



## **PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM**

### **PROTECT: PROphylaxis for paTiEnts at risk of COVID-19 infecTion**

You are being invited to take part in a research trial. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to read the following information carefully and talk to others about the trial if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Section 1 tells you the purpose of this trial and what will happen to you if you take part.

Section 2 gives you more detailed information about the conduct of the trial.

### **Section 1: Purpose of the trial and what will happen**

#### **1. What is the purpose of the trial?**

COVID-19 is an international health emergency which is immediately impacting the lives of all individuals in the UK. There is an urgent need for medicines that can prevent or treat the infection. There are several clinical trials of treatments for COVID-19 underway in the UK, but many of these exclude patients with complex medical conditions or advanced kidney disease. Reasons for exclusion include the presence of existing illness or risk factors, which may make it difficult to interpret results, concerns about potential interactions of a trial drug with usual essential medications, and difficulties finding the correct dose of a trial drug, if it is removed by the kidneys. However, because kidney disease and/or many of the medications used to treat patients with kidney diseases or vasculitis affect the function of the immune system, these individuals may be at increased risk of contracting or becoming very ill from COVID-19. We only have limited information available about how COVID-19 affects immunosuppressed patients and patients on dialysis, but we suspect that if an infection occurs, symptoms are more commonly seen than in the general public and therefore, it is important to test medications that may prevent COVID-19 infection specifically in these groups of patients.

The **PROTECT** trial enrolls patients on dialysis or receiving immunosuppressive medications. The focus of this trial is on prevention of disease, rather than treatment once disease occurs. This will be measured by comparing if COVID-19 develops in people who take the trial treatment against those who receive a placebo (“dummy”) treatment.

## 2. What is the drug being tested?

The drug to be tested in the **PROTECT** trial is niclosamide, a common safe drug that has been used in tablet form for tapeworm infections for decades. Preliminary research has shown it may also help protect against COVID-19 infection. However, niclosamide tablets are poorly absorbed from the gut into the bloodstream. Therefore, in the PROTECT trial, niclosamide will be administered by a nasal spray directly to the lining of the nose, which is where the virus that causes COVID-19 infection usually first takes hold. This formulation of the drug is unlicensed, but has been shown to be safe and well tolerated in a study of healthy volunteers. In the PROTECT trial, participants will receive a total daily dose of 5.6mg of niclosamide administered through a nasal spray (one spray for each nostril) twice daily. This is a much lower dose than the single 2000mg tablet which is taken for tapeworm infections.

## 3. Why have I been invited?

You have been invited to participate in this trial either because you have kidney failure and receive dialysis, or are taking an immunosuppressive medication as a result of having a kidney transplant or a diagnosis of vasculitis or glomerulonephritis. We plan to include approximately 1500 participants in total from hospitals across the UK.

## 4. Do I have to take part?

Participating in this trial is completely voluntary. If you decide to participate you will be asked to sign an Informed Consent Form, but you will be free to change your mind and leave the trial at any time without giving a reason. If you choose not to participate or to leave the trial, your future medical treatment and normal standard treatment will not be affected in any way.

## 5. What will happen to me if I take part?

### Consent

If you agree to participate in the trial, you will sign the Informed Consent Form at the end of this document, and be provided with a copy of this to refer to later. You will then be given a unique trial number. This number will be used instead of your name on trial documentation to help protect your confidentiality.

### Screening

After consenting to participate in the trial, you will be asked some questions and have a blood sample taken (not more than 15mls), to confirm that you can safely receive the trial medication. If you cannot be treated with the trial medication, we will let you know and you will continue with your standard treatment, but will not be able to participate in the trial.

### Randomisation

This trial is a randomised, double-blind, placebo controlled-trial. What does that mean?

- **Randomised:** As we don't know which way of treating patients is best, we need to compare a group who take niclosamide with a group who do not. You will be allocated to one of the groups in a random way (by chance), so we can be sure that the two groups are as similar as possible. This way, any differences between groups can be attributed to the treatment they received rather than any other differences between groups. In this trial, the size of the groups will be the same, therefore you will have a 50% chance of receiving niclosamide.
- **Double Blind:** This means that neither you nor your trial doctor will know which treatment you are receiving; however, your trial doctor can find out if necessary.
- **Placebo:** This is sometimes called the 'dummy' treatment. It looks the same as the treatment but does not contain any of the active ingredients.

