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
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	Salford		
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Telephone	01612064392		
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Full title of study:	British Association of Dermatologists' Biologic Interventions Register
Lead sponsor:	The 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:	16/08/2007
Protocol reference (if applicable), current version and date:	Current Version is v17 01/08/2017. Version submitted with this amendment is v18 01/06/2018
Amendment number and date:	Amendment 11 13/07/2018

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.

a) MREC application form change in study title:
A change in study title to represent the current protocol design from "British Association of Dermatologists Biologic Interventions Register" (BADBIR) to "British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR).

The BADBIR Protocol, Patient Information Sheet and Consent Form have been changed to reflect this change (v5.1 for reference)

Section A10 (1):
To include the Hospital Anxiety and Depression Scale (HADS)1 as an additional patient reported outcome measure
Rationale
Schmitt (2007) 2 found that nearly half of the psoriasis patients with high levels of health related quality of life (HRQoL) impairment tested positive for depression. In addition, the prevalence rate of depression in patients at registration to BADBIR is reported at 22%3 Thus, given the high prevalence of psychological distress in patients there is a clear need for appropriate recognition and management as emphasised in the recent NICE guidance 4. It has been suggested that routine administration of psychometric screening tools such as the HADS could improve detection of common psychiatric disorders. As such tools utilize responses directly from patients they may provide a more accurate indication of their psychological state than an impression gained by a physician during a busy clinic5. It has also been postulated that treatment with anti-TNF alpha might relieve fatigue and symptoms of depression associated with this chronic disease6.

Unlike other screening tools for depression and anxiety, the HADS excludes questions about physical manifestations of depression to make it suitable for those with existing physical symptoms. It has been chosen as the appropriate evaluative tool as it is currently used in some clinics specializing in the management of psoriasis5 and is short (takes approximately 5 minutes to complete) and therefore should not significantly increase burden to the patients whilst contributing positively to their clinical care.

(b) The BADBIR Protocol has been changed to reflect these changes.

(c) Patient Information Sheet and Consent Form will use new study title. No further changes and no update to version number.

References
1. Zigmond A.S., Snaith R.P. The Hospital Anxiety and Depression Scale. Acta Psychiatr Scand. 1983;67:361–370

2. Schmitt JM, Ford DE. Role of depression in quality of life for patients with psoriasis. Dermatology. 2007;215(1):17–27

3. Iskandar I.Y.K, Yiu Z.N., Warren R.B., McElhone K, Lunt M., Ormerod A.D,. Reynolds N.J, Smith C.H., Griffiths C.E.M,

Ashcroft D.M. Baseline characteristics of patients with psoriasis enrolled in the British Association of Dermatologists' Biologic Interventions Register. Br J Dermatol, July 2015

4 https://www.nice.org.uk/guidance/cg153/chapter/1-Guidance#princip les-of-care

5. Richards HL, Fortune DG, Weidmann A, Sweeney SKT, Griffiths CEM. Detection of psychological distress in patients with psoriasis: low consensus between dermatologist and patient. Br J Dermatol 2004; 151: 1227–1233.

6. Krishnan R, Cella D, Leonardi C, Papp K, Gottlieb AB, Dunn M, Chiou CF, Patel V, Jahreis A. Effects of etanercept therapy on fatigue and symptoms of depression in subjects treated for moderate to severe plaque psoriasis for up to 96 weeks. Br J Dermatol 2007; 157: 1275–1277.

Any other relevant information

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

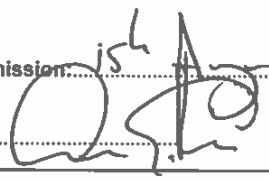
List of enclosed documents

Document	*Version*	*Date*
Protocol	18	01/06/2018
Protocol (with tracked changes)	18	01/06/2018
Hospital Anxiety and Depression Scale (HADS)		
Consent Form	5.1	01/08/2017
Patient Information Sheet	5.1	01/08/2017

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: 15th August 2018

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 Ms Lynne MacRae on 08/08/2018 15:41.

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