PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM FOR PARENT(S)/LEGAL GUARDIAN(S)

STUDY TITLE	**A PHASE 2/3, INTERVENTIONAL SAFETY, PHARMACOKINETICS, AND EFFICACY, OPEN-LABEL, MULTI-CENTER, SINGLE-ARM STUDY TO INVESTIGATE ORALLY ADMINISTERED PF-07321332 (NIRMATRELVIR)/RITONAVIR IN NONHOSPITALIZED SYMPTOMATIC PEDIATRIC PARTICIPANTS WITH COVID-19 WHO ARE AT RISK OF PROGRESSION TO SEVERE DISEASE**
SHORT STUDY TITLE	**Study to investigate treatment of paediatric participants with COVID-19**
SPONSOR	**PFIZER, INC.**
PROTOCOL NUMBER	**C4671026**
IRAS ID	**1005109**
STUDY DOCTOR	**Dr. Simon Bruce Drysdale**
PARTICIPANT ID	

This participant information sheet and informed consent form will be used for legally authorised representatives (LARs, e.g. parent/guardian) of child study participants (6 to 15 years old, inclusive).

If a child (i.e. not legal adult) would like to participate in this study, an LAR needs to sign this participant information sheet and informed consent form.

If applicable, a separate age-specific assent form for children (6 to 15 years old, inclusive) should be signed by the study participant.

During the course of the study, if the study participant turns 16 years of age, informed consent will be taken from the them and they will be asked to confirm if they wish to carry on as a study participant.

1. INTRODUCTION

You are being invited to permit your child to take part in a study that is sponsored by Pfizer (the "Sponsor"). We understand that this may be a difficult decision. This consent document can help you make your decision by explaining **what you can expect to happen to your child during this study**, also known as a clinical trial or a research study.

This research study is different from, and does not replace, your child's regular medical care. As such, if your child participates in this study they may have additional visits, procedures, extra laboratory tests, and/or follow a modified treatment plan.

We encourage you to **have conversations with your family, caregivers, doctors, and study team** about taking part in this study and whether it is right for your child. The study team will work with you to answer any questions that you may have about the study. The study team includes the study doctor, nurses, and others who work with the study doctor.

If you choose to allow your child to participate in this study, **you will be asked to sign this consent document** prior to the study to let the study team know your decision.

You will receive a signed copy of these consent documents for your records. Please keep these consent documents for your reference.

2. PURPOSE OF STUDY

The purpose of the study is to find out if the study drug PF-07321332 (nirmatrelvir) given with ritonavir, (this combination is hereafter referred to as "Paxlovid"), helps treat non-hospitalised symptomatic children with COVID-19 who are at risk of their COVID-19 infection getting worse.

If your child is eligible to participate in this study, your child will be enrolled to receive Paxlovid. The term study drug refers to Paxlovid.

On 31 December 2021, the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted Paxlovid a conditional marketing authorisation for use after it was found to be safe and effective at reducing the risk of hospitalisation and death in adults with mild to moderate COVID-19 infection who are at an increased risk of developing severe disease. Ritonavir is approved for other uses, but not for COVID-19 and is a medication given with nirmatrelvir to increase the levels of nirmatrelvir in the blood so that it may be more effective. Ritonavir is not expected to have any effect on the SARS-CoV-2 virus.

3. WHY HAS MY CHILD BEEN INVITED?

You are being asked to allow your child to take part in this study because they have been diagnosed with symptomatic COVID-19. The purpose of the study is to learn about the effects of the study drug (Paxlovid) and to find the best dose for treating COVID-19. There will be about **140** children taking part in this study. The study is taking place at approximately **55** research sites in approximately **6 countries**.

4. POSSIBLE RISKS AND DISCOMFORTS

There may be some risks involved with taking the study drug or having the study assessments done. These have been outlined below. If needed, the study doctor can give your child other medicines to help with any side effects they may experience.

It is important that you/your child reports all symptoms and side effects to the study team as soon as they happen, even if you feel the study drug or procedure was not the cause.

Risks with Paxlovid:

The safety of Paxlovid has been studied in clinical trials in more than 3800 participants including healthy volunteers, non-hospitalised patients with COVID-19 and household contacts of patients with COVID-19. In these trials, some participants got a placebo instead.

The most common side effects that occurred in greater than 1% (more than 1 patient in every 100 patients) of the participants who received Paxlovid were:

- Change in sense of taste (5.76%)
- Diarrhoea (2.83%)
- Headache (1.65%)
- Vomiting (0.91%)

These events were reported more frequently in participants who received Paxlovid compared with participants who received placebo.

Side effects in patients with COVID-19 who received Paxlovid from a pharmacy and not in a clinical trial were:

- Allergic reactions (0.58%) such as hives, trouble swallowing or breathing, swelling of the mouth, lips, or face, throat tightness, hoarseness, or skin rash
- Nausea (1.73%)
- Increased blood pressure (0.44%)
- Abdominal pain (0.27%)
- Malaise (0.03%) such as discomfort, feeling abnormal, fatigue, weakness, or sluggishness.

The numbers of patients who experienced these adverse reactions are estimated.