### Questionnaires

Because of the need to avoid extra hospital visits in the COVID-19 pandemic, you will not be required to attend in-person for any trial visits aside from the visit at the start of the trial and the end of the trial. You will be asked to either submit information through online questionnaires, via the PROTECT smartphone app, website, by email, post or through telephone calls from your local trial team every week for the first 4 weeks, and then every 2 weeks thereafter. You will be asked about any side effects of the trial medication and any possible symptoms of COVID-19 infection. These questionnaires will take about 5-10 minutes each. You will also need to record all your doses in the dosing diary, in the paper version or the app if you prefer. This will take about 1 minute every day. You will also have to keep all bottles of trial medication until the end of your participation in the trial, when you will return these to your trial team.

Your participation in the PROTECT trial will last for approximately 6-9 months. The exact duration of the trial depends on how quickly COVID-19 infections occur in the trial population, which is unknown in advance.

### Data Collection

For all participants, we will carry out trial assessments via the collection of routinely held data. For this, we will use information already collected about you by other organisations as described below. This will take the place of many of the hospital visits that would normally form part of a trial like this one. In order to identify and obtain information about you, we will be required to send personal identifiers (forename, surname, gender, date of birth, postcode, and NHS/CHI number) to these organisations. The information they return to us may also contain some of these personal identifiers.

All data collected in this way will be stored on highly secure encrypted servers held within the University of Cambridge and will be accessible only to the small team of researchers directly involved with the trial. We will need to retain this data for the duration of the trial and then archive it for up to 15 years in accordance with the

relevant clinical trial regulations and legislation in force at the present time. The data will then be destroyed.

Data will be collected from a number of sources:

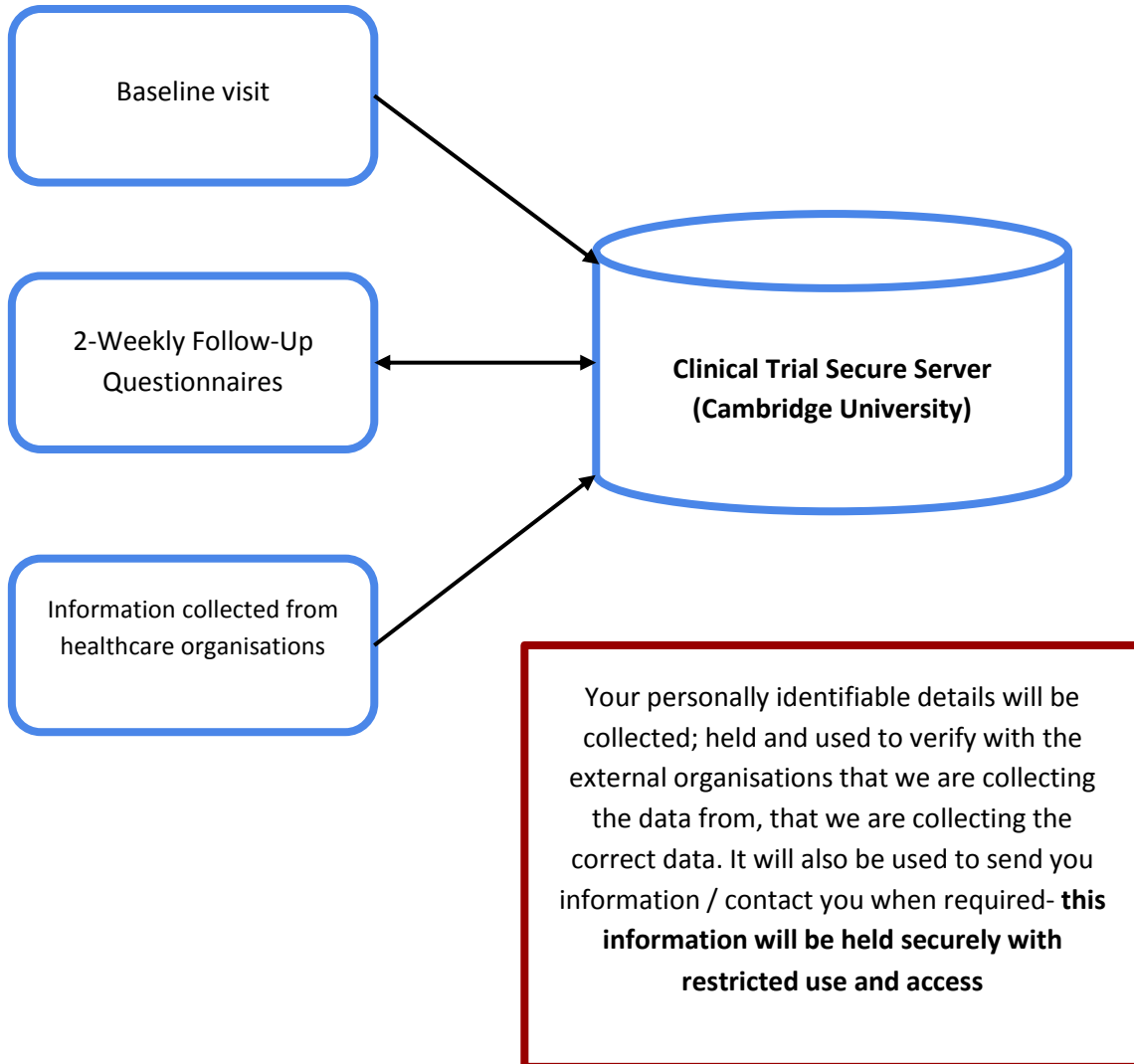
- a) **NHS Digital** - NHS Digital is a national provider of information on healthcare in the United Kingdom and links this information to the specified datasets below.
  - 1. **Hospital Episode Statistics (HES)** - The NHS in England collects information on all hospital admissions, including when, why and for how long they happen. By collecting information from HES, it means that we can use the information the NHS already holds rather than having to ask patients to attend hospital for extra trial visits.
  - 2. **Office for National Statistics** - In the unfortunate event that a person dies, this information is obtained from civil registration data by the Office for National Statistics (ONS). Because it is important for us to know what happens to patients in the trial, NHS Digital will provide the trial team with any information they might have on participants in the trial on behalf of ONS.
- b) **Public Health England (PHE)** - Public Health England is the national organisation responsible for collecting all COVID-19 Testing data across England. PHE will be able to inform us if you have received a positive COVID-19 test result and the date this test was performed.
- c) **Intensive Care National Audit & Research Centre (ICNARC)** - The ICNARC provides information about the quality of care received by patients to those who provide the care, such as the government and the NHS, through national clinical audits and research studies. ICNARC will inform us should you be admitted to intensive care and if so, what treatments you have received.

