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**Health Research Authority  
Research Ethics Committee**

Professor Philip Bath, Chief Investigator  
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28<sup>th</sup> April 2021

Dear Sir or Madam,

Sponsorship Statement

**Re: COVID-19: PROphylactic ThERapy in Care Homes Trial (PROTECT-CH)**

I can confirm that this research proposal has been discussed with the Chief Investigator and agreement to sponsor the research is in place.

An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

Any necessary indemnity or insurance arrangements will be in place before this research starts. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

Wording has been included in the participant information sheets to address the requirements of GDPR for transparency information and has been drafted by the sponsor to ensure consistency and compliance with the University's privacy notice, HRA guidance and the expectations of other organisations, therefore the HRA template wording has not been used verbatim.

Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

The duties of sponsors set out in the UK Policy Framework for Health and Social Care Research will be undertaken in relation to this research.



The trial is a platform trial commissioned by the Department of Health through the NIHR funding stream and has Urgent Public Health endorsement. It is intended to investigate the efficacy of drugs to be used as prophylaxis alongside vaccination, as adjuncts for the prevention and lessening of the severity of COVID-19 disease in elderly residents of care homes. The platform will allow up to three IMPs to be under investigation at any one time, though it is presented in the first instance with two IMPs. The IMPs of choice have been decided by the Government Chief Medical Officer in conjunction with medical experts, including the Chief Investigator, at the University of Nottingham, each taking into account results and emerging data of other trials. Subsequent IMPs will also be decided through this route.

Because each IMP is likely to differ in its mode of delivery, dosage, formulation, pharmacovigilance signals and eligibility criteria we are presenting the protocol for the platform design with the IMP(s) as separate IMP Appendices and associated IMP-D/IB documents. This was agreed in our initial discussions with the MHRA just before the end of last year.

Yours faithfully

Angela Shone

Head of Research Governance  
University of Nottingham