In clinical trials of Paxlovid, a small number of participants had COVID-19 positive viral test results after receiving study treatment and testing negative. This happened in participants who received Paxlovid and in participants who received placebo. This has been referred to as COVID-19 rebound and may also involve a return of symptoms. Participants who experienced COVID-19 rebound in clinical trials did not have more hospitalisation or death than other participants. To date, there has been no evidence that COVID-19 rebound is the result of re-infection or of viral resistance to Paxlovid.

Brief increases in blood pressure were seen in animal studies and some participants from the adult studies had elevated blood pressure.

Because nirmatrelvir is given together with ritonavir, there is a risk for patients with HIV, that has not been diagnosed or is not controlled well to develop resistance to some antiretroviral drugs used to treat HIV, meaning that the antiretroviral drugs may not work properly.

Some medications interact with ritonavir. Taking some medications with ritonavir could lead to serious or life-threatening side-effects and if your child is taking these medications, they may not be eligible for the study. Keep a list of your child's medications to show the study doctor and discuss any changes to the medications with the study doctor before starting them.

Fertility, Pregnancy and Breastfeeding

Currently there is limited data in people who are pregnant/breastfeeding and taking Paxlovid, therefore, until there is more known about this medicine, if your child is pregnant, planning to become pregnant during the study, or breastfeeding a child, they should not take part in this study.

Risks from Study Procedures

A description of the possible risks and discomforts associated with the tests, procedures and assessments required in this study can be found in **Appendix A**: Study Tests, Procedures, Assessments and Associated Risk Details.

Other Risks

There may be other risks that are currently unknown because the study drug is still being developed.

Birth Control and Pregnancy-Related Risks

Use of Birth Control

If your child is able to have children (e.g. females who have begun their menstrual cycle), their urine will be tested to determine if they are pregnant. If they are not practicing abstinence as their birth control, they must use an effective method of birth control consistently and correctly during the study and for at least 28 days after they have stopped taking the study drug. This applies to females who take part in the study. The study doctor will discuss with you and your child (if appropriate) the methods of birth control that they should use whilst in this study. The study doctor will help your child select and discuss the method that is appropriate for them.

Ritonavir may reduce how well hormonal birth control works. Females who may become pregnant should use another effective form of birth control or an additional barrier method of birth control during treatment with ritonavir. If your child is using oestradiol-containing contraceptives, an additional, non-hormonal method of contraception should be considered during the 5 days of study treatment and until one menstrual cycle after stopping study drug.

Birth control methods are not perfect, even when used properly. If your child or your child's partner become pregnant during the study, or they want to stop their required birth control during the study, you should tell the study doctor immediately. They will need to stop taking study medication if they stop using birth control or become pregnant. Before the study, a pregnancy test is done for all women capable of becoming pregnant. If you/your child thinks they are pregnant, tell the study doctor immediately. Pregnancy tests will also be done

whenever a menstrual cycle is missed during the study (or when potential pregnancy is otherwise suspected) and at Day 34 or at early termination visit if prior to Day 34.

If your child/your child's partner becomes pregnant during the study, the study doctor will ask if your child/your child's partner or their health care provider(s) are willing to provide updates on the progress of the pregnancy and its outcome. If your child/your child's partner agree, this information will be provided to the sponsor for safety follow-up.

Your child cannot participate in the study if:

- They are pregnant, planning to become pregnant, or breast-feeding a baby.

5. DOES MY CHILD HAVE TO TAKE PART?

Your child's participation in this study is **completely voluntary (yours and their choice** (where age appropriate)). Take as long as you need to make your decision. You also can choose to allow your child to take part in the study now, and then change your mind later at any time. Please keep in mind that even if your child participates, it may turn out that they do not meet the study's entry requirements.

6. WHAT WILL HAPPEN TO MY CHILD?

Length of Study for Participants

Participants will be in this study for about 5 weeks. If your child is enrolled into the study, they will need to visit the study site (an in-clinic visit) once or twice at the start and then there are 7 more visits (if your child is 2 to 5 years, they will have an additional 2 visits) which can be done at the study site or remotely.

Process for Selecting Study Participants

After you sign this consent document (and your child signs the assent document where appropriate), your child's participation in the study will start with a screening visit to learn about their medical history and to check if they meet the study requirements. If they do not meet the study requirements, they will not be able to take part in the study (be enrolled). The study doctor will explain why and discuss other options with you and your child. If your child meets the study requirements, a description of the study drug, enrolment and procedures for this study are described below.

Study Drug(s)

Your child will start taking Paxlovid either 5 days from the onset of symptoms, or 72 hours from a positive test. The first 3 participants in the study will have their blood tested and PK analysis done, and dependent on the results, this will determine the dosage of Paxlovid for further participants. PK analysis studies how your body takes up, breaks down, and clears the study drug (pharmacokinetic analysis).

