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)
BADBIR

REC details:

Name of main REC:
North West England

REC Reference Number:
07/MRE08/9

NRES form lock code: AB/98888/1

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
	Professor	Christopher E M	Griffiths
Work Address	Dermatology Centre		
	Hope Hospital, Stott Lane		
	Salford		
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Email	christopher.griffiths@manchester.ac.uk		
Telephone	01612064392		
Fax	01612061095		

Full title of study:	British Association of Dermatologists' Biologic Interventions Register
Lead sponsor:	University of Manchester
Name of REC:	North West England
REC reference number:	07/MRE08/9
Name of lead R&D office:	Salford Royal Hospital Foundation Trust
Date study commenced:	16/08/07
Protocol reference (if applicable), current version and date:	BADBIR Study Protocol – Version 15 (01/ 07/2015)
Amendment number and date:	Amendment Nine 01/12/2015

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.

Background and Rationale:
The target of 4000 registrations for the adalimumab group has been achieved. The BADBIR Steering Committee would like to raise this figure incrementally, to an overall maximum of 5000.

The desire to increase the target is driven by several concerns.

Firstly, as a result of a lower take up of infliximab (current recruitment n = 220) and etanercept (current recruitment n = 1524), the overall target (n= 12,000) for the anti TNF group will not be achieved.

Additionally, it has been noted that there is attrition from all of the cohorts (including the adalimumab cohort) over time.
Therefore, increasing the registration target will allow for more person years of follow-up to be collected, negating the impact of patients lost to follow-up and increased power to detect rarer events.

Secondly, in anticipation of the inclusion of the new biologic therapies (such as secukinumab) a contemporaneous cohort of adalimumab patients is desirable as this is likely to be more representative of current prescribing patterns.

Thirdly, as outlined previously in Amendment 8, there is a dearth of information on long-term safety of biologic agents in children. Adalimumab is licensed for management of psoriasis in children, thus continuing recruitment to this cohort will allow for the collection of further data in this small but important sub-group of patients.
The BADBIR protocol (Section 3.2, page 6) has been amended to reflect the proposed change in recruitment numbers.

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*
BADBIR Protocol	16	01/12/2015

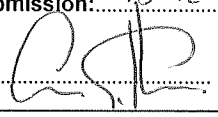
Declaration by Chief Investigator

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: 18.12.15.

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 Mrs Catherine Barrow on 15/12/2015 17:42.

Job Title/Post:	Head of Faculty Research Support Services, Faculty of Medical & Human Sciences
Organisation:	The University of Manchester
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