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Subject: Confirmation of UCL Sponsorship EDGE ID 128931 Study title - Snapshot Obstetric National Anaesthetic Research Project 1 (SONAR 1)
Date: 1 March 2024 at 16:38
To: OCARROLL, James (UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST) james.ocarroll@nhs.net,
MOONESINGHE, Ramani (NHS ENGLAND – X24) ramani.moonesinghe@nhs.net,
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PJ

Dear Prof Moonesinghe,

Confirmation of UCL Sponsorship EDGE ID 128931 Study title - Snapshot Obstetric National Anaesthetic Research Project 1 (SONAR 1)

**** PLEASE RETAIN A COPY OF THIS EMAIL IN YOUR TRIAL MASTER FILE****

I am pleased to let you know that UCL have confirmed sponsorship for your study. **Please note that this is not permission for you to begin your research study; you must additionally have in place appropriate regulatory approvals (e.g., HRA, REC,) and NHS confirmations of Capacity and Capability prior to recruitment/data collection. Failure to have these in place will lead to suspension of your study.**

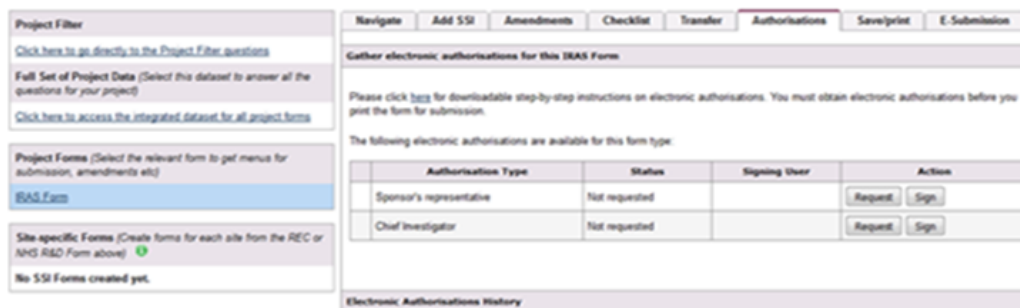
Please save this confirmation in your final documents and complete the following:

- Double check all documents before submitting on IRAS
- ***Once IRAS submission is made, forward all documents submitted as listed on the IRAS Checklist in a Zip Folder to me & Nevan (including authorised IRAS form)***

Please complete the following steps below for IRAS sign off and HRA submission:

IRAS Sponsor authorisation

- Check all the documents (typos, version number and date) and upload them into the IRAS checklist following the **attached E-Submission Guide** (please include all study docs; **UCL insurance confirmation**; OID and schedule of events)
- Please request IRAS authorisations - the CI fields need to be completed first Please then send a final request for sponsor authorisation to Pushpsen Joshi (pushpsen.joshi1@nhs.net) who will sign on behalf of the sponsor. Please use the IRAS form authorisation tab to request the authorisation as per screenshot below:



The screenshot displays the IRAS system's 'Authorisations' tab. On the left, a 'Project Filter' sidebar offers links to project questions, datasets, and forms. The main area, titled 'Gather electronic authorisations for this IRAS Form', provides instructions and a table of available authorisations. The table lists 'Sponsor's representative' and 'Chief Investigator', both with a status of 'Not requested' and buttons for 'Request' and 'Sign'. Below the table is a section for 'Electronic Authorisations History'.

Authorisation Type	Status	Signing User	Action
Sponsor's representative	Not requested		Request Sign
Chief Investigator	Not requested		Request Sign

Health Research Authority (HRA) and Research Ethics Committee (REC)

submission process

Once the IRAS form is signed by both the CI, and sponsor, please proceed with the HRA and REC submission process:

- Before electronically submitting your application for HRA and Ethics Approval you need book a meeting through the webform (<https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/>) before you press the e-submission button to book your REC review. This must be done before you submit your IRAS form on the same day.
Please select an English REC during this period of remote meetings to ensure all relevant regulatory elements are addressed.
- You will receive an email confirming that your application has been booked for HRA Approval. You should enter the booking information on the first page of the IRAS Form.
IMPORTANT NOTE: Do not amend any other part of the IRAS Form as this will invalidate your electronic authorisations.
- On the E-submission tab for the IRAS Form you should click the button to electronically submit your application for Approval. You are expected to do this the same day that you book your application via OBS. This will submit your IRAS Form and the supporting documentation you uploaded to the Checklist. Confirmation of your submission will appear in the Submission History area at the bottom of the E-submission tab.

Portfolio Adoption Form (PAF)

If you are applying for NIHR portfolio adoption, please also remember to complete and submit your PAF in IRAS. Please forward any correspondence or confirmations to your portfolio coordinator

HRA and REC Approval

When you receive a REC opinion letter and HRA approval letter please ensure you send these to uclh.randd@nhs.net and copy me & Nevan in. The final document set as a ZIP file will need to be checked against the HRA/REC approval letters.

TRIAL MASTER FILE

As a condition of UCL Sponsorship please can you ensure you create a Trial Master File for your project. You can use the UCLH SOP for guidance - <https://www.ucl.ac.uk/joint-research-office/resources-and-templates/sops-management-progress-and-close-down-all-uclh-studies>

Amendments:

From this point forwards, if you need to make any amendments to the research documentation, you will need to submit these to the sponsor: uclh.randd@nhs.net as an amendment. Please refer to the following link on the HRA website: <http://www.hra.nhs.uk/resources/after-you-apply/amendments/> for information on the national amendment process and amendment documentation.

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

Regards

Pushpsen

Pushpsen Joshi

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We are committed to delivering top-quality patient care, excellent education and world class research
safety kindness teamwork improving

I am working from home. For urgent queries, please provide your contact number and I will call you back.

E-submission guide (2).pdf