If your child is between the ages of 6 to 17 and can swallow tablets, they will be asked to take one tablet of 150 mg nirmatrelvir, with one tablet of 100 mg ritonavir tablets at approximately the same time of day, every 12 hours for 5 days (for a total of 10 doses). The study team will provide you and your child with blister wallets and bottles of the study drugs at the Day 1 in-clinic visit along with clear dosing instructions. If you think it will be hard for you or your child to open or close this packaging, please tell the study team and other

arrangements may be made. If your child is unable to swallow tablets, then they will be provided with oral powder stick packs (pouches) containing the study drugs nirmatrelvir 150 mg and ritonavir 100 mg. If they are 5 years or younger, they will receive oral powder stick packs (pouches) containing both the study drugs and will be dosed according to their weight.

Nirmatrelvir/ritonavir Dosing Table for Participants who are 5 years of age and younger		
Body Weight (kgs)	Dose Nirmatrelvir/ritonavir	Formulation
≥12 to <20 kg	100 mg/50 mg	Oral Power
≥4.5 kg to <12 kg	50 mg/50 mg	Oral Powder

Your child's first dose of study drug (either tablets or oral powder as appropriate) should be taken while your child is at the clinic.

The remaining study drugs will be taken at home by your child themselves (with your supervision if necessary). They should swallow the study drug tablets whole. The tablets should not be altered or chewed prior to swallowing. The oral powder stick packs (pouches) for ages 6 to 17 years (as needed) and for ages 5 years and younger, are to be taken as per the instructions in the IP Manual for preparation and administration of the oral powder stick packs (pouches). They may take the study drug with or without food every 12 hours for 5 days. If they miss a dose by more than 8 hours, then they should not take the missed dose and instead take the next dose at the regularly scheduled time. They should not double the dose to make up for a missed dose. Study drug should be stored in their original containers. The study doctor and/or the site staff will instruct you and your child on the proper storage requirements for take-home study drug.

Dosing should be stopped at the end of the treatment period (10 doses total). Any remaining tablets or oral powder stick packs (pouches) your child has left should be returned to the study site.

There are certain medications that can interfere with the way the study drug works in the body. The study doctor will review and discuss the medications which your child should not take whilst also taking the study drug.

Your child may receive standard of care (SoC) therapy for COVID-19, in addition to study drug, unless certain medications are not allowed. Current standard of care is supportive treatment e.g. supplemental oxygen, help feeding (e.g. feeding tube, IV fluids), or medication to relieve fever and pain. The study doctor will consult with the sponsor (Pfizer) if a new SoC option becomes available during your child's participation on the study. Your child should not receive convalescent COVID-19 plasma treatment, antiviral treatment (such as molnupiravir), monoclonal antibodies (mAbs), sotrovimab or remdesivir for COVID-19 during their participation in the study. COVID-19 vaccinations are permitted after their last visit.

Assessments

In this research study, your child will have certain assessments. The study doctor may ask you/your child to come in for additional assessments, if necessary, to protect their health.

A more detailed description of the assessments that will be required in this study can be found in Appendix A *Assessments and Associated Risk Details.*

Overview of Study Assessments

Description	Frequency
➢ Obtaining consent and assent (if appropriate) ➢ Demographics and medical history (including COVID-19 vaccine information) ➢ Study eligibility (to be reviewed at screening and baseline if completed on separate days): ➢ COVID-19 risk factor assessments ➢ RT-PCR or Rapid Antigen Test result ➢ Parent(s) /guardian to confirm ability to swallow tablets if 6 years or older ➢ Confirm use of contraception (if relevant) ➢ Weight and height ➢ At home blood sampling device provided and training given ➢ Dispensation of study drug and collection of unused and/or empty study drug and containers ○	1 time
➢ Acceptability and Palatability Questionnaire (which is assessing the swallowability and taste after taking the first dose of study drug) will be completed for the tablets after the first dose and for oral powder stick packs (pouches) after each dose administered during the treatment period	1 time for tablets and 10 times for oral powder stick packs (pouches)
➢ Pregnancy test (for females who can have children)	2 times
➢ Throat swab or nasal swab	7 times
➢ Blood samples taken	Up to 4 times
➢ **6 to 17 years:** Blood sample collection • Day 1 sample collected 1 hour-post dose • Day 4 pre-dose sample • Day 5 pre-dose sample and at 1, 2, 4, 6, 8, and 10 hours post morning dose ➢ **2 to 5 years:** Blood sample collection • Day 1 sample collected 1 hour-post dose • Day 2 within 2-8 hours post morning dose	10 samples Up to 7 samples

• Day 3 within 2-8 hours post morning dose before the evening dose • Day 4 within 2-8 hours post morning dose before the evening dose • Day 5 pre-dose and within 1-3 hours post-dose	
➢ Ask about taking study drug according to the dosing schedule	Up to 2 times
➢ Contraception check (if appropriate)	6 times
➢ Physical Examination	6 times
➢ Collection of vital signs (temperature, heart rate, blood pressure, breathing rate, and check the level of oxygen in the blood).	6 times
➢ Ask about COVID-19 related medical visits other than study visits (e.g.: A&E visits, Doctor's office visits)	6 times
➢ Ask your child about how they are feeling (such as COVID-19 signs and symptoms and general health) ➢ Ask about other procedures they may have received ➢ Ask about other medications they have been taking	Up to 9 times

Biological Samples

Your child must provide blood samples in order to take part in this study. These samples may be sent to or stored in a foreign country. Additional samples may be collected depending on the results of your child's laboratory tests or if a replacement sample is needed. A company hired by the Sponsor may be involved in the collection, transportation, or storage of these samples.

