Dear Ramani

** 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, CAG) 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 [delete as applicable].

Please can I ask you to save the authorised Protocol to your final documents and complete the following:

- Double check that you have the correct and final documents
- Please send to me the confirmed final **complete** document set
- Please ensure you upload the fully signed protocol into IRAS

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; statement of activities and schedule of events
- Please request IRAS authorisations the CI field need to be completed first. Please then send a final request for sponsor authorisation to Pushpsen will sign on behalf of the sponsor. Please use the IRAS form authorisation tab to request his authorisation as per screenshot below:

Project Filter	Navigate	AM SSI	Anendments	CheckSat	Transfer	Authorisations	Savelprint	E-Submission
Click here to go directly to the Project Filter, questions	Gather electronic authorizations for this JRAS Form							
Full Set of Project Data (Select the dataset to answer all the questions for your project)	Please cick ters for downloadable stop-by-stop indirectors on electronic authorizations. You must obtain electronic authorizations before you							
Click here to access the integrated dataset for all project forms		for submission						
Project Forms (Select the relevant form to get menus for automazion, amendments etc)	The following electronic authorisations are available for this form type:							
		Authorisati	on Type	Status		Signing User		Action
6A3.Cem	Sporso	's representativ	•	Not requested			Report 1	ian.
Site specific Forms (Create forms for each site from the REC or	Chief in	estiptor		Not requested			August 1	Ren (
MIS RED Form above)	-							
No SSI Forms created yet.								
	Electronic A	Electronic Authorizations History						

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 to contact the <u>Central Booking Service (CBS)</u> (Tel: 0207 104 8000) 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.
- 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 CBS. 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 your portfolio coordinator and to<u>uclh.randd@nhs.net</u>

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: <u>uclh.randd@nhs.net</u> as an amendment. Please refer to the following link on the HRA website:<u>http://www.hra.nhs.uk/resources/after-you-apply/amendments/</u> for information on the national amendment process and amendment documentation.

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

Kind Regards,

Suzanne Emerton Sponsorship Officer Joint Research Office (part of the Research Support Centre) 1st Floor Maple House (Suite B) 149 Tottenham Court Road London W1T 7DN Postal Address: Joint Research Office, UCL, Gower Street, London WC1E 6BT Telephone: 0203 447 2198 Fax: 0203 108 2312 Website www.ucl.ac.uk/jro