From: PATEL, Reshma (UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST) reshma.patel21@nhs.net
Subject: Fwd: IRAS 265964. HRA & HCRW Approval Status Update - Favourable Opinion with Conditions
Date: 25 February 2025 at 16:57
To: OCARROLL, James (UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST) james.ocarroll@nhs.net

RP

The original favourable opinion here

Sent from Outlook for iOS

From: leicestercentral.rec@hra.nhs.uk <noreply@harp.org.uk>
Sent: Thursday, 11 April 2024 10:54:50
To: MOONESINGHE, Ramani (NHS ENGLAND – X24) <ramani.moonesinghe@nhs.net>; ramani.moonsinghe@nhs.net <ramani.moonsinghe@nhs.net>; PATEL, Reshma (UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST) <reshma.patel21@nhs.net>; ramani.moonsinghe@nhs.net <ramani.moonsinghe@nhs.net>
Cc: RANDD (UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST) <uclh.randd@nhs.net>; leicestercentral.rec@hra.nhs.uk <leicestercentral.rec@hra.nhs.uk>
Subject: IRAS 265964. HRA & HCRW Approval Status Update - Favourable Opinion with Conditions

Dear Professor Moonesinghe,

I am pleased to provide the following update regarding the status of your application.

Please submit the requested information electronically through IRAS. Please provide your answers in the table(s) below and then submit this, with revised documentation where appropriate, underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. A response should be submitted by no later than **11 May 2024**.

To enable the application to progress without delay we encourage you to provide these documents as soon as possible within the timeframes specified.

Ethical Review

The Research Ethics Committee has issued a **Favourable Opinion with Additional Conditions.**

Number	Condition	Response from the applicant
1	Please make the following changes to the Participant Information Sheet: A- Provide some information that post-partum depression might occur or be detected and what measures of support will be provided. B- Add details of when visit will take place after caesarean section and before discharge.	

	C- Though the student's name is mentioned at the start of PIS; it would be useful to add her details- name and role in this study under the section Principal Investigators. D- Add details of the PhD. E- Add contact details of Trust Patient Advice and Liaison Service (PALS) including telephone number as well as Trust Complaints department contact details should be added on page 53 F- Add that participants will be informed about the study results and can receive a lay summary of the study results if they want.	
2	Please make the following changes to the Informed Consent Form: Please add an option that participants can receive a copy of the lay summary if they want and a space where they can indicate how they would like to receive the results i.e. post or email.	
3	Please make the following changes to the Participant Invitation Letter: A- Provide the PALs contact details. B- Explain what the abbreviations EPDS and PCL checklist rating scale is. C- Use the sentence: 'further to our telephone discussion rather than: 'as mentioned on the telephone'	
4	Please make the following changes to the poster: A- The poster states: 'information may be collected,' replace the word 'may' with 'will be'.....and explain the use of questionnaires in the study. B- Revise complex medical terminology like neuroaxial anaesthesia.	

5	Please make the following changes to the Data Collection Questionnaire CRF 2 and 3: A- Remove the reference to interviews. Questions 4-12 include double negatives, revise as appropriate. B- Part 5 is phrased as questions and should be phrased as statements, revise as appropriate.	
	Recommendation	
1	**The following changes are recommendations provided by the Committee on the questionnaires** A- Consider asking participants to express in their own words three aspects of the procedure that they felt went really well followed by a further three that they felt went much less well than expected. B- The questionnaire could conclude with a request to participants to indicate to the research team any other matters which should be brought to their attention with an open question.	

The letter confirming this opinion is attached. You should notify the REC once all conditions have been met and provide copies of any revised documentation with updated version numbers.

Please note, the standard conditions referenced in your REC favourable opinion letter as being attached ("After ethical review – guidance for researchers") can now be accessed through the HRA website.

Assessment - Further information required

In addition, please provide the following information in order to clarify points raised in the assessment of the application

Assessment - Further Information Required	Response from the applicant
1. In the section "What will I have to do?" please detail it is the local research	

team who are also the clinical care team who will visits and answer any questions and ask to sign consent form. Prior to consent no-one outside direct care team would have the legal basis for the access of patient personal data.	
2. In the PIS, clearly indicate who is sponsoring the study	
3. As per the IRAS form, in the PIS, detail that only 3 attempts via text/ email will be made when contacting for the second questionnaires 6 weeks later.	
4. PIS details "All the paper questionnaires will be held in a secure location on the research site where only the research team have access to it, these will be destroyed after the study ends. " whereas IRAS states these will be destroyed after 3 months. Please update the information on the PIS.	
5. In the PIS detail that GP will be informed if the participants scores high on one of the questionnaires.	
6. Please insert IRAS ID to consent form.	
7. I note the HRA recommended GPDR wording has been used in part. Please insert the following section to ensure GDPR compliance: - How will we use information about you? - list what identifiers will be collected by site/Sponsor and where this data will be collected from i.e. questionnaire, medical records etc. "People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. " - In the section "What are your choices about how your information is used?", insert the following sentence: "We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you." - In the section "Where can you find out more about how your information is	

used?" at least one of these contact points should be directed to the Sponsor's Data Protection Officer.	
8. Protocol dated 02/12/2023 whereas on the IRAS checklist it is dated 28/09/2023. Please ensure the document date and version matches what is inserted on the IRAS checklist.	
9. Where will be signed consent form be stored?	
10. IRAS 35 indicates that capacity will be assumed. However, for non-CTIMP studies consent does not endure loss of capacity. Please detail what would happen if during the call it was identified the participants has lost capacity.	

If you have any queries, please do not hesitate to contact me.

Kind regards,

Abitha Paimpillichalil
Approvals Specialist
2 Redman Place | Stratford | Health Research Authority | E20 1JQ
E. leicestercentral.rec@hra.nhs.uk
W. www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest.