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Professor Christopher EM Griffiths
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Dear Professor Griffiths

Application title:	**British Association of Dermatologists Biologic Interventions Register**
CAG reference:	**16/CAG/0043**
IRAS project ID:	**927604**
REC reference:	**07/MRE08/9**

Thank you for your research application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether an application should be approved, and if so, any relevant conditions. This application was considered at the precedent set CAG meeting held on 11 March 2016. The application was considered via the Precedent Set process under criteria 8 – *validity of consent.*

Health Research Authority

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is conditionally approved, subject to compliance with the standard and specific conditions of approval outlined below.

Context

Purpose of application

This application from the University of Manchester set out the purpose of monitoring the long-term safety of biologic treatments in the U.K. and Republic of Ireland for patients with psoriasis. The study will consist of two cohorts comparing (i) patients with psoriasis newly treated with one of the biologic therapies, to (ii) patients with similar disease characteristics treated with non−biologic systemic therapies (including PUVA, methotrexate, ciclosporin and acitretin). Patients will have been exposed to a variety of conventional treatments each with its own risks before starting on the biologic therapies.

Based on recruitment rates of a similar register (the British Society for Rheumatology Biologics Register - BSRBR) it is anticipated that 2000−4000 patients for each biologic therapy will be recruited over a five year period. During the same time period, a cohort of comparison patients on standard therapy will also be recruited. Due to the NICE guidelines recommending that all patients with psoriasis should be registered with a national register, it is envisaged that patients in the biologic cohort will be recruited from all dermatology departments in the UK. The comparison cohort will also be recruited from all contributing centres to reduce the risk of selection bias. However for the size of the comparison cohort it is estimated that a total sample of 4000 patients followed for five years is required to allow the register to detect at least a 3− to 4−fold increase in the risk of non−melanoma skin cancer, a particular concern in these patients who have been exposed to phototherapy.

BADBIR has an existing link with NHS Health and Social Care Information Centre (HSCIC) to receive Death and Malignancy information (Ref: MR1102) and are now applying for access to the Hospital Episodes Statistics data for study participants. However HSCIC has questioned the validity of the consent on the grounds that the consent material did not provide an adequate legal basis for the request to access HES data. HES data will allow a better understanding of the outcomes for patients receiving biologic therapy and up to 4,000 patients treated with conventional therapy to enable the short, medium, and long term safety of biologic treatment as compared to traditional therapy for psoriasis to be ascertained. The applicant has provided copies of the correspondence with the HSCIC as well as the consent forms.

S251 support is requested to allow the disclosure of name, NHS number, address and postcode, date of birth, and gender to the HSCIC for linking purposes.

A recommendation for class 4, and 6 support was requested to link patient identifiable information obtained from more than one source and to allow access to an authorised user for one or more of the above purposes

Confidential patient information requested

Access was requested to name, NHS number, address and postcode, date of birth, and gender

Confidentiality Advisory Group advice

Public interest

Members agreed this was a study with medical purpose in the public interest.

Justification of identifiers

The application was unclear on whether the study was still recruiting or if the cohort was complete. If not members agreed that the patient information leaflet and consent form should be updated to seek consent from that part of the cohort that HSCIC was content with, to do which the applicant must seek advice from HSCIC.

For the cohort already recruited the applicant should ensure that they have satisfied the requirements of principle 1 of the DPA and have made a reasonable attempt to inform all subjects of linkage with HES, albeit a great deal of the spirit of that is already contained in their patient information leaflet. Members recommended that the leaflet should be updated and consulted on with HSCIC as even if section 251 support is recommended, the patent information and privacy notice will be scrutinised during the application to HSCIC (bearing in mind that section 251 support does no lift any of the requirements of the DPA) and HSCIC will not release data unless the requirements of the DPA are satisfied.

Additional points

It was noted that the study aims to collect data from all four jurisdictions of the UK and CAG approval would extend only to data collected in England and Wales. However members noted that this application was restricted to data supplied by the Health and Social Care Information Centre (HSCIC) which is limited to English data only.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Support is limited to the cohort already recruited. If still recruiting new recruits must be consented in a way that satisfies the HSCIC.
2. The Patient information leaflets should be updated in line with recommendations from the HSCIC to ensure it complies with principles of the Data Protection Act (DPA).
3. Favourable opinion from a Research Ethics Committee.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-cag-application-advice/ and contact Exeter.helpdesk@nhs.net with any queries.

Please provide confirmation that the above conditions have been accepted and/or met. Once provided, the response will be reviewed and if satisfactory, the HRA will

confirm final approval. Support only comes into effect once this final approval letter has been received.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised)		
Confidentiality policy		
Covering letter on headed paper		
Other [5. Response from HSC IC on initial HES application]		
Other [List of UK Participating Sites]		
Other [BADBIR HSCIC Data Flow]		
Patient Information Materials		
Research protocol or project proposal		

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item or submitted written comments are listed below.

Yours sincerely

Ben Redclift

Email: HRA.CAG@nhs.net

Enclosures: *List of members who considered application*
Standard conditions of approval

Confidentiality Advisory Group sub-committee meeting 11 March 2016

Group Members:

Name	*Profession*	*Present*	*Notes*
Dr Kambiz Boomla		Yes	
Dr Patrick Coyle		Yes	
Mr Marc Taylor		Yes	

NHS
Health Research Authority

Standard conditions of approval

The approval provided by the Health Research Authority is subject to the following standard conditions.

The applicant will ensure that:

1. The specified patient identifiable information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant.

4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities are consistent with the Data Protection Act 1998.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.