TO BE PRINTED ON HEADED PAPER

PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM – MONOCLONAL ANTIBODY TREATMENT ARM

PROTECT-V: 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 has been a large effort to create vaccines against COVID-19 to prevent infection. Unfortunately, vaccines do not work for everyone. In particular, those that have an immune system that doesn't work normally, or that take medicines which suppress the immune system, may not get as good protection from vaccines.

PROTECT-V is a platform trial. A "platform trial" is a clinical trial with a master protocol, which allows for multiple treatments to enter or exit the trial over the course of the study. PROTECT-V is testing a number of medications to see if they help protect against COVID-19 infection. This specific part of the **PROTECT-V** trial enrols patients who have had a poor response to COVID-19 vaccines. 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 (a monoclonal antibody), against those who receive a placebo ("dummy") treatment. A monoclonal antibody is a laboratory made protein which is designed to act like human antibodies and help our immune system recognise and bind to specific proteins; in this case on the virus that causes COVID-19 infection. Monoclonal antibodies have been used successfully to treat many other diseases.

2. What are the drugs being tested in this part of the PROTECT-V trial?

The drug being tested in this specific arm of the trial is called Sotrovimab. It is a monoclonal antibody which is designed to block COVID-19 virus particles from binding to the cells of your body. Research using this drug so far has suggested that people with COVID-19 infection who are given this treatment early on are less likely to develop severe disease. It is hoped that the medicine will protect people from COVID-19 if they have had a poor response to a vaccine. The medicine has been used to treat thousands of people with early COVID-19 and it has been tolerated well.

Though the medicine has been used in thousands of people before, this is the first time this particular dose of the medication has been used.

Sotrovimab is administered into a vein by infusion. The infusion lasts approximately 30-90 minutes. You would have one infusion, and it is hoped the effect of the medicine will last up to 24 weeks (about 6 months).

3. Why have I been invited?

You have been invited to participate in this study because you have a condition which places you in one of the following groups:

- You are receiving dialysis treatment
- You have an immunodeficiency (primary or secondary)
- You have an Oncology (cancer), Haemato-Oncology (blood cancer) or Haematology (blood disorder) diagnosis, and you have received chemotherapy or have a weakened immune system as a result of your disease or treatment
- You have a diagnosis of an autoimmune/inflammatory disease and you are currently receiving immunosuppression (Prednisolone ≥20mg daily for at least 4 consecutive weeks is considered a form of immunosuppression in this study)
- You are a solid organ or haematopoietic stem cell transplant recipient

We plan to include approximately 1800 patients 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 Visit

After consenting to participate in the trial, you will be asked some questions, and have an electrocardiogram (ECG) performed. An ECG is a simple test used to check your heart's rhythm and electrical activity using sensors attached to the skin. You will also have a urine sample and a blood sample taken, to confirm that you meet eligibility criteria and can safely receive the trial medication. One of the tests will look at whether you have had a response to COVID-19 vaccines. If you have responded to the vaccine and developed a protective level of antibodies, you **will not** be eligible to participate in this part of the PROTECT-V trial. You will not be required to attend any further study visits and you will continue with your standard care.

If you are on dialysis, have a renal transplant or vasculitis/glomerulonephritis/systemic lupus erythematosus and are receiving immunosuppression, you may still be eligible for the other medicines being trialled in PROTECT-V for prevention of COVID-19. Please ask your study doctor or nurse if you wish to consider the other medicines.

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 active drug 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 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 two groups will be the same; therefore you will have a 50% chance of receiving sotrovimab.

- **Double Blind:** This means neither you nor your trial doctor will know which treatment you are receiving. If necessary, your trial doctor can find this out.

- **Placebo**: This is sometimes called the 'dummy' treatment. It looks the same as the treatment but does not contain any of the active ingredients.