Equivalent national health record organisations exist in Wales (Secure Anonymised Information Linkage, Public Health Wales) and Scotland (electronic Data Research and Innovation Service, Public Health Scotland). If you live in these areas, the same central healthcare records will be obtained from these sources.

By consenting to the PROTECT trial, you agree that the trial team will provide your personal data to the organisations listed above (or equivalent organisations in the devolved nations) for linkage to the specified datasets.

As part of the trial and after it is completed, trial data that does not include your identifying details may be shared with other researchers. There is more information about this later in point 16 'Will my taking part in this trial be kept confidential?'

The picture below shows how the information we collect will be kept secure.



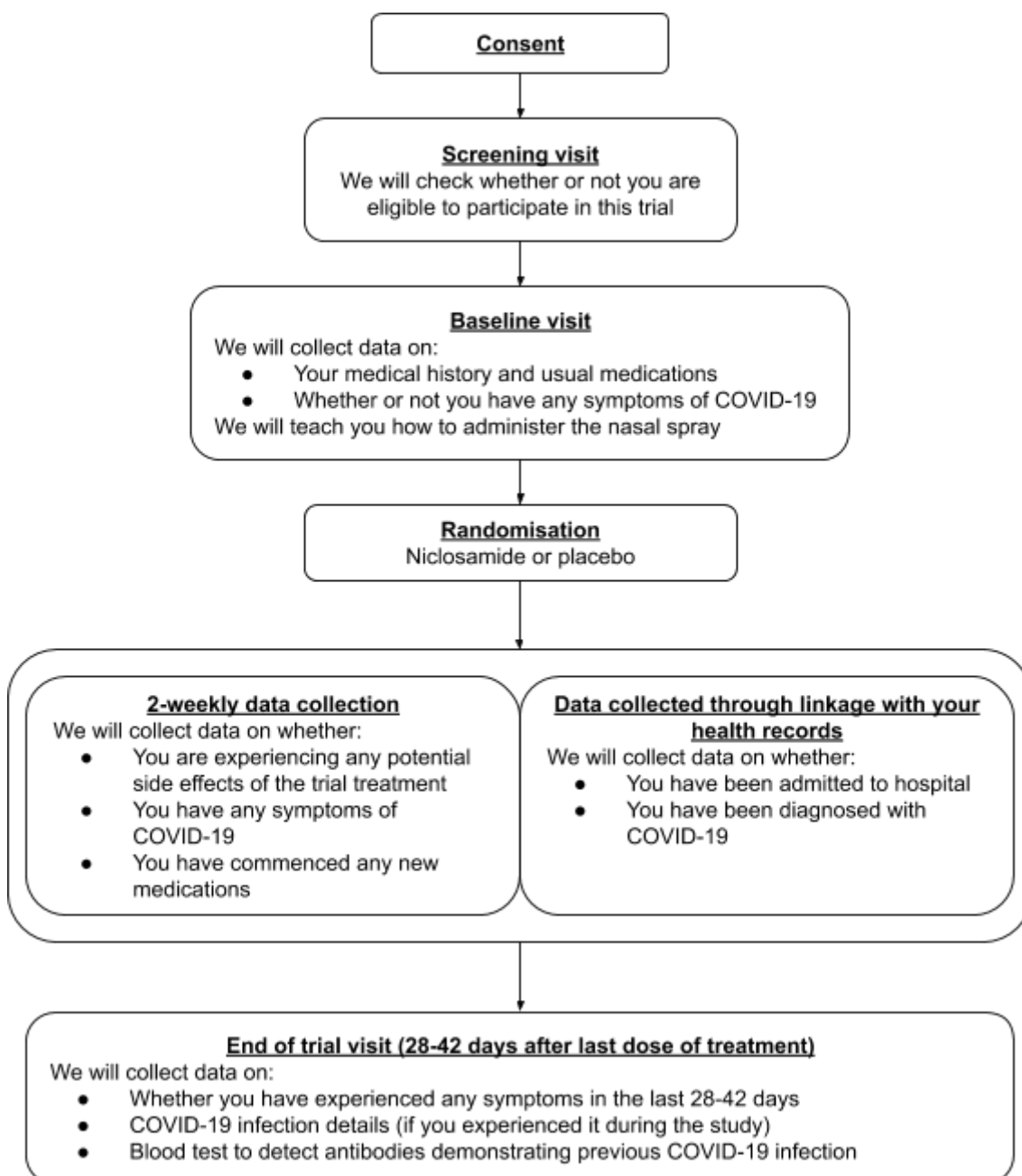
### Research samples

A blood sample (not more than 10mls) will be taken during your first visit to measure the presence of antibodies against SARS-COV-2 before starting the trial treatment. Furthermore, three blood samples (no more than 5 mls per sample) will be taken from the first 70 dialysis patients enrolled into the trial to measure drug levels on day 7 (or on the 3rd dialysis session), day 14 and day 21 after commencing therapy. This