The total blood sampling volume for your child in this study is approximately 40 mL (8 teaspoons) for 6-17 years of age. The actual collection times of blood sampling may change. Additional blood samples may be taken for safety assessments at times specified by Pfizer, provided the total volume taken during the study does not exceed 550 mL (about 36 tablespoons) during the study.

The total blood sampling volume for 2 to 5 years of age will be approximately 22 mL (just over 4 teaspoons) and for less than 2 years of age will be approximately 17 mL (just over 3 teaspoons). Every effort will be made to ensure that minimal blood volumes will be used for required sampling during the study.

Stopping Study Drug and Impact on Study Tests, Procedures and Assessments

If for any reason your child is asked to stop taking the study drug or you or your child wants to stop taking the study drug, your child may continue to participate in the study. Even though your child would no longer take the study drug, your child will be given the End of Treatment procedures and will continue to complete the study follow up visits.

7. EXPENSES AND PAYMENTS

You and your child will not receive any payment for participating in this study, but you will be reimbursed for reasonable expenses (such as parking, meals, travel) that you may have while taking part in this study.

The Sponsor may use information and biological samples resulting from the study to develop products or processes from which it may make a profit. There are no plans to pay you or your child or provide you or your child with any products developed from this study. The Sponsor will own all products or processes that are developed using information and/or biological samples from the study.

8. WHAT WILL MY CHILD HAVE TO DO?

You/your child must:

- Follow instructions you and your child are given by the study team and discuss all prescription and non-prescription medications, supplements, or vaccines before your child takes them.
- Do not throw the study drug in the bin or flush it down the toilet. Do not give your child's study drug to any other person. Keep the study drug out of the reach of other children and those who cannot read the label. You/your child will need to bring empty or partially used containers back to the study doctor at each visit.
- If your child is a female participant of childbearing potential, they must agree to use a highly effective birth control method during the study treatment period and for at least 28 days after the last dose of study drug.
- Your child must not receive a dose of a COVID-19 vaccination until after the Day 34 (last) visit.
- Your child will be given a card with important emergency contact information, including a 24-hour phone number. Show this card to any health care provider if your child seeks emergency care during this study. This card includes information about the study that will help the health care provider treat your child.
- All medication has a potential risk of causing an allergic reaction, which (if not treated quickly) could become life-threatening. Your child should get medical help right away or call your local emergency number and contact the study doctor if you think they have any of the following symptoms of a serious allergic reaction: trouble breathing or swelling of the face, mouth, lips, gums, tongue, or neck. Other allergic reactions may include rash, hives, or blisters.
- A courier will need to pick up any blood samples collected at your home. This should be arranged either by yourself or your research staff team.

9. WHAT ARE THE ALTERNATIVES INSTEAD OF THIS STUDY?

Other options may be available to your child if you choose for them not to participate in this study. Talk to the study doctor or your child's regular doctor about these other options.

The study doctor can discuss with you and your child the major risks and benefits of the standard of care and alternative treatment options.

10. POSSIBLE BENEFITS OF PARTICIPATION

Your child's participation may help future patients by increasing our understanding of Paxlovid. It is possible that your child's condition or health may improve, worsen, or stay the same because they are taking part in this study. There is no guarantee that your child will benefit in any way.

11. WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

The study drug will be given to your child only during this study, and not after the study is over.

12. WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

While your child is participating, the study doctor will tell you in a timely manner if new information is learned that could change your mind about your child being in this study.

13. WHAT IF I CHANGE MY MIND?

Your child can stop participating in the study at any time. Your/your child's decision will not affect their regular medical care or any benefits to which your child is entitled. Tell the study doctor if you/your child decide to stop so that they can end participation in the safest way. The study doctor will explain how to return the study drug and what other steps may occur.

The study doctor may also decide to take your child off the study drug and/or remove them from the study (even if you do not agree) in the following situations:

- They are unable or unwilling to follow the instructions of the study
- The study doctor decides that the study is not in their best interest or that they are no longer eligible to be in the study; or
- The study is stopped by the Sponsor, or independent ethics committee (IEC) (a group of people who review the study to protect study participant rights), or by a government or regulatory agency.

Information about your child's health will continue to be collected and used as described in the "Will information about my child be kept confidential?" section and in the privacy section.

You may request that any samples that have been collected from your child as part of the study be destroyed, and in some countries, local laws or regulations may require that your child's samples be destroyed regardless of whether you specifically make such a request. However, we cannot guarantee the destruction of samples because, for example, the samples may no longer be traceable to your child or the samples may have been used up.

14. WHAT IF THERE IS A PROBLEM?

If your child experiences a research injury, emergency medical treatment will be provided at no cost to you. A research injury is any physical injury, illness or disability caused by:

1. administration of the Pfizer study medicine; or
2. any study procedure that would not have occurred but for your child's inclusion in the study.

Compensation may be available for such research injuries, depending on a number of factors including the seriousness of the disease, the likelihood of adverse reactions, any warnings given, the risks and benefit of established treatments relative to these of the study medicines and compliance with study directions. The study doctor will advise you about these factors.

