Health Research Authority

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09 February 2018

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 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 CAG meeting held on 25 January 2018.

Health Research Authority Approval Decision

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.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of Application

This application from Cardiff University set out the purpose of medical research aiming to better understand the effects of diabetes on educational outcomes. It was acknowledged that education may also have an impact on an individual's diabetes management. The applicants have an interest in how other factors influence the relationships between health and education, these include characteristics of the child (e.g. gender), their families (e.g. single parent families), and the health services they use (e.g. type of diabetes clinic). The project aims to use linked health and education records to quantify the associations between differences in levels of HbA1c (an indicator of longer-term blood glucose levels) and educational outcomes.

The application involves 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 will also be 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. Corresponding clinical data will be released direct to the Secure Anonymised Information Linkage databank (SAIL), which will then be linked with psedonymised demographic data.

The applicants clarified that HESA are providing all of the additional education data – for students in England and Wales at University plus school education data for students from English schools. The school education data for pupils from Wales is already provided by Welsh Government routinely into SAIL where is it is available in psuedonymised format for linkage to the new datasets.

The legal basis for the collection of National Diabetes Audit (England) is by Directions, National Diabetes Audit (Wales) the legal basis is "section 251" (Reference: 17/CAG/0124) and for the National Paediatric Diabetes Audit the legal basis is "section 251" (Reference: ECC 2-03(c)/2012).

A recommendation for class 1, 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

All birth cohorts between 1983 and 2013 within England and Wales, for whom diabetes audit data (NPDA and NDA) from 2003 to 2018 and education data from 2003 to 2018 will be requested. It is anticipated that there will be 17,195 patients included within the project.

The following items of confidential patient information are required for the purposes defined:

- NHS number – used to create anonymised linkage field,
- Date of birth – used to create anonymised linkage field, validation and translated for analysis (week of birth),
- Gender – validation and analysis,
- Postcode – validation and translated to LSOA for analysis.

Wider clinical information will be provided from the diabetes audits for inclusion in the analysis dataset.

Confidentiality Advisory Group Advice

Public Interest

The CAG was assured that the application defined a medical purpose through medical research and it was acknowledged that there was public interest in the research question, which aimed to gain an understanding of the relationship between diabetes and the educational attainments of children with the condition.

Scope of Support

The remit of the CAG set out in the Health Service (Control of Patient Information) Regulations 2002 applies to confidential patient information (as defined within the NHS Act 2006). The recommendation of support provided extended to the release of confidential patient information from the National Diabetes Audit (England), the National Diabetes Audit (Wales) and National Paediatric Diabetes Audit datasets only. It was noted that it was the responsibility of the data controller for the HESA education data to ensure that a legal basis had been established to support any disclosures from this dataset.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members were assured that consent was not feasible for the proposal due to the sample size to be included.

- Use of anonymised/pseudonymised data

It was acknowledged processing of confidential patient information was required in order to link the relevant datasets. Analysis would be undertaken on an anonymised dataset.

Justification of Identifiers

Applicants should justify the necessity of each identifiable data item in the context of how each is essential to achieve the aims, and as part of this justification consider whether less identifiable variants of each item would be sufficient e.g. month and year instead of full date of birth. The Group was assured that the items of confidential patient information requested were proportionate and justified in order to achieve the aims of the project.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. It was acknowledged that the exit strategy from support under the Regulations was the anonymisation of the dataset for analysis. The applicants had asserted that the process of data linkage and anonymisation would be achieved within a six-month period of all relevant approvals being in place. Members acknowledged that there would be a

lead-in time, prior to any data release whilst the applicants were seeking the relevant approvals. It was commented that, should the processing of confidential patient information extend beyond this period, submission of an amendment would be required to extend the duration of support provided under the Regulations.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead.

The activity which had been undertaken in this area was acknowledged, however, Members commented that there had been no engagement with children with diabetes who were now adults. The Group agreed that this was an important cohort and further activity should be undertaken to seek the views of this group.

It was further commented that the patient and public engagement activity which had been undertaken to date had not explored the acceptability of using confidential patient information without consent in order to establish the anonymous dataset which would be used for analysis. The Group agreed that further work would be required in this area to seek the opinions of patients and the public around the use of confidential patient information in the creation of the analysis dataset.