is to confirm that niclosamide does not accumulate in patients with impaired kidney function. The trial team will let you know which days these samples will be taken and write down instructions in your medication diary for when to take your doses on those days. The blood sample will be taken whilst on the dialysis machine, at the start of the session, and will not require an additional blood draw or extra visits. We will confirm when you are enrolled in the trial if you are one of the first 70 dialysis patients that will have these blood samples taken.

### End of Trial visit

You have a final in-person trial visit 4-6 weeks after your final treatment in the trial. You will bring all completed medication diaries and all used and unused trial medication bottles and cartons to this visit. You will be asked a series of questions to identify any additional symptoms experienced since your last follow up assessment and a blood sample will be taken to measure development of antibodies against SARS COV-2 (not more than 10mls).

The figure below shows what will happen throughout the trial:



All data collection will be carried out online, via the smartphone app, by telephone or post, or during your usual dialysis sessions and will not require any additional visits to hospital.

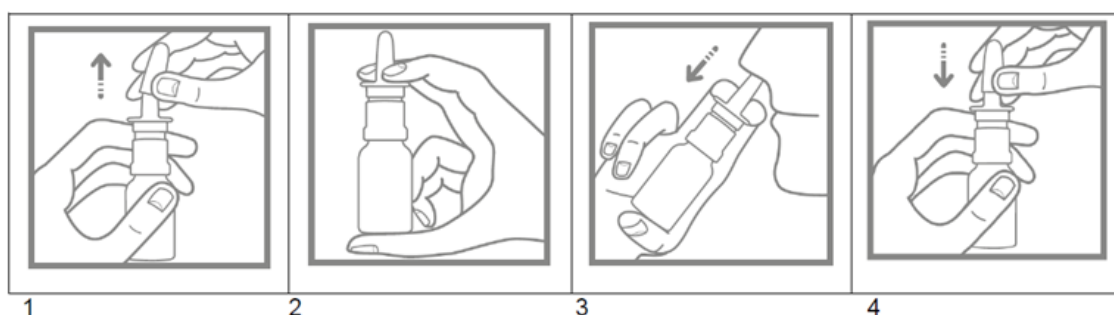
## 6. What will I have to do?

