Health Research Authority
2 Redman Place
Stratford
London
E20 1JQ

Email: cag@hra.nhs.uk

10 August 2026

Professor Richard Warren
BADBIR
The University of Manchester
1st Floor Bright Building
Pencroft Way
Manchester
M15 6GZ

Dear Professor Warren,

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 modification request to the above research application, submitted for support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Supported 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 supported, and if so, any relevant conditions.

Health Research Authority decision

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

1. The modification, to include linkage to the Electronic Prescribing and Medicines Administration (ePMA) in Secondary Care, held by NHS England. is supported, subject to compliance with the standard conditions of support.

Modification request

The applicants have existing support for processing of confidential patient information to undertake the British Association of Dermatologists Biologic

Interventions Register (BADBIR). BADBIR monitors the long-term safety of biologic treatments for psoriasis patients in the UK and Republic of Ireland. The applicants have support to allow the disclosure of confidential patient information from BADBIR to NHS England for linkage to HES and the return of a linked dataset. This support was needed as, while patients had consented to linkage to NHS England held data on death and malignancy, their consent did not include HES data. Support was limited to the cohort recruited prior to 2017 and new recruits consented to HES data linkage, as well as to Mortality Status and Cancer Registration data.

In this request, the applicants seek to include linkage to the Electronic Prescribing and Medicines Administration (ePMA) in Secondary Care, held by NHS England. Support for this linkage is requested for all patients recruited to BADBIR before 2017, and from 2017 to now, as their consent did not cover this linkage to prescription data.

Prospectively, consent for linkage to prescription data will be sought from new patients joining the BADBIR study.

Confidentiality Advice Team advice

The modification requested was considered by the Confidentiality Advisory Group. The Group agreed that the request was in the public interest.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this modification and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS England 24/25 DSPT reviews for **University of Manchester & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 13 July 2026)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 24 June 2026.**

Reviewed documents

Document	*Version*	*Date*
CAG Amendment-request-template-v4.1_05Mar25_AS		
2026 03 19 BADBIR_protocol_v22_Clean	v22	
2026 03 19 BADBIR_protocol_v22_TC	v22	
REC Approval SA15 07_MRE08_9_AM181_Favourable_opinion_of_a_substantial_modification		24 June 2026

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

Kathleen Cassidy
Confidentiality Advisor

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Enclosures: Standard conditions of Support

cc. haydock.rec@hra.nhs.uk

NHS
Health Research Authority

Standard conditions of support

Support to process confidential patient information without consent, given by the Health Research Authority, is subject to the following standard conditions of support.

The applicant and those processing the information will ensure that:

1. The specified confidential patient 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, in addition to other national guidance.

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

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

6. Activities remain consistent with the General Data Protection Regulation and Data Protection Act 2018.

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. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be supported via formal modification prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken / to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.