In assessing claims for compensation regarding any injury caused by taking part in this study, Pfizer follows the terms of the guidelines of the Association of the British Pharmaceutical Industry ("ABPI") a copy of which is available on request. The complaints procedure of the study site where the trial is being conducted is also available.

15. WILL INFORMATION ABOUT MY CHILD BE KEPT CONFIDENTIAL?

Medical and research records collected during this study will be stored by the study team at the study site and may also be stored on a third-party cloud-based platform paid for by the Sponsor. These medical and research records will be reviewed to verify that clinical trial procedures and/or data are correct.

Your child's medical and research records may be accessed by:

- The study doctor and other study team members
- The Sponsor and its representatives (including its affiliated companies)
- People, or organizations providing services for, or collaborating with, the Sponsor
- Other researchers, including researchers involved in the study at sites other than the one at which your child is participating with in the study
- Any organisation that obtains all or part of the Sponsor's business or rights to the product under study
- Government or regulatory authorities including those located in other countries;

In order to keep records that identify your child confidential, the study site will replace your child's name with a unique code. The records and information labelled with the code are called "**Coded Information**." The study site will keep the link between the code and your child's name confidential. Your child's information will be transferred to the Sponsor using the unique code assigned to them. The Sponsor's employees and those with whom your child's Coded Information is shared are required to protect your child's coded information and will not attempt to re-identify them.

Your child's personal information will be collected, used, and shared (together called "processing") in compliance with applicable privacy laws.

Under certain circumstances, information that identifies your child by name may leave the study site in connection with the study and be sent to a vendor contracted by the Sponsor, in order to:

- provide you/your child with reimbursement, as allowed by the study, for certain expenses related to your child's participation

- provide you/your child with transportation and similar support to enable your child's participation in the study
- provide your child with the option to have certain study visits and procedures conducted by home health care professional at your home
- deliver drug to your home **or** pick up specimens/samples
- check up on your child's health status, including using available records (e.g., public databases or the internet) should the study team be unable to contact you using information held on file
- conduct study-specific procedures and testing and lab testing.

The people and/or organisations contracted by the Sponsor to provide these services must keep your child's personal information private, and they will not share with the Sponsor any information that can directly identify them.

You will also be provided a separate Privacy supplement (which is considered part of this consent document) that further describes how your child's information, biological samples, and/or images will be processed and your child's privacy rights.

For more information on your child's data and how and why it is used, please visit this website: http://www.hra.nhs.uk/patientdataandresearch

16. INVOLVEMENT OF THE GENERAL PRACTITIONER (GP)

Your child's General Practitioner (GP) will be told that they are taking part in this study and may also be contacted by the study doctor to obtain information regarding their medical history.

17. RETAINED RESEARCH SAMPLES

Up to 18 mL, approximately 4 teaspoons, of your child's blood will be collected during the course of study participation, stored in a research tissue bank, and used to learn more about the study drug and COVID-19. Biological substances in your child's samples, including their genes, may be studied.

This may include analysing all your child's genetic information (called "whole genome sequencing"). While collection of genetic information does not expose your child to physical risk, collection of such information may result in a loss of your child's privacy if their genetic information is lost or stolen.

There is a very small chance that your child's genetic information could be misused by people not involved with the research, including to discriminate against your child. However, steps are in place to prevent a particular result from being linked to your child and to prevent unauthorised people from even knowing genetic research was done. Genetic analysis may not occur until many years after the trial is over, therefore the results of tests on your child's samples will not be given to you, the study doctor, any insurance company, your child's employer, or any doctor who treats them.

18. WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

A description of this clinical trial will be available on **http://www.ClinicalTrials.gov**, as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

- If you need assistance to understand the content in a different language, please ask a member of the study team.
- The Sponsor will provide the study doctor with information about the study results when all participants have completed the study.
- The study results, when available, may also be found on **www.pfizer.com** and **https://www.clinicaltrialsregister.eu/** *and* **https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/**

The Sponsor will provide the study doctor with information about the study results when all participants have completed the study. However, your child's individual study results will not be given to you, your child's doctor (if different from the study doctor), your family, your child's employer, or any insurance company.

If any exploratory research is done, it may not be possible to link any results from that exploratory research to specific individuals, including your child. The Sponsor does not plan to return information from any exploratory research to your child, the study doctor, or your child's doctor (if different from the study doctor).

19. WHO IS ORGANISING AND FUNDING THE RESEARCH?

The Sponsor is providing funding to the study site to conduct the study.

20. WHO HAS REVIEWED THE STUDY?

All research in the United Kingdom is looked at by an independent group of people, called a Research Ethics Committee, to protect your child's interests. This study has been reviewed and given favourable opinion by **London - Fulham Research Ethics Committee**.

It has also been reviewed and approved by the UK regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA).

21. FURTHER INFORMATION AND CONTACT DETAILS

The study team will address any questions, concerns, or complaints you/your child may have before, during, and after they complete the study. Contact information for your child's study site and study doctor are listed below.

