Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

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18 December 2017

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

Dear Dr French

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

The Research Ethics Committee reviewed the above application at the meeting held on 13 December 2017. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Summary of discussion at the meeting

Social or scientific value; scientific design and conduct of the study

The Committee noted that this study was essentially a single-person standalone study using linked data on people with diabetes. The study will be using existing data from various databases which requires information governance permissions from database holders, rather than consent from identified participants. There is no direct contact with participants and therefore no consent/PIS or risks to participants or the researchers.

The Committee agreed that as this study is using data which already exists, there is therefore no need for consent. The database holders are national bodies: Higher Education Statistics Agency (HESA), National paediatric Diabetes Audit (NPDA), National Diabetes Audit (NDA) You will be collating datasets with very robust linkage procedures via NHS Wales Informatics Service (NWIS) with existing Secure Anonymised Information Linkage (SAIL) data on education. The Committee noted that the linkage procedures involved NWIS who were a third party named by SAIL. The linkage procedures are standard, and similar arrangements have received REC approval.

It was noted that further datasets may be required unless existing SAIL data on education also covers England as traditionally SAIL involves looking at Welsh data. *You stated that having the Welsh and English data would aid the power.*

The Committee noted that throughout the application the study referred to type 1 diabetes however, in A59 type 2 diabetes is mentioned. The Committee were unclear whether this could skew the results of what you were trying to achieve in the research question. *You stated that the primary case is for type 1 however, for future projects, type 2 would also have to be included.*

The Committee was satisfied with this response.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee agreed that the information governance procedures were satisfactory.

It was noted from the project filter that data would be accessed outside the care team and therefore could break the line of confidentiality. It was agreed that people who would be accessing the data would also be responsible for the coding. It was agreed that this element would fall under the Confidentiality Advisory Group (CAG). The Committee were unclear whether CAG approval had already been obtained. *You confirmed that this was in the process of being obtained and that patient notes would be excluded from going to SAIL directly.*

The Committee was satisfied with this response.

Other general comments

The Committee noted that funding of £460,000 had been secured from the MRC and questioned what these monies were for. It was agreed that the MRC considered this study to be of very high value and that some of the funding may be towards the first part of the fellowship. It was considered that the amount would probably include the whole package and salary of which, the salary element would be a considerable part of the package. It was agreed that it was not the Committee's decision to say who received the most funding and that every project should be judged on its own merits. *You confirmed that the funding was very restricted and to cover all you would be required to do. You will identify and create the anonymised linkage under section 251 and then do the same for stage 2.*

The Committee was content with this response.

Please contact the REC Manager if you feel that the above summary is not an accurate reflection of the discussion at the meeting.

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Cardiff University Insurance & Public Liability V1a 15_7_2017]		
IRAS Application Form [IRAS_Form_22112017]		22 November 2017
IRAS Application Form XML file [IRAS_Form_22112017]		22 November 2017
IRAS Checklist XML [Checklist_22112017]		22 November 2017
Letter from sponsor [Cardiff University Sponsorship V1a 21_11_2017]		
Research protocol or project proposal [Project proposal V1c 21_11_2017]	V1c	21 November 2017
Summary CV for Chief Investigator (CI) [Robert French CV 22_11_2017]	V1a	22 November 2017

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

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/

17/WA/0410	**Please quote this number on all correspondence**

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

Yours sincerely

pp
Dr M J Lawrence
Vice Chair

E-mail: penny.beresford@wales.nhs.uk

Enclosures:	*List of names and professions of members who were present at the meeting and those who submitted written comments*
	"After ethical review – guidance for researchers" [*SL-AR2 for other studies]*
Copy to:	*Ms Jane Jones, Cardiff and Vale NHS University Health Board* *Dr John Lowe, Research & Innovation Services, Cardiff University* *Confidentiality Advise Team*

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Attendance at Committee meeting on 13 December 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Jill Burgess	Lay Member	No	
Ms Anne Cowper	Lay Member	Yes	
Prof Roy L. Evans	Hon Assoc Professor - Chairman	Yes	
Dr Iveta Garaiova	Senior Research Manager	Yes	
Dr Gail Holland	Trials Unit Manager	Yes	
Dr Matthew Lawrence	Research Officer	Yes	
Dr Ryan Lewis	Clinical Scientist	Yes	
Dr Nadja Melo	Andrologist	No	
Mr Amol Pandit	Urologist	Yes	
Mrs Roberta Parker	Retired	Yes	
Dr Suresh Pillai	Consultant in Emergency Medicine & Intensive Care	No	
Dr John Rees	GP - retired	Yes	
Dr Ahmed Sabra	Cardiology Registrar	No	
Dr Mark Turtle	Consultant Anaesthetist & Pain Management Physician	Yes	
Dr Alan Watkins	Senior Lecturer in Statistics	Yes	
Professor Paul Willner	Emeritus Professor of Psychology	No	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Penny Beresford	REC Manager