You will need to comply with the following instructions and restrictions as part of your participation in this trial:

### Medication

You will be given a nasal spray that you will have to use in each nostril twice daily following the instructions in the diagram below. If you are using any other nasally administered or inhaled medication (such as asthma medication inhaler), please space

the use of the trial medication and any other nasal spray or inhaled medication by at least 1 hour. The trial treatment will continue daily for an average of 6 months, but as an individual you may receive more or less treatment than this. You can contact the PROTECT trial team at any point with any questions, using the contact details at the end of this information sheet. You may collect your trial treatment during your dialysis sessions or outpatient clinic visits, if possible; otherwise, the local team will send you the trial treatment via courier. If a courier is used, we will share your personal details (name and delivery address) with them to enable delivery of your medication and may check to ensure you have received it. You will need to store your medication in upright position, in a cool dry place, **not refrigerated**. You will use each medication bottle for a maximum of 14 days, even if there is remaining liquid. Then you will keep the used bottles and cartons until the end of your participation and bring them back to your last visit.



You will not be able to participate in any other trials testing medications or vaccines to prevent COVID-19 infection. However, if you are offered an approved vaccination against COVID-19 infection as part of routine care, we encourage you to have the vaccine. If you are admitted to hospital with COVID-19, your participation in this trial will end, and you can be considered for enrolment in treatment studies.

### **Questionnaires**

Every week for the first 4 weeks, and then every 2 weeks thereafter, all participants in both groups will be asked to answer a short series of questions about your current symptoms, if any, which may be potential side effects of niclosamide (if applicable), or of COVID-19 infection.

### **Pregnancy and Breastfeeding**

Trial medicines could harm an unborn baby or nursing infant. You will not be able to take part in this trial if you are pregnant or breastfeeding. You will be asked if you are pregnant before starting the treatment, and a pregnancy test will be performed in women of child bearing potential. If, while you are taking the drug, you think you might be pregnant please contact the trial team or your clinician immediately. Your trial doctor will discuss all the options available to you. The outcome and progress of any pregnancy would be followed and you would be asked questions about the



pregnancy and baby, if appropriate. These details would also be shared with the manufacturer of the trial medicine for safety reasons.

### **Contraception**

Women who are able to have a baby must use a reliable form of contraception for the entire duration of treatment and for 90 days after your last treatment with the trial drug. This includes any of the following:

- Oral contraceptive (either combined or progestogen alone)
- Contraceptive implant, injections or patches
- Vaginal ring
- Intrauterine device (IUD, coil or intrauterine system)
- Condom and cap or diaphragm plus spermicide (chemical that kills sperm)

You do not need to use contraception if:

- You have only one partner, and the man has had an operation to cut the tubes that carry sperm (vasectomy) or
- You are a woman who cannot become pregnant
- You are a post-menopausal woman or
- You practice true abstinence as part of your usual and preferred lifestyle (confirmed negative pregnancy test at screening visit and no sexual activity until 90 days after the last dose of trial medication). If you become sexually active, you must use one of the methods listed above.

### **Side Effects (also known as adverse events)**

You should tell the trial team if you feel unwell or different in any way. If you have any major concerns or are feeling very unwell please contact your trial doctor immediately using the contact numbers at the end of this information sheet. The common side effects of niclosamide are listed below under point 7 “What are the side effects of the drug being tested?”

### **Health Insurance**

You should discuss your participation in this trial with any insurance provider you have (e.g. travel insurance, health protection insurance, life insurance, income protection, critical illness cover and private medical insurance) and seek advice if necessary, as failure to notify them may affect or invalidate your cover.