Study visits

Because of the need to avoid extra hospital visits during the COVID-19 pandemic, we have minimised the number of in-person visits in the study. You will need to attend hospital for 5 visits, during this study:

- Your screening visit (see section above)
- Drug infusion visit
- Assessments, which include blood tests, at 4 weeks, 12 weeks and 24 weeks after you have received the study medication.

Drug Infusion Visit

If you are eligible for the study, you will need to attend the hospital within 2 weeks of the screening visit for the drug infusion. This will either be sotrovimab or placebo (salty water solution) depending on the group you are randomly assigned to. Prior to the infusion, you will have some observations (including blood pressure, heart rate, oxygen levels) taken. A cannula (needle into the vein) will be inserted and blood samples taken. The infusion will take between 30 to 90 minutes. You will then need to be observed for up to 2 hours, and have a further blood sample taken to measure the level of drug in your blood. The whole visit will take approximately 3 to 4 hours.

In-person study visits

You will have in-person visits at day 29 (week 4, +/- 3 days), day 85 (week 12, +/- 7 days) and day 169 (week 24, +/- 7 days). There is some flexibility around the dates of these visits, and the local study team should be able to give you options so that the in-person visits are done at a time that is convenient to you. During these visits, you will have your observations (including blood pressure, oxygen levels and heart rate) recorded; a blood sample taken; we will check your usual medications, ask you about any potential side effects of the trial medication and about symptoms of COVID-19 infection. If you have had a COVID-19 vaccination during the time you are taking part in the study, we will ask you to attend for a blood test approximately 28 days after having the vaccination, so that we can see whether you have had a good response to that vaccine or not.

Some participants (approximately 60) will have an additional home visit to take a blood sample. You will be informed on the day that you receive the infusion whether or not you will need to have this visit. The visit will happen 2 to 4 days after you receive the study medication. You will not need to come to the study centre to have this blood sample taken. If you decide to take part and would prefer to come in, please discuss this with your study team to see if this is possible.

The figure on the next page shows what will happen throughout the study.

