Professor Philip Bath
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Nottingham
NG7 2UH

Email: approvals@hra.nhs.uk

30 April 2021

Dear Prof Bath

Initial Assessment Letter

Study title:	**COVID-19: Prophylactic therapy in care homes trial-CH**
IRAS project ID:	**294832**
EudraCT number:	**2021-000185-15**
Protocol number:	**21001**
REC reference:	**21/SC/0166**
Sponsor	**University of Nottingham**

Thank you for your application for HRA and Health and Care Research Wales (HCRW) Approval. I am writing to confirm that you are now able to share the Local Information Pack with participating NHS organisations in England and Wales in order to invite them to arrange of capacity and capability to deliver your study. Please note that **the research should not begin** at any participating NHS organisations in England or Wales until HRA and HCRW Approval is issued.

To share the Local Information Pack with participating NHS organisations in England and Wales please use the template email available on the IRAS website.

Once the Local Information Pack has been shared, please work with participating NHS organisations to arrange capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

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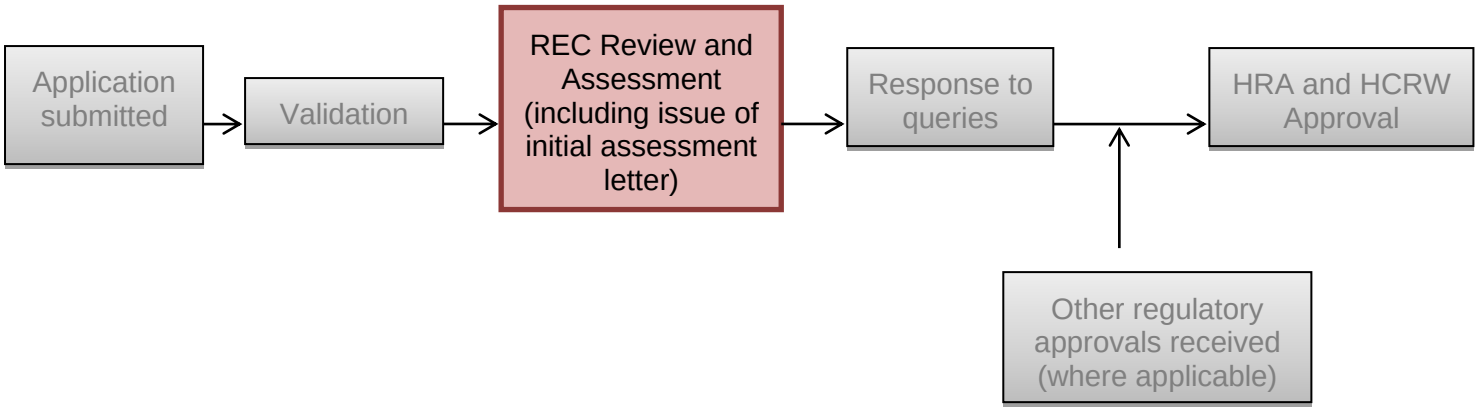
What happens next with my application for HRA and HCRW Approval?

Your application is progressing. Please find below an indication of where you are in the process (indicated by the red box).



I am undertaking the assessment of the application and you will receive any queries following the REC meeting.

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 in Northern Ireland and Scotland.

If you indicated in your IRAS form that you have participating organisations in Northern Ireland and/or Scotland, the national coordinating function of each participating nation has been informed and provided with the initial document set. The relevant national coordinating function/s will contact you as appropriate. We will provide them the final document set and study wide governance report when available.

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.

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 **294832.** Please quote this on all correspondence.

Yours sincerely,

Alex Thorpe

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Ms Angela Shone and Ms Cally Rick, Sponsors Representatives*

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Information to support study set up

The below provides all parties with information to support the arranging 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. As part of the application process, details may change prior to a Letter of HRA and HCRW Approval being issued.

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
For the purpose of this study, the applicant has explained that sites are determined by investigator and not location. Each Principal Investigator will be responsible for coordinating and overseeing the study at the GP surgeries and care homes within that region.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The agreement has been modified and the sponsor has explained that a list of modifications has been provided to sites. These changes are to clauses around	Please note that the SoECAT submitted for this study has been authorised by an AcoRD Expert. No funding will be provided to NHS organisations acting as recruiting sites. Funding will be provided to GP surgeries and care homes as per agreements.	A Principal Investigator should be appointed at study sites of this type.	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university

		indemnity, finance and sponsorship arrangements. They are provided by the sponsor and the HRA and HCRW take no position on the acceptability of these changes. Participating NHS organisations should now determine its acceptability and liaise with the sponsor to confirm the content of the agreement.			employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

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 do intend to apply for inclusion on the NIHR CRN Portfolio.