### **COVID-19 guidelines**

It is very important that you continue to follow current advice on social distancing and/or shielding and follow any advice issued by your usual clinician or dialysis unit. Should you develop symptoms suggestive of COVID-19 infection (cough, shortness of breath, fever, loss of sense of smell or taste, nausea/vomiting or diarrhoea or any other new symptom concerning for infection), you must arrange a COVID-19 test via

the NHS Test and Trace system or national equivalent, booking online or calling 119 to organise an appointment at your nearest testing facility or ask the trial team for a test kit to be sent in the post. You should also request a flu swab at the same time as your COVID-19 test, however if this isn't performed by the testing facility you should request a flu testing swab from your trial team. If you are diagnosed with COVID-19 during the trial, then you should follow current guidance with regards to isolation and comply with national contact tracing processes.

#### **7. What are the side effects of the drug being tested?**

Niclosamide is unlicensed in this formulation. The trial formulation of niclosamide has been tested so far in 36 participants for a treatment period of 2 and a half days in a safety assessment trial. During that trial it has been reported that it can cause mild symptoms after administration potentially including:

- irritation in the throat
- cough after inhalation
- sneeze
- loss of taste
- a tingling feeling on the tongue
- hoarseness

These symptoms should disappear within 60 to 75 minutes after each dose. If you develop these or other symptoms for a longer period of time, seek medical advice. You should also be aware that the trial treatment is a red-coloured liquid; do not be alarmed if soon after administering the treatment you observe red colouring when blowing your nose. This effect should also disappear within 90 minutes.

You should make sure your doctor or other healthcare professional knows you are participating in this trial before starting any new medicine during the trial. If you experience any serious side effects during the trial, the trial doctor will monitor your health until the side effect has stabilised or resolved.

#### **8. What are the possible disadvantages and risks of taking part?**

The PROTECT trial has been designed to place the minimum burden on you as the patient, and on the healthcare workers looking after you at this time. As this formulation of niclosamide has only been given to a very small number of people to date, there is a chance that you may experience additional side effects other than those listed above in point 7.

#### **9. What are the possible benefits of taking part?**

There is no guarantee that you will benefit from taking part in this trial. You may or may not be protected from COVID-19 by niclosamide and we do not yet know if niclosamide will be an effective medication for this indication. However, information collected as part of your participation in this trial will help other people in the future.

**10. What are the alternatives for treatment?**

If you are offered an approved vaccination against COVID-19 infection as part of routine care, we encourage you to have the vaccine. However, patients with renal failure or receiving medications that suppress the immune system often producesuboptimal responses to vaccination, and so nasal niclosamide is being tested to see if it offers additional protection. If you decide not to participate in this trial, you will continue to receive all your usual care, but will not be given niclosamide as part of this trial.

**11. What happens when the trial stops?**

This trial is short, as it is vital that we get an answer quickly in the COVID-19 pandemic. The average time that you will be in the trial is about 6 months. The trial may stop earlier if it becomes clear that the treatment works, or if new information emerges. If this happens, you will be informed by the trial team. If you are diagnosed with COVID-19, and are well enough to stay at home, you will continue treatment for another 28 days. Should you be admitted to hospital, treatment will stop. If the trial finds that niclosamide protects against COVID-19, we hope that niclosamide will be available for ongoing use outside of this trial but we cannot guarantee this. Once the trial is complete, you will continue to receive your usual care, with your usual clinical team.

**12. Will I be paid for taking part?**

You will not receive any payment for participating in this trial, but we will reimburse any reasonable travel related expenses incurred by your participation in this trial. However, we have kept trial visits to an absolute minimum, and wherever possible they will be scheduled to coincide with your routine hospital appointments.

**Section 2: Trial Conduct**

**13. What if new information becomes available?**

Sometimes during the course of a trial, new information becomes available which might affect your decision to continue participating in this trial. In this case, your trial doctor will contact you about the new information to discuss whether you wish to continue participating in PROTECT. If you wish to continue on the trial, you will be asked to sign a new Informed Consent Form.

**14. What if I decide I no longer wish to participate in the trial?**

You are free to stop participating in this trial at any time. You can do this by speaking to your trial doctor or by indicating your wish to withdraw on the trial smartphone app or website. You do not need to provide a reason, and your decision will not affect your future care or medical treatment. If you decide to stop participating you will no longer receive the trial treatment. You can decide whether you would still be happy for us to continue to collect data remotely from your central healthcare records without receiving any trial treatment or completing the trial questionnaires, or to stop participating in the trial altogether (no data collection from questionnaires

or central healthcare records). However, any data already collected about you will continue to be used in the analysis and where possible you will be contacted one month after withdrawal to ask you a short series of questions about your health.