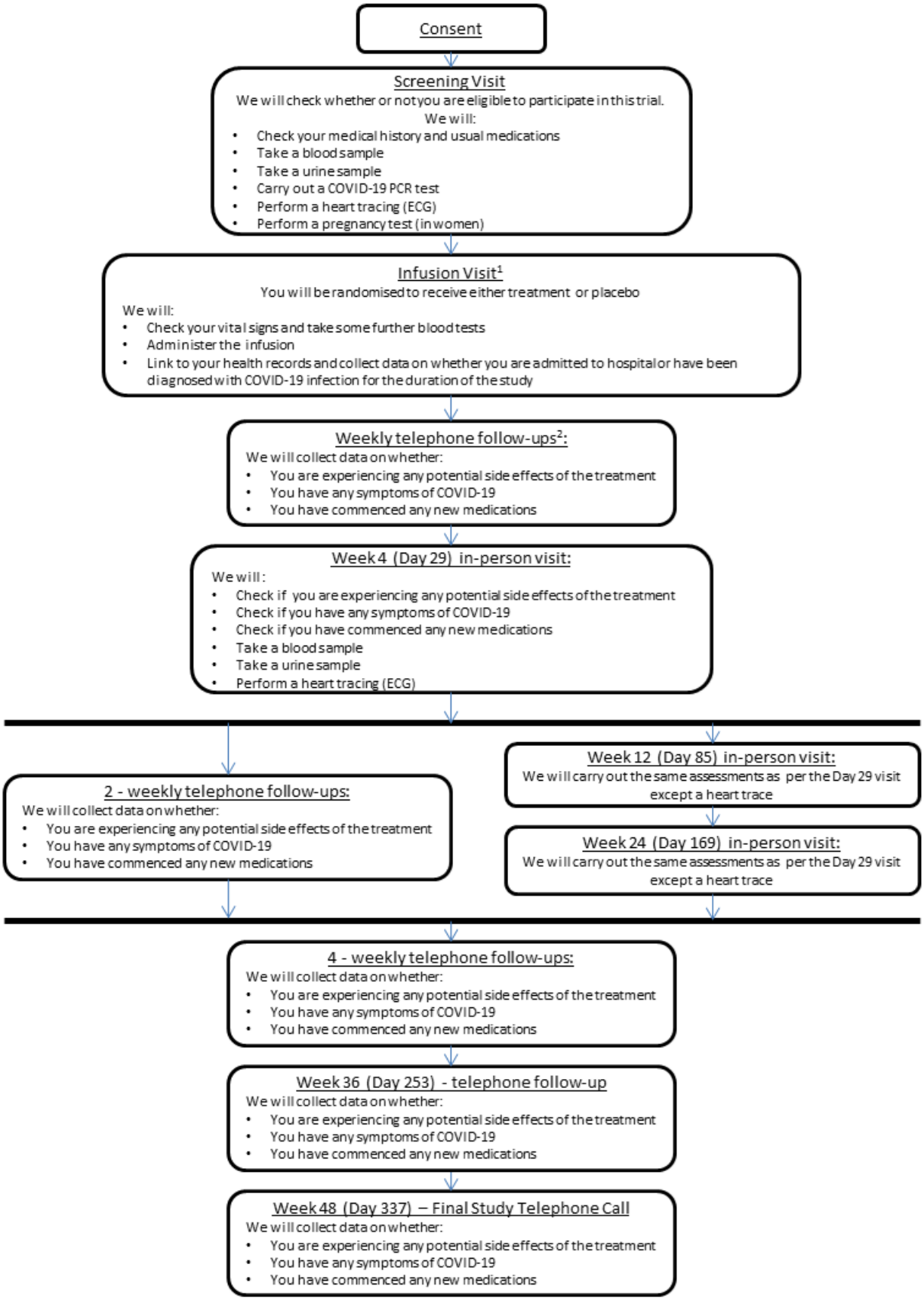
Questionnaires

In between these in-person visits, your local trial team will telephone you and ask some questions every week for the first 4 weeks, every 2 weeks between weeks 4 and 24, and

then every 4 weeks until week 36. There will then be one last phone call at 48 weeks after you received the study medication. You will be asked about any possible side effects of the trial medication, any new medications or vaccinations and any possible symptoms of COVID-19 infection. These questionnaires will take about 5-10 minutes each. Some participants (about the first 180 in the trial) will also have an additional telephone call asking about any possible side effects of the trial medication 1-2 days after receiving the study medication. The study team will let you know whether or not to expect this phone call.

Your participation in the PROTECT-V trial will last for 48 weeks.

All data collection will be carried out by telephone or during your usual hospital attendances such as dialysis sessions, clinic visits, or at the in-person scheduled visits. Other than the in-person visits, no additional visits to hospital will be required for the study.



[1]Some participants will have an additional blood sample taken 2 to 4 days after they receive the study medication. Someone will come to your home to collect this blood sample. If you decide to take part, the study team will let you know if you should expect this.

[2]Some participants will receive an additional telephone call 24-48 hours after they receive the study medication. If you decide to take part, the study team will let you know if you should expect this telephone call.

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 (ONS)** - In the unfortunate event that a person dies, this information is obtained from civil registration data by the 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 the ONS.

b) **Public Health England (PHE)/UK Health Security Agency (UKHSA)** - The national organisation responsible for collecting all COVID-19 Testing data across England. The UKHSA collects COVID-19 lateral flow test (LFT) results reported by the public via the government website (https://www.gov.uk/report-covid19-result). UKHSA (formerly 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-V 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?'.

Research Samples

Screening visit:

At screening, about 25mL (which is less than 1.5 tablespoons) of blood will be taken for routine clinical tests, including checks on your kidney and liver function, a full blood count and also measurement of antibodies against SARS CoV-2. This will be repeated at Days 29, 85 and 169, and at the time of COVID-19 infection should you develop it. If you receive a COVID-19 vaccine at any point during the trial, a 10mL sample to measure for antibodies will be taken at 28 days (+/-7 days) afterwards.