Study Doctor Dr Simon Bruce Drysdale **Phone Number 0208 725 5382**

Study Staff Cecilia Hultin **Phone Number 0208 725 3887**

If you/your child need to report side effects or are feeling unwell, there is a 24 hour contact number:

Phone Number 0782 181 0046

If you have questions about your child's rights as a research participant, or do not feel comfortable speaking with the study doctor please ask the study site for details or contact:

St George's University Hospital Patient Advice and Liaison Service (PALS):

Phone Number: 020 8725 2453 Email address: pals@stgeorges.nhs.uk

PARTICIPANT CONSENT FORM FOR PARENT(S)/LEGAL GUARDIAN(S)

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PARTICIPANT ID	

Your consent

Please initial each box

I have had enough time to read this consent document (or, if I cannot read, an Impartial Witness‡ has read it to me) and have had the opportunity to ask questions. All of my questions have been answered to my satisfaction.	
I have been told that my child's participation is voluntary, and I can refuse to allow my child to participate or can withdraw at any time.	
I understand the relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from the Sponsor or its representatives, or the regulatory authorities, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my child's records.	
I agree to the use of my child's biological samples as outlined in the participant information sheet and informed consent form.	
I consent to the collection, processing, reporting and transfer of my child's data within and outside the UK for healthcare and/or medical research purposes where the data protection may not be as good.	
I acknowledge that I have received a copy of the Privacy supplement.	

I agree to my child's GP being informed of my child's participation in this study and providing relevant medical information about my child to the study doctor if necessary.	
I understand that if my child has their first positive COVID-19 test as part of this study, the result may be reported to the local authorities.	
I understand I will receive a copy of this participant information sheet and informed consent form.	
I agree to my child taking part in the study.	

_____

Printed name of parent or legally authorised representative

_____ _____

Signature of parent or legally authorised representative Date of signature[§]

_____

Parent's/legally authorised representative's relationship to child participant

Person Obtaining Consent:

_____

Printed name of person conducting the consent discussion

_____ _____

Signature of person conducting the consent discussion[†] Date of signature

Consent of Parent or Legally Authorised Representative Who Cannot Read or Cannot Write:
The parent or legally authorised representative has indicated that he/she is unable to read or is unable to write. An impartial witness has read the consent document to the parent or legally authorised representative, discussed it with the parent or legally authorised representative, and gave the parent or legally authorised representative an opportunity to ask questions. The information in the consent form was accurately explained to, and apparently understood by, the parent or legally authorised representative who provided informed consent to participate in the study.

_____
Printed name of impartial witness ‡

_____ _____
Signature of impartial witness Date of signature§

☐ Not applicable (*Check this box if the signature of an impartial witness is not required. Signature of an impartial witness is required if the participant's participant or legally authorised representative cannot read or cannot write.*)

§ Parent/legally authorised representative/impartial witness must personally date their signature.
† The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same discussion when the parent or legally authorised representative signs the consent document.
‡ Impartial witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the entirety the informed consent process if the parent or the legally authorised representative cannot read or cannot write, and who reads the informed consent document and any other written information supplied to the parent or legally authorised representative. Refer to the *Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance; EU Clinical Trial Regulation 536/2014 Art. 29(1).*

Thank you for your participation

Your child's participation in this study matters. Your study team is here to support you and your child throughout your journey with us, and we at Pfizer want to sincerely thank you and your child for your time and commitment to this research.

When completed, 1 for parent/legally authorised representative; 1 for researcher site file; 1 (original) to be kept in medical notes of participant.

APPENDIX A: STUDY ASSESSMENTS AND ASSOCIATED RISK DETAILS

- **Demographic Questions**

  Demographic questions ask for personal information, such as your child's name, date of birth (if under 2 years), race, NHS number, etc. and this data is collected at the screening visit. While collection of demographic information does not expose your child to physical risk, collection of such information may result in a loss of your child's privacy if the information is lost or stolen.

- **Vital Signs**

  - **Blood Pressure**

    Blood pressure test measures the pressure in your arteries as your heart pumps. The test is usually painless, however as the blood pressure cuff squeezes your child's arm while it inflates it may be uncomfortable. This feeling lasts only a few seconds. Blood pressure and heart rate measurements will be assessed in a seated position for children ⩾3 years of age or older and lying down for children younger than 3 years of age.

  - **Blood Oxygen Level (Pulse Oximetry)**
    Pulse oximetry is a painless way to measure the oxygen level of your blood.
    A pulse oximeter is a small device that will be placed on your child's finger. A pulse oximeter will be provided to you/your child at the screening visit and training will be given.

- **COVID-19 Signs and Symptoms**

  Throughout the study, the study doctor will monitor your child's COVID-19 related signs and symptoms and you/your child will also be asked about any COVID-19 related medical visits (A&E visit, GP visit etc.) that they have attended during their participation in the study.

- **Health and Medication Questions**

  Questions will be asked about your child's health, medical history, medications (prior or current medicines), vaccines, procedures, therapies, change in residence, and sexual history or practices. These questions and conversations may be sensitive in nature. You/your child may refuse to answer any question that makes you/your child feel uncomfortable. If you have concerns after responding to these questions, you should tell the study doctor.

