire, Version 5, Date 01/11/2004
BSR Guidelines for anti-TNFα therapy in psoriatic arthritis July 2004 (page 12)
[Full document available at:]
https://www.msecportal.org/portal/editorial/PublicPages/bsr/536883013/FinalPsoriaticArthritisGuideline.pdf