A urine sample, to measure the amount of protein in your urine, will be taken at screening, Days 29, 85 and 169 and at the time of COVID-19 infection should you develop it.

For women of child bearing potential a serum pregnancy test will be taken at screening and a urine pregnancy test on day 169.

A COVID-19 swab will also be taken at screening.

Infusion Visit:

On the day of the drug infusion, 60mL (approximately 4 tablespoons) of blood will be taken and stored for later analysis of the functioning of your immune system. Please refer to section 16 “What will happen to any samples I give?”

COVID-19 positive:

Should you test positive for COVID-19 whilst taking part in the study via either PCR or LFT, you may be asked to come into the study site, or a nurse will visit your home, to take a blood sample as close to the time of the positive COVID-19 test as possible. You will also be asked to attend in person 28 days later to have the same samples taken again (approximately 85mL [5 tablespoons] each time). We will organise home visits for the

first sample if necessary so that you can continue to self-isolate in accordance with COVID-19 guidelines. The local trial team will arrange with you whether you will come in to have these samples taken, or if a home visit will be arranged.

Over the whole trial, about 160mL of blood will be collected if you do not develop COVID-19 infection, and about 300mL (less than a unit of blood donation) should you develop COVID-19 infection.

If you test COVID-19 positive then you will also be given further COVID-19 swabs to be done every week until you test negative. Your trial team will tell you when you can stop doing the swabs. You will be given instructions on how to do the swabs if and when you test positive.

6. What will I have to do?

You will not be able to participate in any other trials testing medications or vaccines to prevent COVID-19 infection at the same time as PROTECT-V. However, if you are offered an approved vaccination against COVID-19 infection as part of routine care, we encourage you to have the vaccine.

Questionnaires

These will occur every week for the first 4 weeks, every 2 weeks until 24 weeks (approximately 6 months), every 4 weeks until 36 weeks, and then a final one at 48 weeks after you received the study medication. You will be asked to answer a short series of questions about your current symptoms, if any, which may be potential side effects of the medication, or of COVID-19 infection. This will be done via telephone for visits that are remote (not done in-person).

In-person visits

You will be asked to attend in-person at the hospital on 5 occasions; screening, day of infusion and then 4 weeks (29 days), 12 weeks (85 days) and 24 weeks (169 days) after you receive the study medication or placebo. There is some flexibility around the dates of these visits, and the local study team should be able to give you options so that the in-person visits are done at a time that is convenient to you. At these visits, you will be asked to complete the same questionnaires but you will also have a blood and urine sample taken. If you are at the Cambridge or Birmingham clinics you will have a saliva sample taken.

Pregnancy and Breastfeeding

It is not known whether the 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, breastfeeding or planning to conceive a child at any point during the study. 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 part in the study, 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. You will also have a urine pregnancy test performed at your week 24 in-person visit.

Contraception

Women who are able to have a baby must use a reliable form of contraception for the entire duration of the study (i.e. for at least 48 weeks after having had the drug infusion). 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 or
- 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 the end of the study). 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 trial medications are listed below under point 7 "**What are the side effects of the drugs 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. 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 take a COVID-19 lateral flow test or preferably a PCR test if possible, depending on the tests you have access to via the NHS.

If you encounter any problems with arranging a test (lateral flow test or PCR), please contact the site trial team. At the same time, you may be swabbed for influenza. If this is not done routinely with the COVID-19 test in your area, you may be provided with a swab, labels and request form for the influenza test at enrolment by your local study site.

If you use the lateral flow test, please take a photograph of the lateral flow test result including the QR code, and forward this photograph together with the date of the test and your Trial ID number to your site trial team. Please also report this LFT result via the government website at (https://www.gov.uk/report-covid19-result). If you need help reporting your result, please contact the site trial team.

