Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Wales Research Ethics Committee 5
Bangor

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**Please note:**
**This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval**

07 July 2021

Dr Lisa Newington
Research Associate
Imperial College London
Education Building (corporate nursing)
Charing Cross Hospital
Fulham Palace Road, London
W6 8RF

Dear Dr Newington

| | |
|---|---|
| **Study title:** | **Interview study to explore participants' views of taking part in healthcare research** |
| **REC reference:** | **21/WA/0229** |
| **Protocol number:** | **N/A** |
| **IRAS project ID:** | **298078** |

The Proportionate Review Sub-committee of the Wales REC 5 reviewed the above application on 06 July 2021.

**Ethical opinion**

On behalf of the Research Ethics Committee (REC), the sub-committee 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.

**Good practice principles and responsibilities**

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

**Conditions of the favourable opinion**

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

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) 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 and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

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 research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

**N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months**.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

**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).**

### 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, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

### Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

### Approved documents

The documents reviewed and approved were:

| *Document* | *Version* | *Date* |
|---|---|---|
| Copies of materials calling attention of potential participants to the research [Flyer] | 1.0 | 02 June 2021 |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance] | 1.0 | 05 August 2020 |
| Interview schedules or topic guides for participants [Interview schedule] | 1.0 | 06 April 2021 |
| IRAS Application Form [IRAS_Form_28062021] | | 28 June 2021 |
| Letter from funder [Grant award letter] | 1.0 | 29 April 2021 |
| Letter from sponsor [Sponsor letter] | 1.0 | 23 June 2021 |
| Letters of invitation to participant [Invitation text] | 1.0 | 11 May 2021 |
| Non-validated questionnaire [Screening questions] | 1.0 | 06 April 2021 |
| Participant consent form [Consent form] | 1.0 | 09 June 2021 |
| Participant information sheet (PIS) [Participant information sheet] | 1.0 | 17 June 2021 |
| Referee's report or other scientific critique report [Peer review certificate] | 1.0 | 03 June 2021 |
| Referee's report or other scientific critique report [Responses to peer reviewers] | 1.0 | 16 March 2021 |
| Research protocol or project proposal [Study Protocol] | 1.0 | 02 June 2021 |
| Summary CV for Chief Investigator (CI) [CV] | 1.0 | 28 June 2021 |

### Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

### Statement of compliance

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.

**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 Learning**

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

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

| **IRAS project ID: 298078** | **Please quote this number on all correspondence** |
|---|---|

Yours sincerely

**Dr Jason Donal Walker**
**Chair**

Email: Wales.REC5@wales.nhs.uk

Enclosures: List of names and professions of members who took part in the review

"After ethical review – guidance for researchers" [SL-AR2]

Copy to:

Lead Nation

**Wales REC 5**

**Attendance at PRS Sub-Committee of the REC meeting on 06 July 2021**

**Committee Members:**

| *Name* | *Profession* | *Present* | *Notes* |
|---|---|---|---|
| Dr Swapna Alexander | Consultant Physician | Yes | |
| Dr Jason Donal Walker | Consultant Anaesthetist (Chair) | Yes | |
| Mrs Carolin Williams | Postgraduate Research Student | Yes | |

**Also in attendance:**

| *Name* | *Position (or reason for attending)* |
|---|---|
| Miss Leanna Bourke | Approvals Administrator |
| Ms Mair Davidson | Approvals Specialist |