- **Physical Examination**

  A physical examination will be performed at certain study visits and is an examination of certain body systems such as the heart and lungs. There are no known risks associated with a physical exam.

- **COVID-19 Testing**

  To be able to participate in this study, a confirmed COVID-19 infection as determined by RT-PCR or another method of diagnosis (e.g.: Rapid antigen test) approved by a health authority is required. This

assessment is done at screening. The initial positive COVID-19 test will be reported to the local authorities (if not already done).

At certain study visits, nose or throat swabs will be performed and nasal secretion samples will be taken to determine how the body responds to the study drug and/or disease progression. These samples will also be used to test the amount of COVID-19 present in your child's body. These samples may also be used to learn more about the COVID-19 virus and the study drug, immunogenicity, and/or biomarkers, as well as for other internal research purposes. The risks and possible discomfort from nasopharyngeal swabs may include some pain and general discomfort. Sometimes, it may cause the nose to bleed.

- **Acceptability and Palatability Questionnaire**

An acceptability and palatability questionnaire will be completed by your child (self-reported) or yourself to help to better understand your/your child's view of taking the study drug.

- **Blood Tests and Samples**

A blood test is the process of collecting blood for specific tests from a vein through a needle. The needle is connected to a small tube in which the blood is stored until it is tested. If only a very small amount of blood is needed, it may be collected through a finger stick or by a blood sampling device. In that case, your child's finger (for a finger stick) or arm, back or other location on their body (for using the blood sampling device) would be pricked by a small sharp point and the drops of blood collected. A blood test may cause faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight chance of infection. Your study doctor can provide additional safety information related to the use of the blood sampling device.

Blood tests are done to:

- Measure how well your child is tolerating Paxlovid and to monitor their body's response to COVID-19
- Determine how the study drugs are changed and eliminated from your child's body. These samples may also be used to develop and/or evaluate the test procedures used to measure study drug, immunogenicity, and/or biomarkers, as well as for other internal exploratory purposes.
- Determine how your child's body responds to the study drug and/or disease progression.

- **Pregnancy Test**

Pregnancy testing is a test in females of blood or urine to check for pregnancy. If your child is female and able to have children, they will have urine pregnancy testing performed during this study. There are no known risks associated with a urine collection.

If a urine pregnancy test cannot be accurately read, then a blood test will be performed to determine whether your child is pregnant.

- **Remote Visits (telemedicine and home health visits)**

  These may be used to assess your child's safety and collect study related information. Telemedicine system use includes the exchange of healthcare information and services via telecommunication technologies (e.g., audio, video, video-conferencing software) remotely, allowing you/your child and the study doctor to communicate on aspects of your child's study-related care, including medical advice, reminders, education, and safety monitoring. If you/your child are unable to visit the study site for protocol-specified safety laboratory evaluations, testing may be conducted at home if permitted by local regulations.

  A home health care service may be used to complete study visits. Home health visits include a healthcare provider conducting a study visit at your home or another approved location by your study doctor.

UK PRIVACY SUPPLEMENT (VERSION 10 JULY 2021)

In this Privacy Supplement "you" refers to your child.

This Privacy Supplement describes how the study site and the Sponsor will collect, use, transfer, store, analyse and share your personal information (called "processing") to conduct the study based upon its legitimate interests in (1) ensuring high standards of quality and safety in medicinal products and (2) conducting and publishing research. It also describes your privacy rights.

A. What information may be collected about you during this study?

In order to conduct the study, your study team will collect information about you. Information about you may include personal information that directly identifies you, demographics, and sensitive information such as your medical history and data from this study (including diagnoses, treatment, genetic information, race, and ethnicity). If required by this study, the study team may also collect biological samples from you and take images or make audio/video recordings of you.

Information may be collected from electronic devices if you use a mobile application or other digital tool during the study. You should review the main consent document as well as the terms and conditions and privacy policy of any digital tool or mobile application used in the study to understand further how information collected through those digital tools and applications may be used.

If you provide an emergency contact or details of family medical history, you should inform that person or those persons you have done so and that their information will be used as described in this document.

B. How will your information be used?

Your information will be treated in compliance with applicable data protection laws. Any information collected about you during this study will be entered into records, including health records, maintained by the study team at your study site. The Sponsor is the controller for any information collected about you by the site for purposes of conducting the study and is also the controller of your coded information once it leaves the site. The study site will retain your information for the period necessary to fulfil the purposes outlined in this Privacy Supplement, in the main consent document, and/or for the maximum period permitted by applicable law, which could be at least 25 years after the end of the study.

Your information may be accessed and used by:

- The study team;
- The Sponsor (including its affiliated companies) and its representatives, for example, study monitors and auditors;
- People and/or organisations providing services to or collaborating with the Sponsor;
- Any organisation that has or obtains rights to the product under study or that obtains all or part of the Sponsor's business;

- Other researchers, including researchers involved in the study at sites other than the one at which you are participating in the study;
- Regulatory authorities, including those located in other countries, such as the United States Food and Drug Administration;

Typically, your name will be removed from your information before it is sent outside the study site. As described in the main consent document, your name will be replaced with a unique code before your information and your biological samples, images and/or audio/video recordings, (if collected as part of the study) leave the study site. This information is referred to as your "Coded Information." Data generated using biological samples, images and/or audio/video recordings of you if collected during the study, will be handled in the same way as your Coded Information, unless otherwise stated in this Privacy Supplement or the main consent document. Sometimes the study site may be unable to remove information that can identify you from your images, meaning that the images shared with others may be identifiable as yours.