If it is possible, your site trial team may also try to arrange a PCR test for you. The site trial team will then file a copy of the results in your medical notes, and within their file for the trial.

If your LFT is negative but you have symptoms consistent with COVID-19 infection, please contact the site trial team who may arrange a PCR test for you, or advise you to repeat your lateral flow test. If you develop COVID-19 symptoms during the study – see Appendix 1 at the end of this information leaflet for a list of things we would ask you to do.

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. You should also contact your local study team and inform them of the positive result.

If you are diagnosed with COVID-19, in addition to your normal care, we will ask you to undertake weekly COVID-19 PCR swabs (which we will supply for you) until your test becomes negative. We will also ask you to undertake additional weekly questionnaires about your COVID-19 infection symptoms (which we will carry out over the telephone). The questionnaires will stop once your symptoms stop or 28 days after you tested positive – whichever happens first. We will also arrange for a nurse to come to your home, or in some instances ask you to come in person to take blood tests at the time you get infection. You will also be asked to attend in person to have blood tests taken 28 days later. Taking part in this study will not prevent you from having any other treatments routinely available for COVID-19 infection.

7. What are the side effects of the drugs being tested?

In all studies so far, sotrovimab has been well tolerated. Approximately 1 in 100 individuals who receive sotrovimab have an infusion-related reaction (within 24 hours of drug administration). These may include pain at the infusion site, fever, chills, dizziness, rash, itchiness and shortness of breath. Other rare side effects that may take longer to manifest may include nausea, insomnia, headache, rash or itchiness. Serious allergic reaction to the medication (anaphylaxis) is rare and may affect up to 1 in 1000 people. We will be monitoring for all of these side effects throughout the study.

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

The PROTECT-V 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. All medications have side effects and it is possible that you may experience one or more of these.

You will be required to come into your local study centre for the in-person visits. We have kept in-person visits to a minimum, but this may expose you to increased risk of acquiring COVID-19 or other infections from the healthcare setting. All test centres will be following appropriate COVID-19 precautions, in line with the current relevant national guidance.

You will also have to have some blood samples taken. The main risks of this are discomfort and possible bruising at the site where the needle goes in. These are usually minor and resolve shortly after the tests have been done.

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 these medications and we do not yet know if these medications will be effective. 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, you have been identified as having had a poor response to vaccination, and so these medications are 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 study medications 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. You will be in the trial for 48 weeks. The trial may stop earlier if new information emerges. If this happens, you will be informed by the trial team. If the trial finds that one or more of these medications protects against COVID-19, we hope that they 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 you for 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 local trial team will contact you about the new information to discuss whether you wish to continue participating in PROTECT-V. If you wish to continue in the trial, you will be asked to sign a new Informed Consent Form.

The trial sponsor, the regulatory authority or the trial doctor may decide to stop the trial at any time. If this happens, we will tell you why the trial has been stopped and arrange for appropriate care and treatment for you.

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. You do not need to provide a reason, and your decision will not affect your future care or medical treatment. You can decide whether you would still be happy for us to continue to collect data remotely from your central healthcare records without 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 or any tests already performed on you or your

samples will continue to be used in the analysis. 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.

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?

All samples that are collected in this trial will be taken locally. All research samples will be processed, analysed and securely stored in a central laboratory and will only be accessible by authorised trial staff only. We will be checking the levels of the study medication in your blood, and whether you develop any antibodies to the drug. Some of the specialist tests performed on your blood in this way may be performed in third party laboratories sub-contracted in the USA or the EU. You will not be able to be identified from these samples.

Unused samples will be stored for future tests related to this study, and for future ethically approved research projects. Future ethically approved studies may include genetic studies to look at how your DNA or RNA affects the function of the immune system. The results of these studies will not have a direct impact on your clinical care, or that of any relatives, and will not be routinely shared with you.