The trial doctor may choose to withdraw you from the trial if they feel it is in your best interests, or if you have been unable to comply with the requirements of the trial. Reasons for trial withdrawal could include:

- You have experienced a serious side effect
- You become pregnant
- The trial doctor feels you are no longer eligible for this trial (e.g. due to a change in your other medications or healthcare)
- If you develop COVID-19, the trial treatment will be stopped after 28 days if you are well enough to stay at home. If you are hospitalised the trial treatment will stop immediately. This will allow you to enter other trials exploring treatments for COVID-19.

#### **15. What if there is a problem?**

Any complaint about the way you have been dealt with during the trial or any possible harm you might suffer will be addressed. If you have any concerns about any aspect of this trial you should speak to your trial doctor. Alternatively, you may wish to discuss concerns about the way you have been approached or treated during this trial through the NHS complaints procedure. In this instance it may be helpful to contact the *(to be completed locally as appropriate – in England this will refer to the Patient Advice and Liaison Service (PALS) - in Scotland this will refer to the Patient Advice and Support Service (PASS))* at your hospital.

In the event that something does go wrong and you are harmed due to someone's negligence, then you may have grounds for legal action for compensation against Cambridge University Hospitals NHS Foundation Trust or the University of Cambridge. The normal NHS complaints mechanisms will still be available to you (if appropriate). The University has also obtained insurance which provides no-fault compensation (i.e. for non-negligent harm) which you may be entitled to claim for.

#### **16. What will happen to any samples I give?**

To assess whether you have had COVID-19 infection before participating in this trial and to assess whether you have developed immunity against SARS-COV-2 by the end of the trial, you will have blood samples taken at the beginning and at the end of your participation in the trial. These samples will be identified with your trial number. These samples will be frozen and then analysed in batches at a central laboratory.

If you are part of the first 70 dialysis centre participants recruited, you will have 3 extra blood samples taken to assess whether the trial treatment accumulates in your body. These samples will be taken by the local trial team and labelled with your trial number.

Then they will be processed at your site and sent to Cambridge University Hospitals for storage until all 70 sample sets have been collected. The analysis of these samples will be performed by a subcontracted laboratory in the European Union. No personal information will be shared with said laboratory and once analysed, they will be disposed of according to EU law.

If at any point during the trial you wish to withdraw and these blood samples have already been taken, you will have the right to decide whether they can be used as previously explained or they should be disposed as per local guidelines.

**17. Will my taking part in this trial be kept confidential?**

Cambridge University Hospitals NHS Foundation Trust and The University of Cambridge are the Sponsors for this clinical trial based in the UK. In the context of a clinical trial, "Sponsor" means the organisation(s) ultimately responsible for the conduct of the trial. They will be using information from you and your medical records in order to undertake this trial and will act as the data controller for this trial. This means that they are responsible for looking after your information and using it properly. The Sponsor organisations will keep identifiable information about you for 15 years after the trial has finished to ensure your safety and allow the trial to be reviewed by the authorities after it is finished.

Your rights to access, change or move your information are limited, as the Sponsor organisations need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsors use your information using the information below:

- For Cambridge University Hospitals NHS Foundation Trust, please visit:  
<https://www.cuh.nhs.uk/patient-privacy/patient-privacy-notice/>, or email the Data Protection Officer at: [gdpr.enquiries@addenbrookes.nhs.uk](mailto:gdpr.enquiries@addenbrookes.nhs.uk)

- For University of Cambridge, please visit:  
<https://www.medschl.cam.ac.uk/research/information-governance/>, or email the Information Governance team at: [researchgovernance@medschl.cam.ac.uk](mailto:researchgovernance@medschl.cam.ac.uk)

**For participants recruited at CUH:**

Cambridge University Hospitals NHS Foundation Trust will collect your name, NHS number, date of birth, gender and address or telephone number to contact you about this trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this trial. Cambridge University Hospitals will pass these details to the

Sponsors along with the information collected from you and your medical records. The only people in the Sponsor organisations who will have access to information that identifies you will be people who need to contact you in relation to this trial and to audit the data collection process. Cambridge University Hospitals will keep identifiable information about you from this trial for 15 years after the trial has finished.

**For participants recruited at other participating sites:**

*(Add site name)* will keep your name, (NHS number) and contact details to contact you about this trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Certain individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this trial.

