

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 complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

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 Confidentiality Advisory Group 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 Bldg, Oxford Road, Manchester
PostCode	M13 9PL
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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 sub-study protocols: 1) certolizumab and anti-TNF (v3: 15/10/2010) 2) tocilizumab (v1.1: 17/01/2011)
Amendment number and date:	Amendment 21: 12/10/2015

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 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 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.

The British Society for Rheumatology has developed a Biologics Registers general information leaflet to be distributed in the rheumatology clinics of sites involved in the BSRBR-RA study. The aim of the leaflet is to make potential participants aware of the study as well as providing a general overview of how it works. 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.ctoolkit.ac.uk/news/itsoktoaskthenihrsnewpatientempowermentcampaign>

The leaflet also provides information for researchers on how to access study data and includes links for clinicians regarding which cohorts of drugs are currently open to recruitment.

Any other relevant information

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

List of enclosed documents

Document	Version	Date
BSR - Biologic Registers Leaflet.PDF	v1	23/09/2015

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: 24/11/15

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 23/11/2015 12:31.

Job Title/Post: Faculty Research Practice Coordinator

Organisation: University of Manchester

Email: lynne.macrae@manchester.ac.uk