Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Toxicity from Anti-TNF Therapy

REC details:

Name of main REC:
North West 5 Research Ethics Committee

REC Reference Number:
00/8/53

NRES form lock code:

1. Select one category from the list below:

- ○ Clinical trial of an investigational medicinal product
- ○ Study only involving data or tissues not identifiable to the researcher

If your work does not fit any of these categories, select the option below:

- ◉ Other study

2. Does the study involve the use of any ionising radiation?

○ Yes ◉ No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

- ☑ England
- ☑ Scotland
- ☑ Wales
- ☑ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ◉ England
- ○ Scotland
- ○ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Do you plan to include any participants who are children?

○ Yes ◉ No

5. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

6. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

NOTICE OF SUBSTANTIAL AMENDMENT
Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Prof	Deborah	Symmons
Work Address	Arthritis Research UK Epidemiology Unit, 2nd Floor Stopford Building, Oxford Road, Manchester		
PostCode	M13 9PL		
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Telephone	01612755044		
Fax	01612751640		

Full title of study:	Prospective observational study of the long term hazards of anti-TNF therapy in rheumatoid arthritis
Lead sponsor:	University of Manchester
Name of REC:	North West 5 Research Ethics Committee
REC reference number:	00/8/53
Name of lead R&D office:	Central Manchester University Hospitals NHS Foundation Trust
Date study commenced:	01/12/2000 (date of original ethical approval)
Protocol reference (if applicable), current version and date:	Main protocol dated 06/10/2003. Two current substudy protocols: 1) certolozimab and anti-TNF (v3: 15/10/2010) 2) tocilizumab (v1.1: 17/01/2011)
Amendment number and date:	Amendment 19: 25/07/2014

Type of amendment

(a) Amendment to information previously given in IRAS

○ Yes ◉ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

○ Yes ◉ No

If yes, please submit <u>either</u> 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.

A new recruitment poster has been developed to be placed in hospital clinic waiting rooms.

Is this a modified version of an amendment previously notified and not approved?

( ) Yes (•) No

If yes, please explain the modifications made under "Summary of changes" below

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
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.

A BSRBR-RA patient recruitment poster has been developed to be displayed in the waiting rooms of rheumatology clinics. This will make potential participants aware of the study, and if they are interested to know more or become involved then they can ask their rheumatologist or members of the clinical research teams within their hospital. This allies with the NIHR 'OK to Ask' campaign, which is a patient empowerment campaign to emphasise that it is 'OK to ask' about clinical research opportunities that are available. More information can be found about this campaign here: http://www.ct-toolkit.ac.uk/news/its-ok-to-ask-the-nihrs-new-pati ent-empowerment-campaign

The poster outlines the study and the main eligibility criteria, as well as providing contact details for the study coordination team at the University of Manchester if further information is sought.

The poster has been reviewed by the Research User Group at the Arthritis Research UK Centre of Excellence for Epidemiology, which is a group of lay individuals who have an active interest in musculoskeletal health who assist the study – and other studies within the Unit - in all aspects of research. Positive comments were received, such as: 'Excellent poster, very now, very relevant. This will appeal to all ages, is easy to read and punchy' and any suggestions, including clarification of terms and suggestions for making the poster more patient-focussed, were adopted. Representatives from the National Rheumatoid Arthritis Society (NRAS), who describe themselves as 'the voice of people affected by rheumatoid arthritis' have also suggested amendments, which have now been incorporated. They are happy for their logo to be used on the poster.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

The study has now received funding from the British Society for Rheumatology to continue until at least 31st December 2018.

List of enclosed documents

Document	*Version*	*Date*
Poster for patient recruitment	1	25/07/2014

Declaration by Chief Investigator

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

Date of submission:.....

Signature:.....

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

Signature: .....

Print Name:

Post:

Organisation:

Date: *(dd/mm/yyyy)*

Does this amendment involve new types of exposure or increased exposure to ionising radiation?

◯ Yes ◯ No

If Yes, please provide details below:

Does this amendment involve inclusion of adults lacking capacity or a change to the arrangements relating to adults lacking capacity?

○ Yes ○ No

If Yes, please provide details below:

Declaration by Sponsor's Representative

This section was signed electronically by Lynne MacRae on 11/08/2014 09:57.

Job Title/Post:	Faculty Research Practice Coordinator
Organisation:	University of Manchester
Email:	lynne.macrae@manchester.ac.uk