*(Add site name)* will keep identifiable information about you from this trial for 15 years after the trial finished

All information collected about you as a result of your participation in the trial will be kept strictly confidential, and will be used for the purposes of research only. Your personal and medical information will be kept in a highly secure server within the University of Cambridge and handled securely in accordance with the data protection law(s) to ensure that all information about you is handled in the strictest confidence.

Once you have agreed to participate in this trial you will be allocated a unique trial number which will be used on all your trial documentation. This number will be linked to your personal information; however you will only be identified by this unique number in the final trial data. Your consent to the use of your individual level trial data or your personal data will last for 15 years, but you may withdraw your consent at any time by notifying your trial doctor.

In cases where medication has to be sent to you by courier, your local team will pass your contact details and home address to the authorised personnel of the IMP courier company.

We will follow your medical status on an on-going basis for the duration of the trial. This involves collecting, processing, and transferring your personal data (name, gender, date of birth, postcode, and NHS/CHI number) for medical research purposes only. This will be done by sending the named personal data to the national health record organisations mentioned in point 5. For this process to work, it will involve storing some of your personal data on a secure, password-controlled database with access given to only a very small number of delegated PROTECT trial staff. The healthcare organisations' systems will be asked for information which will then be stored in our database on a computer server housed in a highly secure environment within the University of Cambridge, School of Medicine, disconnected from the internet.

We will need to inform your GP of your participation in this trial so that any medical decisions made by your GP account for any treatment you are receiving as part of this trial.

At the end of the trial, your anonymised trial data may be shared with other researchers outside the University of Cambridge, both in the United Kingdom and abroad to further knowledge on COVID-19. Link anonymised information will also be shared with Union Therapeutics (based in Denmark and who will become the data controller of this anonymised data once received and deal with it in accordance with the General Data Protection Regulation) who are supplying the trial treatment for ongoing safety evaluation, which includes adverse events and pregnancy during your participation in the trial. Anonymised information will also be shared with the NHS and the Department of Health as part of our efforts to combat COVID-19. No information will be shared from which you can be identified as an individual, such as your name, NHS number and date of birth. Your anonymised information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. It will not be used to make decisions about future services available to you, such as insurance.

We will also ask for your consent to use the information we collect during your participation in this trial for future research. Any future research will have received approval from an Ethics Committee, but you will not be asked to sign another consent form to participate. This is optional, and should you not wish to consent for your data to be used in future research studies, you will still be able to participate in this trial. Cambridge University Hospitals and the University of Cambridge will keep information about you for 15 years after completion of the trial. This is a legal requirement.

### **18. What will happen to the results of the trial?**

The results of the trial will be anonymous and you will not be able to be identified from any of the data produced. When the results of this trial are available they may be published in peer reviewed medical journals and used for medical presentations and conferences. They will also be published on the EU Clinical Trials Register website, a central registry for all clinical trials conducted in the EU. The EU Clinical Trials Register is accessible to members of the public ([www.clinicaltrialsregister.eu/](http://www.clinicaltrialsregister.eu/)). We will also publish the main findings of the trial on the trial website.

If you would like to obtain a copy of the published results, please contact your trial doctor directly who will be able to arrange this for you. If you have provided an email address when you registered for the trial, we will send you trial newsletters if you wish. This will include trial results when the trial is completed.

**19. Who is funding the trial?**

Funding for the trial is provided by LifeArc, Kidney Research UK, The April Trust, Addenbrooke's Charitable Trust and the Addenbrooke's Kidney Patient Association. The trial treatment, and additional financial support is being provided by Union Therapeutics.

**20. Who has reviewed this trial?**

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by the Cambridge East Research Ethics Committee. The Medicines and Healthcare Products Regulatory Agency (MHRA) who are responsible for regulating medicines in the UK have also reviewed this trial. The trial has also been reviewed by members of the Cambridge Bio Resource Centre patient and public involvement team.

**21. Further information and contact details**

For further information about the trial, please contact *[Sites to enter name, address, email address, telephone numbers]*

The Patient Advice and Liaison Service (PALS) should be contacted for any complaints. Your local PALS is *[Enter local details]*

**In the event of an emergency please contact:**

*List, site level 24 hour emergency contact details here*



**INFORMED CONSENT FORM**

**Trial Title: PROTECT: PROphylaxis for paTiEnts at risk of COVID-19 infecTion**

**Principal Investigator:** \_\_\_\_\_

**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 2.0, dated 05 January 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 1.2, dated 25 November 2020. 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 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.	

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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 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.