Royal Free London
NHS Foundation Trust

INFORMED CONSENT FORM

Trial Title: PROTECT-V: **PRO**phylaxis for pa**T**i**E**nts at risk of **C**OVID-19 infec**T**ion

Principal Investigator:___Prof Alan Salama_____ **Participant Identifier:** _____

If you agree with each sentence below, please initial the box		**INITIALS**
1	I have read and understood the Participant Information Sheet version 2.1, dated 23 April 2021 for the above trial and I confirm that the trial procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my participation in this trial is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.	
3	I understand that my personal information will be collected and used in accordance with the information sheet version 2.1, dated 23 April 2021. This information will be kept in the strictest confidence and none of my personal data will be published.	
4	I understand that sections of my medical notes or information related directly to my participation in this trial may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel where it is relevant to my taking part in research and that they will keep my personal information confidential. I give permission for these individuals to have access to my records.	
5	I understand that my GP will be informed of my participation in this trial and sent details of the PROTECT-V trial.	
6	I understand that my name, gender, date of birth, postcode, and NHS/CHI number will be used to access my central healthcare data that are held and maintained by the national health record organisations described in point 5 on page 3 to provide information about my health status as part of this trial. I understand that, if I live in Scotland or Wales, this information will be obtained from the equivalent sources described.	
7	I have read and understood the compensation arrangements for this trial as specified in the Participant Information Sheet.	
8	I understand that the doctors in charge of this trial may close the trial, or stop my participation in it at any time without my consent.	
9	I have read and understood my responsibilities for the trial, including adherence to contraception guidance.	

10	I agree to provide blood samples for monitoring of drug levels and for them to be sent to an approved laboratory in the EU as described in this document, if applicable (only for first 70 haemodialysis patients enrolled).	
OPTIONAL CONSENT		
11	I consent for the data collected during my participation in the PROTECT-V trial to be used in future ethically approved research studies.	YES / NO

I agree to participate in this trial:

Name of patient Signature Date

Name of person taking consent Signature Date

Time of Consent (24hr clock) _____:_____

1 copy for the patient, 1 copy for the trial team, 1 copy to be retained in the hospital notes.

Consent has to be in person so please don't send us the completed form. Contact one of us and we will arrange a visit for you to enrol

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