Mrs Sara Ma
Lecturer in Nursing
York St John University
School of Science, Technology and Health
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York St John University, Lord Mayors Walk
YO31 7EX

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

13 August 2024

Dear Mrs Ma

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

Study title:	**A mixed methods study using co-production to develop an intervention to help nurses improve the assessment and care of the sexual health needs of men with Inflammatory Bowel Disease**
IRAS project ID:	**334340**
Protocol number:	**334340 YP**
REC reference:	**24/EE/0158**
Sponsor	**YORK AND SCARBOROUGH TEACHING HOSPITALS NHS FOUNDATION TRUST**

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.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

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 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) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

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 standard conditions 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.

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 **334340**. Please quote this on all correspondence.

Yours sincerely,

Mathew Barnes
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Deborah Phillips, YORK AND SCARBOROUGH TEACHING HOSPITALS NHS FOUNDATION TRUST*

List of Documents

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

Document	*Version*	*Date*
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [York St John University Ethical Approvals (CI employer)]		
Contract/Study Agreement template [NIHR Contract]		17 March 2024
Copies of materials calling attention of potential participants to the research [MenSH Poster 1 v2.0]	2.0	12 August 2024
Copies of materials calling attention of potential participants to the research [MenSH Poster 1 v2.0 (clean)]	2.0	12 August 2024
Copies of materials calling attention of potential participants to the research [MenSH Poster 2 v2.0]	2.0	12 August 2024
Copies of materials calling attention of potential participants to the research [MenSH Poster 2 v2.0 (clean)]	2.0	12 August 2024
Interview schedules or topic guides for participants [MenSH Focus group facilitation guide v2.0]	2.0	08 August 2024
Interview schedules or topic guides for participants [MenSH Focus group facilitation guide v2.0 (clean)]	2.0	08 August 2024
Interview schedules or topic guides for participants [Interview Guide (single participant)]	1.0	01 May 2024
Interview schedules or topic guides for participants [Interview guide (dual participant)]	1.0	01 May 2024
IRAS Application Form [IRAS_Form_05072024]		05 July 2024
Letter from funder [NIHR Award Letter]		18 January 2024
Letter from sponsor [Sponsorship email]		07 May 2024
Letter from statistician [Letter from statistician]		28 June 2024
Letters of invitation to participant [MenSH Invite Survey 2 v2.0 (clean)]	2.0	08 August 2024
Letters of invitation to participant [MenSH Invite letter focus groups v2.0]	2.0	08 August 2024
Letters of invitation to participant [MenSH Invite letter focus groups v2.0 (clean)]	2.0	08 August 2024
Letters of invitation to participant [MenSH Invite letter interviews 2.0]	2.0	08 August 2024
Letters of invitation to participant [MenSH Invite letter interviews v2.0 (clean)]	2.0	08 August 2024
Letters of invitation to participant [MenSH Invite letter survey 1 v2.0]	2.0	08 August 2024
Letters of invitation to participant [MenSH Invite survey 1 v2.0 (clean)]	2.0	08 August 2024
Letters of invitation to participant [MenSH Invite letter survey 2 v2.0]	2.0	08 August 2024
Non-validated questionnaire [Survey of IBD services]	1.0	21 June 2024
Non-validated questionnaire [Survey of IBD nurses]	1.0	21 June 2024
Non-validated questionnaire [Survey of IBD nurses]	1.0	26 June 2024
Other [Participant support leaflet to signpost]	v1.0	01 May 2024
Other [York St John University Indemnity]	1	01 August 2024
Other [MenSH Participant support leaflet v1.1]	2.0	08 August 2024
Other [MenSH Participant support leaflet v1.1 (clean)]	2.0	08 August 2024
Other [MenSH Prize draw survey 1 v2.0]	2.0	12 August 2024
Other [MenSH Prize draw survey 2 v2.0]	2.0	12 August 2024

Other [MenSH Expression of interest form v1.0]	2.0	12 August 2024
Other [Letter to REC]	1	13 August 2024
Participant consent form [MenSH Consent v2.0]	2.0	08 August 2024
Participant consent form [MenSH Consent v2.0 (clean)]	2.0	08 August 2024
Participant information sheet (PIS) [MenSH PIS v2.0]	2.0	08 August 2024
Participant information sheet (PIS) [MenSH PIS v2.0 (clean)]	2.0	08 August 2024
Research protocol or project proposal [MenSH Protocol]	1.1	01 May 2024
Summary CV for Chief Investigator (CI) [CI CV]		21 March 2024
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Flow Chart]	1.0	01 May 2024

IRAS project ID	334340

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
This is a single site study sponsored by the participating NHS organisation therefore there is only one site type.	The single participating NHS organisation of this type is also sponsoring the research. You should work with your sponsor R&D office to make arrangements to set up the study. The sponsor R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.	This is a single site study sponsored by the participating NHS organisation therefore no agreements are expected.	External study funding has been sought.	Principal Investigators are expected to be in place at participating NHS / HSC organisations where locally employed staff take responsibility for research procedures.	Where an external individual will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold a Letter of Access. This should be issued be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm Occupational Health Clearance and standard DBS checks.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.