De-identified information about your health and care and de-identified samples collected during the study may be made available for other research studies run by CUH and/or the University of Cambridge or other organisations, subject to required ethical and regulatory permissions being in place. These organisations may be NHS or other public sector organisations, academic institutions, charities and commercial companies

in the UK or abroad. Before your data is shared with other organisations all personal identifiers, such as names, addresses and dates of birth, will be removed.

Making information and samples from trials available for further research helps maximise the benefit of conducting trials and allows other researchers to verify results and avoid duplicating research. Any samples not used will be disposed of in accordance with Human Tissue Authority codes of practice.

Unless explicitly told otherwise by you, any samples already collected will continue to be used in the trial analysis should you decide to withdrawal from this trial early.

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 ensuring your safety and allowing the trial to be reviewed by the relevant 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

- 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

For participants recruited at Cambridge University Hospitals:

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, 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 has finished.

All information collected about you as a result of your participation in this 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.

If you develop COVID-19 infection in the trial and need to have a blood test at home, your local team will pass your contact details and home address to the authorised personnel of the private company providing this service.

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-V 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. De-identified information relevant to the sotrovimab arm will also be shared with GlaxoSmithKline Plc. (GSK) either to a GSK entity in the UK and/or to a GSK entity abroad. GSK who will become the data controller of this de-identified data once received and deal with it in accordance with the General Data Protection Regulations, including any other relevant privacy laws applicable to it. GSK may use this de-identified data in regulatory filings, for further research or other purposes. GSK are supplying the sotrovimab 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 or 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 published. 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/). 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 local trial team 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 and, Addenbrooke's Charitable Trust. The sotrovimab trial treatment, and additional financial support is being provided by GlaxoSmithKline Plc and Vir Biotechnology Inc.

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 a favourable opinion by the South Central - Berkshire 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

Appendix 1

PROTECT-V
PROphylaxis for paTiEnts at risk of COVID-19 infecTion

INFORMATION FOR PARTIPANTS IN THE MONOCLONAL ANTIBODY TREATMENT ARM

WHAT TO DO IF YOU DEVELOP SYMPTOMS OF COVID19

If you develop any 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), then please do the following:

1) **Inform your trial site that you are having symptoms**

2) **Perform a lateral flow test**
   (If you are having difficulty doing this, please contact your site for assistance)

3) **If it is positive, report your lateral flow test result via the government website:** https://www.gov.uk/report-covid19-result
   (If you need help to do this, please contact your site for assistance)

4) **If your lateral flow test is positive, take a photograph of the test including the result and the QR code. An example can be seen below:**

You can contact your site using the details below:

[Sites to enter name, email address, telephone numbers]

5) **If your lateral flow test is negative, but you are still having symptoms then repeat the test. If it remains negative, then please contact your site for further advice.**

TO BE PRINTED ON HEADED PAPER

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:_____ **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 3.2 dated *01 Sep 2022* 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, and that any data and samples already collected or tests already performed will continue to be used in the trial as described in this information sheet.	
3	I understand that my personal information will be collected and used in accordance with the information sheet version 3.2 dated *01 Sep 2022*. 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 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, urine, and saliva samples (where collected) as outlined in the patient information sheet, and understand that these samples will be stored for up to 15 years.		
11	I agree to provide blood samples and for them to be sent to an approved laboratory in the US and the EU, as described in this document. These may be commercial or academic laboratories.		
12	I understand that de-identified information collected during my participation in the PROTECT-V trial may be used to support other future ethically approved research studies, including research conducted by both commercial and non-commercial organisations in the UK and abroad, and that analysis of the samples may occur that involves DNA/RNA collected from my donated blood samples.		
OPTIONAL CONSENT		**INITIAL** **YES**	**NO**
13	I agree to be approached to take part in studies that I am eligible for in the future		

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.