

**CLINICAL RESEARCH NETWORK
COORDINATING CENTRE**

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Dear Chris

**RE: Amendment to PRINCIPLE: Platform Randomised trial of INterventions
against COVID-19 In older peoPLE**

Thank you for submitting the amendment of the PRINCIPLE study to the NIHR Urgent Public Health Group for review. It was agreed to support the amendment, subject to ethical permission. If you have not already done so, it is recommended that you seek urgent regulatory approval for the amendment to your study as a National Priority UPH study.

As you are no doubt aware, resources for supporting National Priority UPH studies are limited and therefore it is helpful for the UPH Group to have sight of amendments to studies. This will assist the UPH Group to review other studies submitted for UPH badging, and help to avoid the risk of conflict or duplication with UPH-badged studies. Therefore we would be grateful if you could inform the UPH Group of any future amendments to the study.

The NIHR CRN Research Delivery team will be updated on this amendment to the study, and a member of the team will be in touch with you shortly to discuss the support required. However, if there is something that you would like to discuss as a matter of urgency please get in touch with us through the urgentpublichealthcrn@nihr.ac.uk email address.

Finally, you may find the following information helpful:

Core datasets

To ensure key information needed by decision makers about the effects of interventions is included in your study, please consider the use of core outcome sets such as the COMET initiative <http://www.comet-initiative.org/Studies/Details/1538>

As outlined in the application form, a small dataset of information about your study will be uploaded to the NIHR website and linked to the Health Research Agency website. If you have any queries regarding sharing these data publicly, please contact covid19application@nihr.ac.uk

Media activity

If you wish to publicise this research in UK media (including social media), please notify pressoffice@nihr.ac.uk 24 hours in advance. The NIHR press office team is maintaining a centrally-held media grid for COVID-19 research. In the event that journalists contact you after information about your study is uploaded to the NIHR website and prior to any planned publicity, please contact the NIHR press office regarding an expedited approach.

ISRCTN registration

It is compulsory for **all** Urgent Public Health (UPH) badged studies to be entered on the ISRCTN registry. ISRCTN is able to offer same-day registration for UPH badged studies. To access this please contact info@ISRCTN.com before creating or logging into your ISRCTN account and making your ISRCTN application through the ISRCTN online submission portal. Alternatively, you can apply for your ISRCTN registration through our Central Portfolio Management System (CPMS) on receipt of your CPMS ID. Instructions on how to do this will be provided. All non-commercial studies badged as UPH are able to have their registration fee paid by the Department of Health and Social Care. Reimbursement is not possible if you have already applied and received an ISRCTN before confirmation of your UPH badging and inclusion on the NIHR CRN Portfolio.

Demographic data collection

Following NICE guidelines

(<https://www.nice.org.uk/covid-19/support-for-developers-of-medicinal-products-for-covid-19>) a full range of baseline patient characteristics should be collected so that the relevance of the patient population to the NHS patient population can be evaluated. This includes sex, age, ethnicity, comorbidities, smoking status, residence in care home, functional status, and confinement status.

Patient Information Leaflets (PILs) translation

For UPH studies, the NIHR CRN is offering a PILs translation service which provides full and certified translation of PIL into languages specified. The aim of this service is to enable increased opportunity and equity for participation, increase the speed of trial delivery and reduce burden on sites and LCRNs. The following six languages are offered: Polish, Bengali, Urdu, Punjabi, French, Portuguese. Study teams can access this service through the Research Delivery Directorate.

PPIE and participation support for UPH studies

The CRN has a Public Advisory Forum to provide PPIE support to UPH studies. The forum consists of lay Research Champions who have been trained around health research and have received an induction around coronavirus research specifically. UPH study teams can seek involvement from the Public Advisory Group around any specific issues related to the design and delivery of UPH studies, by contacting crncc.ppie@leeds.ac.uk

To support UPH studies with any specific challenges around the participation of BAME communities in COVID-19 studies, the University of Leicester (NIHR ARC East Midlands) Centre for BME Health (<https://centreforbmehealth.org.uk/>) is offering expert guidance for study teams and research delivery teams. If you have specific enquiries about engaging BAME communities with your UPH study please contact ppie.crncc@leeds.ac.uk who will connect you with the Centre.

Future Study Amendments

If you plan to make an amendment to your research project, these should be submitted for NIHR Urgent Public Health Group review via the [online submission form](#).

With best wishes



Nick Lemoine
Medical Director, NIHR Clinical Research Network

cc. Chelsea Drake NIHR CRN Head of Communications
Lead LCRN: Thames Valley and South Midlands
Research Delivery Directorate
Business Development and Marketing Directorate
Devolved Nations Representatives