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**OPACE TRIAL: Optimising azithromycin prevention treatment**

**in COPD to reduce exacerbations**

You are being invited to take part in a research trial because you have a condition called chronic obstructive pulmonary disease (COPD) and are on long term azithromycin (or an equivalent macrolide antibiotic) for this. Please take the time to read the following information carefully and ask us if you have any questions.

There is also video that also explains the OPACE trial which you may find helpful to view if you have access to the internet. You can access the video here via this link <https://opacecopd.org.uk/participant-information/> or scan the QR code below.



MORE INFORMATION IS AVAILABLE AT [www.opacecopd.org.uk](http://www.opacecopd.org.uk)

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge are the joint Sponsors (responsible organisations) for the OPACE trial being conducted across the UK, and the trial is funded by the National Institute of Health and Care Research.

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

You have a condition called COPD (‘Chronic Obstructive Pulmonary Disease’) and are prescribed a long-term treatment called azithromycin or another equivalent macrolide antibiotic to reduce the chance of flare-ups (also called exacerbations) occurring. Azithromycin and equivalent macrolides are types of antibiotic medicine. However, side effects of azithromycin or equivalent macrolide antibiotics may affect some people. Azithromycin/equivalent macrolide antibiotics can sometimes cause heart problems, hearing problems and antibiotic resistance is a concern with long term treatment.

We currently do not know whether to advise people to continue or stop taking azithromycin once their COPD has become more stable, or whether to advise them to stop it over the summer when fewer flare-ups tend to occur. We also do not know if azithromycin is more effective in some people or more likely to cause side effects in others. The purpose of this trial is to be able to answer these questions to find out how best to use azithromycin in managing COPD.

Within the trial in addition to finding out how best to use azithromycin in COPD, we also aim to find out more about frailty in people with COPD from the trial data collected. We also aim to answer important questions about best approaches to aid recruitment and retention in clinical trials.

**2. What is the drug being tested?**

Long term azithromycin will be compared to either dummy azithromycin (placebo pills), or a combination of azithromycin over the winter (six months of azithromycin from October to March) and dummy azithromycin (placebo pills) over the summer (six months of placebo from April to September).

**3. Why have I been invited?**

You have been invited to participate in this trial because you have COPD and are prescribed long term treatment azithromycin or equivalent macrolide antibiotic for COPD flare-ups. We plan to include 1311 participants with COPD on azithromycin from 135 GP practices or hospitals across the UK. Your trial research team who will be your point of contact for the trial and any trial queries, will monitor you during the trial.

**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. However, you are still free to change, reduce or completely withdraw your participation after you agree to join this trial and can do so at any time. Any period of participation in the trial, even if short, is greatly appreciated and valued and will help us with much needed evidence we hope to gain from the trial.

It is important to know that if your trial team or clinical team think your participation in the trial has to change or be stopped, in order to protect your safety or well-being, then this will be explained to you. If you choose not to participate, change your participation or to leave the trial, your future medical treatment and normal standard of care will not be affected in any way.

**5. What will happen if we lose contact with you*?***

We may use telephone, email or post as a means to contact you. We may also contact your next of kin if you have provided the trial team with their contact details.

**6. What will happen to me if I take part?**

If you agree to take part in this trial, you will be asked to sign the Informed Consent Form at the end of this document and you will be given of copy of this to refer to later.

If you take part in the trial you will be randomly allocated by a computer system to a trial medication arm, which will be either:

* Azithromycin (provided as a trial medication but will match your routine prescription), or
* Placebo (dummy azithromycin), or
* Azithromycin in the winter months, placebo in the summer.

The trial medication prescription will match your azithromycin routine prescription. However, you and your trial team will not know if you are on real azithromycin or dummy azithromycin to avoid any influence on the trial results, but your trial team can find out if necessary.

Please be aware, tablets may vary from your regular azithromycin prescription and may vary slightly in appearance in different batches - this is perfectly normal and is nothing to be concerned about.

You will be part of the study and followed up under the care of the trial team for about 24 months. It may be shorter than this if the trial finishes sooner. In the trial, if you have a flare-up or exacerbation, it is important to let us know as we may decide to stop your trial medication and advise you to restart your routine prescription. We would still like to follow you up in the trial if this is the case and you are happy for this.

You will have **three trial visits:** one at baseline on entering the study, then at 12 and 24 months. The first trial visit may be up to 1 hour long. Visits 2 and 3 may last about 30 minutes.

**We can arrange for any or all the trial visits including baseline to be conducted remotely while you are at home (phone or video consultation), if you prefer**. The trial medication will be delivered to your home. We will ask for your age, ethnicity and sex as part of the study. This is to enable anonymised reporting of these characteristics in the final report of the study.

The phone calls will be about 10 minutes long. We will telephone you. We will ask you to complete some questionnaires which are about your COPD, symptoms and general mental health.

There is a blood test and breathing test at baseline if this is possible to arrange and only if you are able to.

You will be given a diary card to record information about your flare-ups. We will ask you to let us know when you have a flare-up if possible. Your trial research team will explain to you how to let them know this information. As mentioned above, your trial team may decide that you stop your trial medication and restart your usual azithromycin prescription based on this information, so it is important to let us know.

