



Health Research Authority

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29 June 2021

Dr Robert French
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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 NHS Digital to create a linkage key, and for NHS Digital to share NDPA/NDA identifiers with ONS-DAP to create a 'DAP' linkage key, is 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.

Currently confidential patient information flows from NHS Digital to Department for Education to create a linkage key. To enable better linkage across all the datasets this amendment requests the use of two further linkage keys

- NHS Digital will create an NHS Digital linkage key (note that this is done within NHS Digital and does not result in any external flows of Confidential Patient Information and send the key to the ONS-SRS
- NHS Digital to send NDPA/NDA identifiers to ONS-DAP to create a 'DAP' linkage key (this key is sent to ONS-SRS but does not include any Confidential Patient Information)

Within ONS-SRS the DfE, NHSD and DAP linkage keys are combined. The purpose of using the three keys is that it will enable better linkage between the health and non-health datasets.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair's Action. This was considered by the chair and vice chair who agreed that the amendment would enable improved linkage and were supportive of the amendment.

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 19/20 DSPT review for NHS Digital was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 21 June 2021)
2. Confirmation of a favourable opinion from a Research Ethics Committee.
Confirmed as not necessary by the REC.

Reviewed documents

<i>Document</i>	<i>Version</i>	<i>Date</i>
Amendment request form		28 May 2021
Fair Processing Notice		

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

Paul Mills
Confidentiality Advice Service Manager

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Enclosures: Standard conditions of Support

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.