- The study site will upload your information (which will not include any information that personally identifies you) to a designated secure electronic system maintained by a third party engaged by the Sponsor. The Sponsor and/or the Sponsor's representatives will use this secure system to review and verify study data as they would at the study site. The Sponsor is the controller of the information uploaded to this electronic system. These uploaded records will be kept for the period necessary to fulfil the purposes outlined above and in the main consent document, as required by applicable law and/or for the maximum period permitted by applicable law on the secure electronic system.

The individuals and groups listed above will use your information, including your Coded Information, to:

- conduct this study;
- comply with legal or regulatory requirements, including for all of the purposes listed in the main consent document that you were provided and to seek approval from government or regulatory agencies to market study drug;
- publish the study results;
- improve the quality, safety, and design of this study and other research studies

The Sponsor may be required to provide information gathered from this study, including your Coded Information, to regulatory authorities for public disclosure. In such cases, the Sponsor will take steps to minimise the risk that you could be re-identified.

Some of the people and/or organisations using your information may be based in countries other than your country of residence, including the United States. When transferred to countries with legal standards that have not been found by the European Commission to offer an adequate level of protection of personal information, the Sponsor uses officially approved agreements (called Standard Contractual Clauses) to ensure a similar degree of protection is afforded. A copy of the agreement may be obtained by contacting your study team.

The Sponsor will retain your Coded Information for the period necessary to fulfil the purposes outlined in this Privacy Supplement and in the main consent document, indefinitely or the maximum period permitted by applicable law after the end of the study.

C. Can your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of the study, be used for other research?

Yes. The Sponsor may use and has a legitimate interest in using your Coded Information and biological samples, images and/or audio/video recordings, if collected as part of the study, in the future to support and advance other scientific research projects, including improving the quality, design and safety of other research studies, research supporting public health aims and developing medicines, vaccines, diagnostic products and tools.

At this time, we do not know the specific details of these research projects; however, your Coded Information and biological samples, images, and/or audio/video recordings, if collected as part of the study, could be used in combination with data from other sources, not related to you or this study. Reasonable safeguards will be used to protect your Coded Information, biological samples, images and/or audio/video recordings used in any future research and may include: (a) limiting access to individuals bound by duties of confidentiality; (b) taking steps to minimise the risk that you could be re-identified; and (c) obtaining approval of ethical review boards. Furthermore, if your Coded Information and biological samples, images and/or audio/video recordings, if collected as part of the study, are anonymised such that they can no longer be identified with you, they may be used for future research purposes.

D. What are your rights to your personal information?

You may request access to your personal information, to correct, delete or restrict its processing; however, these rights are limited, as your information needs to be managed in specific ways in order for the research to be reliable and accurate or to comply with legal duties. The right to object to further research may also be limited by applicable law. To exercise any of these rights, contact the study site (please see the **contact information at section 21** of the main consent document) and not the Sponsor. However, you may find contact details for the Sponsor's data protection officer at DPO.Pfizer.com. You also have the right to file a complaint with a Data Protection Authority in the place you live, work or where any breach of data protection law may have occurred. Contact details of UK and EU Data Protection Authorities can be found by consulting the list here: http://ec.europa.eu/justice/data-protection/article-29/structure/data-protection-authorities/index_en.htm.

E. What happens to your information, and biological samples, images, and/or audio/video recordings that may be collected as part of the study if you do not wish to continue with the study?

As noted in the main consent document, you are free to stop taking part in this study at any time. If you stop taking part in the study and you do not tell the study team, your contact information may be used by the study team to contact you, your family or your personal doctor, or to search publicly available records to find out how you are doing.

These uses of your information may continue until the Sponsor determines the study is complete, which may take many years. Your information will continue to be used in accordance with the main consent document, this Privacy Supplement and applicable law, as the Sponsor needs to manage your information in specific ways

in order for the research to be reliable and accurate. The Sponsor, may continue to use your Coded Information even if you stop taking part in some or all of the study activities as necessary for the Sponsor (a) to comply with its legal and regulatory obligations; (b) for the Sponsor's legitimate interests in guaranteeing the integrity of the study and ensuring high standards of quality and safety of its products and advancing public health and scientific research and publishing the results of its studies; and (c) any other purposes permitted under applicable data protection and privacy laws.

No new information, biological samples, images and/or audio/video recordings will be collected about you or from you by the study team, unless you have told the study team that you agree to provide new information or samples. Even if you do not agree to the collection of new information or samples, the study team may continue to report any adverse effects or other safety event that you experience due to your participation in the study to the Sponsor.

In the event the Sponsor has already removed all information that could reasonably be used to identify you, it may use all resulting anonymised data for any purpose.

Any biological samples that have been collected about you or from you will be handled as described in the "What if I change my mind" section in the main consent document.