

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		
PostCode	M6 8HD		
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 NHS Foundation Trust
Date study commenced:	16/08/07
Protocol reference (if applicable), current version and date:	BADBIR Study Protocol – Version 14 (12/12/2012)
Amendment number and date:	Amendment Eight 01/07/2015

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.

A1. Extending Study End Date (section A3, p.4 of MREC / not referenced directly in protocol)

Background and Rationale:

BADBIR is now regarded as the gold standard pharmacovigilance registry for psoriasis nationally and internationally and both NICE and BAD guidance recommend that all patients treated with biologic therapies are registered. There are an increasing number of new biological and small molecule therapies due to become available for the management of psoriasis including: IL-17 inhibitors (e.g. secukinumab, ixekizumab);, IL-23 inhibitors (e.g. guselkumab, tildrakizumab); biosimilars and; small molecules (eg. apremilast, tofacitinib)¹ In order to facilitate inclusion of these treatments in BADBIR using the current study design we propose extending the study end date for another 10 years to 31/07/2028.

B1 Removing the Minimum Age Limit for Patients Joining the BADBIR Study (section A10.1, p.8 of MREC / p.4-5 protocol for rationale, p.7-8 for inclusion criteria, p.12 for questionnaire summary)

Background and Rationale:

The BADBIR Steering Committee would like to amend the study to include psoriasis patients under the age of 16 years who are being treated with either a biologic or conventional therapy.

Etanercept and adalimumab are currently the only biologic treatments licensed for treatment of psoriasis in children and young people. However, a recent survey undertaken by the BAD of all dermatologists in the UK revealed variation in how paediatric patients are managed with ustekinumab and with conventional systemic treatments ².

The results of this survey indicated that the number of children (the majority were aged 8 years or over) with psoriasis treated with biologic or conventional therapies was small relative to the numbers of adults. Despite the small numbers, it remains important that the long term safety is evaluated in this group as the combination of exposure to immunosuppressive therapy on an immature immune system and a potentially high lifetime exposure (due to the chronic nature of the disease) may place them at a higher risk than adults.

The BADBIR Steering Committee considers that as psoriasis is a lifelong disease it is more prudent to incorporate this relatively small group of paediatric patients within BADBIR as it allows for their seamless follow up as they move into adulthood. Therefore, it is proposed that the minimum age limit for entry to BADBIR be removed so all patients on eligible treatment may be included in the study.

Study Procedures:

The parent/guardian will be provided with the adult version of the current BADBIR Patient Information Sheet (Version 4, dated 14/05/2009). In addition, an age appropriate version of the BADBIR information sheet will be provided and discussed with the child participant. Guidance is provided as to the suitability for the different age ranges but the version used will be at the discretion of person taking the consent.

In addition, age appropriate consent procedures will be put in place as follows:

Participants under the age of 16 will sign the Assent Form (version 4, 14/05/2009). In addition, the parent or guardian will sign the Parent Or Guardian's Consent Form (both version 4, 14/05/2009). Both forms will be required to register participants under the age of 16.

The following Patient Reported Outcomes measures: Children's Dermatology Life Quality Index Microsoft (CDLQI) I and EQ 5D-Y and Child Health Assessment Questionnaire (CHAQ) will be substituted for the adult versions at each assessment i.e. as applicable to the age of the child and at the discretion of the clinician.

B2. Increasing the 4000 Maximum for the Conventional Cohort (section A10.1, p.8 of MREC / p.7 of protocol)

Background and Rationale:

The target of 4000 registrations for the conventional comparison group is set to be achieved by the end of 2015 based on current recruitment. The BADBIR Steering Committee would like to raise this figure incrementally, to an overall maximum of 7000.

The desire to increase the target is driven by several concerns. Firstly, in anticipation of the inclusion of the new biologic therapies a contemporaneous comparator cohort of patients is desirable as this is likely to be more representative of current prescribing patterns.

Additionally, it has been noted that there is attrition from the conventional cohort as over time, therapy may be changed to a biologic drug. It is estimated that by the end of study in July 2018, 1800 of the total 4000 conventional group patients will have switched to the biologic cohort (Figure 1 - attached)

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.

C1. Updated System Level Security Policy Document

The System Level Security Policy (SLSP) document for BADBIR's electronic database was originally included as part of the study documentation with Amendment 6 in February 2012. This version is updated to reflect the University of Manchester's current I.T. policies and also adds an up-to-date list of the participating NHS Trusts.

C2. Minor Revision to Questionnaires

The Clinical Follow-up Questionnaire Version 7 was approved as part of amendment 6 in February 2012. Since this date, minor revisions to this questionnaire have been made to guide better data collection. The revisions clarify the type of information required as opposed to collecting more information with the exception of the "batch number" of the medication which is being added to comply with European Medicines Agency regulations.

References:

1. Yiu, Z. & Warren, R. (2015). Efficacy and safety of emerging immunotherapies in psoriasis. *Immunotherapy*, 7 (2), 119-133.
2. Lam, M., Burden, T., Taibjee, S., Taylor, A., Webster, S., Dolman, S., et al. (2015, March). A United Kingdom (UK) multi-centre audit of the assessment and management of psoriasis in children. *British Journal of Dermatology*, 172 (3), 789-792.

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

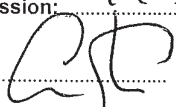
<i>Document</i>	<i>Version</i>	<i>Date</i>
BADBIR Protocol	15	01/07/2015

BADBIR Assent Form for Children	4	14/05/2009
BADBIR Information Sheet for Very Young Children	1	01/07/2015
BADBIR Information Sheet for Young Children	1	01/07/2015
BADBIR Information Sheet for Children	1	01/07/2015
BADBIR Consent form for Parent / Guardian	4	14/05/2009
Children's Dermatology Life Quality Index Microsoft (CDLQI)	Word Version	04/05/1993
Children's Dermatology Life Quality Index(CDLQI)	Cartoon version	04/12/1996
EQ-5D-Y UK (English) © 2008 EuroQol Group EQ-5D™	1	01/12/2014
Child Health Assessment Questionnaire (CHAQ)	N/A	
BADBIR Clinical Baseline Questionnaire	8	01/07/2015
BADBIR Clinical Follow-up Questionnaire	8	01/07/2015
BADBIR System Level Security Policy	2	01/07/2015
Figure 1. Conventional Cohort Switches to Biologic Cohort	NA	

Declaration by Chief Investigator

- 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.*

Date of submission: 24 Aug 2015

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 06/08/2015 10:44.

Job Title/Post: Faculty Research Practice Coordinator

Organisation: University of Manchester

Email: lynne.macrae@manchester.ac.uk