



# Health Research Authority

Skipton House  
80 London Road  
London  
SE1 6LH

Tel: 020 7104 8100  
Email: [cag@hra.nhs.uk](mailto:cag@hra.nhs.uk)

13 April 2021

Dr Robert French  
Cardiff University  
UHW  
The Heath  
Cardiff University  
CF14 4XN

Dear Dr French

**Application title:** Trajectories of diabetes related health measures (from linked lab data) and subsequent health and educational outcomes  
**CAG reference:** 18/CAG/0002  
**IRAS project ID:** 230333  
**REC reference:** 17/WA/0410

Thank you for your amendment 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 amendment, to allow the disclosure of confidential patient information from NHS Digital to DfE, and to allow confidential patient information to be disclosed for the National Diabetes Audit and National Paediatrics Diabetes Audit from NHS Digital to NWIS, is fully supported, subject to compliance with the standard conditions of support.

## **Amendment request**

The applicants have existing support for the disclosure of confidential patient information from both the National Diabetes Audit (Adults – England) and National Diabetes Audit (Adults – Wales) (held by NHS Digital) and the National Paediatrics Diabetes Audit (held by the Royal College of Paediatrics and Child Health) to NHS Wales Informatics Services (NWIS). Data is also released from the Higher Education Statistics Agency (HESA) dataset to NWIS; however, this is out of the CAG's remit as it is not confidential patient information.

The current approval uses SAIL as the data linkage repository. SAIL use NWIS as the data processor to create the 'linkage ID' from the confidential patient information. The applicant confirmed that the new repository is for the linkage of English data and that SAIL was used for the linkage of Welsh data in the original application to CAG.

The applicants are now seeking to include ONS Secure Research Service (SRS) as a second linkage repository for the English data. ONS-SRS will use DfE as the data processor to create the 'linkage ID' from the confidential patient information. De-identified data only will be processed by ONS-SRS, therefore support is not required for this. Support is needed for the disclosure of confidential patient information from NHS Digital to DfE.

The applicants also seek support to allow NHS Digital to disclose confidential patient information for the National Paediatric Diabetes Audit (NPDA), as well as for the National Diabetes Audit in England, to NWIS. NHS Digital would undertake this disclosure instead of the Royal College of Paediatrics and Child Health (RCPCH). However the applicants seek to retain support for the disclosure of confidential patient information from the NPDA via the RCPCH, in case of any problems with the transfer from NHS Digital.

On review by the CAG Chair, further details were requested around the retention of identifiers from the RCPCH. The Chair understood that this may be to ensure against data loss from NHS Digital, but either a time limit needed to be given or an explanation as to why the data needs to be retained for a longer period. The applicant advised that they would wish to continue to use data directly from RCPCH, as explained in their original application to the CAG. However, the proposed change in the amendment is to use an existing flow for the transitions audit under the legal arrangements for transitions audit. The data is retained by the audit for its own audit purposes and is not controlled in any way by the applicants for this study.

## **Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the amendment was in the public interest.

## **Confidentiality Advisory Group conclusion**

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

## **Specific conditions of support**

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

**Confirmed:** The NHS Digital 2019/20 DSPT reviews for NHS Digital, the Royal College of Paediatrics and Child Health and the SAIL Databank and SeRP UK were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 22 February 2021).

**Confirmed:** the Caldicott: Principles Into Practice (CPIP) for NWIS was confirmed on 15 June 2020.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **The REC confirmed that an amendment was not required on 16 December 2020.**

### Reviewed documents

| <i>Document</i>   | <i>Version</i> | <i>Date</i>      |
|---|----------------|------------------|
| Amendment request form  | 4              | 11 December 2020 |
| Original HRA REC Approval Letter  |                | 18 December 2018 |
| 18CAG0002_AmendmentSRS_Supporting Document_NDA Patient Notification Materials V7  | 7              |                  |
| 18CAG0002_AmendmentSRS_Supporting Document_NPDA Patient Notification Materials V4 | 4              |                  |
| 18CAG0002_AmendmentSRS_Supporting Document_Figures_V2                             | 2              |                  |
| REC confirmed no amendment needed   |                |                  |

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](mailto:cag@hra.nhs.uk)

Enclosures: Standard conditions of Support

cc. [Wales.REC6@wales.nhs.uk](mailto:Wales.REC6@wales.nhs.uk)

### **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 amendment 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.