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12 November 2018

Dear Dr Trivedi

**Letter of HRA and HCRW Approval for a study
processed through pre-HRA Approval systems**

Study title:	A UK Collaborative Study to Determine the Genetic Basis of Primary Sclerosing Cholangitis (UK-PSC)
IRAS project ID:	196928
Sponsor	Cambridge University Hospitals NHS Foundation Trust
Amendment number:	Amendment 5
Amendment date:	08 March 2018

Thank you for your request to bring the above referenced study, processed under pre-HRA Approval systems, under HRA and HCRW Approval.

I am pleased to confirm that the study has been given **HRA and HCRW Approval**. This has been issued on the basis of an existing assessment of regulatory compliance, which has confirmed that the study is compliant with the UK wide standards for research in the NHS.

The extension of HRA and HCRW Approval to this study on this basis allows the sponsor and participating NHS organisations in England and Wales to set-up the study in accordance with HRA and HCRW Approval processes, with decisions on study set-up being taken on the basis of capacity and capability alone.

Please note that the amendment submitted to bring this study under HRA and HCRW Approval (referenced above) is also approved by issue of this letter. You should not expect anything further regarding the amendment. If the submitted amendment included the addition of a new NHS organisation in England and/or Wales, the addition of the new NHS organisation is also approved and should be set up in accordance with HRA and HCRW

Approval processes (e.g. the organisation should be invited to assess and arrange its capacity and capability to deliver the study and confirm once it is ready to do so)

Participation of NHS Organisations in England and Wales

Please note that full information to enable set up of participating NHS organisations in England and Wales is not provided in this letter, on the basis that activities to set up these NHS organisations is likely to be underway already.

The sponsor should provide a copy of this letter, together with the local document package and a list of the documents provided, to participating NHS organisations in England and Wales that are being set up in accordance with [HRA Approval Processes](#). It is for the sponsor to ensure that any documents provided to participating organisations are the current, approved documents.

For non-commercial studies the local document package provided to NHS organisations should include an appropriate [Statement of Activities and HRA Schedule of Events](#). The sponsor should also provide the template agreement to be used in the study, where the sponsor is using an agreement in addition to the Statement of Activities. Participating NHS organisations in England should be aware that the Statement of Activities and Schedule of Events for this study have not been validated, but it is expected that the sponsor provides these to participating NHS organisations. Any changes that are appropriate to the content of the Statement of Activities and Schedule of Events should be agreed in a pragmatic fashion as part of the process of assessing, arranging and confirming capacity and capability to deliver the study.

For commercial studies the local document package should include a validated industry costing template and the template agreement to be used with participating NHS organisations in England and Wales.

It is critical that you involve both the research management function (e.g. R&D office and, if the study is on the NIHR portfolio, the LCRN) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

If subsequent NHS organisations in England and/or Wales are added, an amendment should be submitted.

After HRA and HCRW Approval

In addition to the document, *“After Ethical Review – guidance for sponsors and investigators”*, issued with your REC Favourable Opinion, please note the following:

- HRA and HCRW Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing.

- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review using the form provided on the [HRA website](#), and emailed to hra.amendments@nhs.net.
- Amendments will be categorised (for both substantial and non-substantial) and issued confirmation of continued HRA and HCRW Approval.

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

Scope

HRA and HCRW Approval provides an approval for research involving patients or staff in NHS organisations in England and Wales.

If your study involves NHS organisations Northern Ireland and/or Scotland, please contact the relevant national coordinating functions for support and advice. Further information can be found at <http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/>.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>.

Your IRAS project ID is 196928. Please quote this on all correspondence.

Yours sincerely

HRA Assessment team

Email: hra.approval@nhs.net

Copy to: