Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Health Research Authority

Miss Krystynne Harvey
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Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

11 July 2018

Dear Miss Harvey

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**To identify what factors influence the optometric referral reply rate (RRR): a mixed methods study of communication between optometrists and medical professionals with regard to feedback on optometric referrals.**
IRAS project ID:	**227869**
REC reference:	**17/LO/1886**
Sponsor	**London South Bank University**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Professor Nicola Thomas
Tel: 02078158045
Email: nicola.thomas@lsbu.ac.uk

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **227869**. Please quote this on all correspondence.

Yours sincerely

Aliki Sifostratoudaki
Assessor

Email: hra.approval@nhs.net

Copy to: *Professor Nicola Thomas, London South Bank University, Sponsor Contact*
Ms Becky Dilley, NHS Canterbury and Coastal CCG, R&D Contact

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Covering letter on headed paper [cover letter]		08 September 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [sponsor's insurance]		08 August 2017
HRA Schedule of Events [227869_SOE-Research sites_19.06.2018]	1	19 June 2018
HRA Statement of Activities [227869_SOA-Research sites_19.06.2018]	1	19 June 2018
Interview schedules or topic guides for participants [phase 2 data sheets]	1	08 August 2017
Interview schedules or topic guides for participants [Interview topic guide]	2	08 July 2018
IRAS Application Form [IRAS_Form_16102017]		16 October 2017
Letter from sponsor [LSBU sponsor letter]		08 September 2017
Letters of invitation to participant [participant invitation]	1	08 September 2017
Other [Optometric practice consent form - version 3]	3	27 February 2018
Other [Interview Consent Form- patient - version 3]	3	27 February 2018
Other [Interview consent form version 3 - professional]	3	27 February 2018
Other [Ethics committee reply]	2	20 December 2017
Other [RRR study spreadsheets]	1	20 December 2017
Other [participant request email]	2	08 July 2018
Participant information sheet (PIS) [OPTOMETRIC PRACTICE PARTICIPANT INFORMATION SHEET- version 3]	3	08 July 2018
Participant information sheet (PIS) [INTERVIEW PARTICIPANT INFORMATION SHEET -PATIENT - version 3]	3	08 July 2018
Participant information sheet (PIS) [INTERVIEW PARTICIPANT INFORMATION SHEET -PROFESSIONAL STAFF - version 3]	3	08 July 2018
Research protocol or project proposal [Research protocol]	2	11 September 2017
Summary CV for student [Krystynne Harvey cv]	1	05 September 2017
Summary CV for supervisor (student research) [Professor Edgar cv]	1	08 September 2017
Summary CV for supervisor (student research) [Professor Agarwal cv]		11 September 2017

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	GP practices within the Surrey and Sussex CRN will be approached to take part in this study.
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The Sponsor contact has confirmed that the Statement of Activities and the Schedule of Events will form the agreement between the Sponsor and the research sites. No judgement on the cost attributions has been made. Some participants may also be recruited outside the NHS. HRA approval does not cover activity outside the NHS. Before recruiting outside the NHS the research team must follow the procedures and governance arrangements of responsible organisations
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	This study is not receiving external funding (Project that is part of a fellowship/ personal award/ research training award).

Section	Assessment Criteria	Compliant with Standards	Comments
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	The Applicant confirmed that the clinical records will only be accessed by a member of the patient care team. Only anonymised data will be extracted. No patient records or copies of patient records will be removed from the practices. The completed spreadsheet (containing only the anonymised data) will be sent by the optometric practice to the chief investigator. Consent forms will be kept at the University.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There is one site type in this study – research sites. Research sites will be responsible for all activity as listed in the Protocol. The Chief Investigator or sponsor should share relevant study documents with participating NHS

organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Local Collaborator would be expected at the participating NHS organisation to facilitate access on site for the external research team to undertake the study activities on site. A Principal Investigator (PI) would not be expected as all study activities will be undertaken by the external research team. GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
It is expected that the principles of the HR Good Practice Pack are followed for researchers working in primary care. Researchers are advised to follow the processes of the local primary care management function.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.