It was agreed that a report would be required at the time of first annual review around the additional activity which had been undertaken in this area. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Within the submission, the applicants had provided details of the patient notification materials of NPDA, NDA and HESA for information. It was noted that any individual who had registered a dissent against the use of their data with these three organisations would not be included within the project specific database established for this research.

The applicants had also provided project-specific notification materials, which would allow patients the opportunity to register their dissent against the use of their data within the project. It was identified that any project-specific dissent would need to be raised in advance of the data providers releasing information to NWIS and SAIL. Members considered this and agreed that the project-specific patient notification materials would need to be displayed with a lead-in time ahead of data release, to ensure that any objections received could be respected. The Group agreed that project-specific notifications should be displayed for a two month period, ahead of data release, to facilitate patient objections. The cut-off for receipt of project-specific objections would need to be added to section ‘Opting out of the study’.

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 (Final)

1. Support extends to the release of confidential patient information from the National Diabetes Audit (Adult – England) and National Diabetes Audit (Adult – 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).
2. Patient Notification and Dissent:
    a. Project-specific patient notification materials should be displayed for a two-month period ahead of any release of data from the National Diabetes Audit and the National Paediatric Diabetes Audit datasets, to facilitate patient objections.
    b. The section titled 'Opting out of the Study' should be updated to include confirmation of the cut-off date for the receipt of objections.
3. Patient and Public Involvement and Engagement – further work should be undertaken in this area to address the following points:
    a. Children who are now adults with diabetes, who will be included in the project should be approached about the study, in order to seek their views on the proposed activity,
    b. Further work should also be undertaken to seek the views of patients and the public around the acceptability of using confidential patient information as described in the application in order to establish the anonymous dataset to be used in analysis,
    c. A report should be provided at the time of first annual review around the actual activity which has been undertaken in this area, together with any feedback or outputs,
    d. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
4. Favourable opinion from a Research Ethics Committee (**Confirmed – 05/12/2017**).
5. Security Assurance Arrangements – **NWIS have provided a CPIP (Caldicott: Principles into Practice) report showing a 94% satisfactory assessment rate**.

As the above conditions have been accepted or met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Annual Review

Please note that your approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided no later than **09 February 2018** and preferably 4 weeks before this date.

Reviewed Documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG Form]		01 December 2017
Data Protection Registration [DPR for Velindre NHS Trust]		11 December 2000
Other [Cardiff University Sponsorship]	1	21 November 2017
Other [HESA Student Collection Notice]		
Other [NDA Fair Processing]		
Patient Information Materials [NDA Poster - Hospital]		
Patient Information Materials [NDA Poster - GP]		
Patient Information Materials [NDA Information Leaflet - People At High Risk Of Diabetes]		
Patient Information Materials [NDA Information Leaflet - Patient]		
REC favourable opinion letter and all correspondence [REC Favourable Opinon]		18 December 2017
REC favourable opinion letter and all correspondence [17/WA/0410 REC Favourable Opinion Letter]		18 December 2017
Research protocol or project proposal [HESA Data Flow Diagram]	1b	17 November 2017
Research protocol or project proposal [NDA Data Flow Map]	1a	17 November 2017
Research protocol or project proposal [NPDA Data Flow Map]	3e	17 November 2017
Research protocol or project proposal [Project Summary]	1c	21 November 2017

Membership of the Committee

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

There were *no* declarations of interest in relation to this item.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R & D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

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.

With the Group's best wishes for the success of this project.

Yours sincerely

Miss Kathryn Murray
Senior Confidentiality Advisor

On behalf of the Health Research Authority

Email: HRA.CAG@nhs.net

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

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Confidentiality Advisory Group Meeting 25 January 2018

Group Members:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Ms Sophie Brannan	Yes	Lay
Dr Tony Calland	Yes	Chair
Dr Patrick Coyle	Yes	Vice Chair
Mr Anthony Kane	Yes	Lay
Dr Rachel Knowles	No	Apologies received
Professor Jennifer Kurinczuk	Yes	
Mr Andrew Melville	Yes	Lay
Dr Murat Soncul	Yes	Alternate Vice Chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	Head of the Confidentiality Advice Service
Miss Kathryn Murray	Senior Confidentiality Advisor
Mr Dave Murphy	Observer – HRA Communications Manager

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.