We will analyse data whilst the trial is active rather than just at the end of the trial. This is because we may decide to stop one of the trial arms if needed. If the trial medication arm you are assigned to is stopped, we will inform you and your GP as soon as practically possible. You may restart your usual azithromycin prescription if advised to by your doctor or nurse.

If you have stopped trial treatment for any reason, and if you are able and willing to continue trial visits, we will still arrange these. However, if you do not want to continue with trial visits either, with your consent we can use routinely collected healthcare information for trial purposes until the end of the whole trial. This information is available to us via your electronic heath records and would not require you to do anything further.

We will let your GP know you are taking part in the trial. If anything comes up in the trial which may be important for you and your GP to know for your general and mental health, we will inform both you and your GP. You will not need to take your regular azithromycin prescription from your GP whilst you are on the trial.

**7. Sub-study to gain your feedback on your experience of the OPACE trial:**

An optional sub-study of the OPACE trial to gather feedback on your participation in this clinical research trial will also be offered to you. You do not have to participate in this sub-study, it is optional. The purpose of this sub-study is to gain important feedback from participants in the trial to help us improve how we conduct future research trials for participants. Patients with COPD have helped us in designing the trial and gaining feedback from participants in the trial is really important. We hope to survey about 100 participants. If we have reached a sufficient number of participants for this sub-study, we will let sites know straight away and you may not be able to take part.

If you consent to this sub-study, your trial team will send or give you a questionnaire to complete as a short survey of your experience. This is a short survey of your experiences soon after entering the study, around 6 months and possibly at end of the study. The survey can be given to you or sent out to you to complete and given back to your site, or returned in a stamped addressed envelope or can be conducted online (via a survey platform hosted by the University of Cambridge) if preferred. The survey is anonymous and does not require any identification and will ask about your experience with taking part in the OPACE trial, as well as some questions about age, ethnicity, whether you have a disability or not etc. This is to help us understand what other factors may influence whether a person will take part in research or not. You can select ‘prefer not to answer’ for any question.

In addition, we are planning to interview by telephone a smaller number of participants for more in-depth feedback. This is optional too. It is a one-off telephone call and will likely take place around 3 months from enrolment. You can consent to undertake the survey only and not the telephone interview. If you consent to the interview this will be conducted by the central OPACE clinical team at Cambridge University Hospitals NHS Foundation Trust. To enable the team to do this and contact you to conduct the interview, your contact details will be sent via a secure email from your local site to the central OPACE clinical team based at Cambridge University Hospitals NHS Foundation Trust. It is anticipated the interview will be about 20-30 minutes long and it takes place once only. We will arrange with you a time convenient to telephone you and we will call you. The call will be recorded if you consent to take part in the interview, to allow us to analyse for themes that may be important regarding participants experiences of taking part in the research trial. We will store your audio file which will be password protected on a secure NHS computer until a script of the file is made. In the script, any identifiable details for example, your name(s) will be removed. The audio file will then be destroyed, and the anonymised script will be stored in a password protected file on a secure NHS computer.

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

The possible disadvantage may be that you experience more flare-ups of your COPD; or you may experience side effects related to azithromycin, although you have been on it (or another equivalent macrolide) for a while. You will be followed up during the trial, and it is important to let us know this type of information. We may decide to stop your trial medication because of it.

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

You may have no personal benefit from taking part in this trial. You will have trial related monitoring and interactions with healthcare professionals during the trial. You may experience fewer azithromycin related side effects. However, the results from this trial will benefit patients with COPD in the future because it will help us know how best to use azithromycin long term treatment for people with COPD. Information from the trial will also help us better understand frailty in COPD from the data we collect as we follow patients up. We also hope to gain information to answer important questions about best approaches to aid recruitment and retention to clinical trials.

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

**Azithromycin**: is a licensed medication, therefore expected side effects are well known. All medications can have side effects. Although you are already on azithromycin (or equivalent macrolide antibiotic), it is important as part of the trial to let you know side effects of the drug (azithromycin) being tested.

**Very Common** (more than 10 in 100 patients): diarrhoea, abdominal pain, flatulence, nausea.

**Common** (less than 10 in 100 patients): vomiting and heart burn, loss of appetite, dizziness, rash, itching headache, change in taste, burning/tingling sensation, visual impairment, joint aches, fatigue, blood test changes, deafness (this could be irreversible)

**Uncommon** (less than 1 in 100 patients): include abnormal blood tests, gastrointestinal symptoms, liver inflammation, ringing in the ears, vertigo, palpitations, infection including thrush, numbness, sleep disorders, skin disorders, allergic reaction.

**Placebo:** the placebo or dummy pill used in this trial will not contain any active ingredients. There are no known side effects of the placebo.

**11. What will I have to do?**

You will be in the trial for about 24 months. We will provide you with a diary to record any flare-ups and you should let us know if possible if you do have a flare-up as we may decide to stop the trial medication. Trial medication will be delivered to your home. You will be telephoned in the trial and this can be scheduled at a time/date expected for you to answer the call. If you have any concerns about the trial, please contact your trial team to discuss using the contact numbers at the end of this information sheet. If you are feeling unwell, then please seek medical help as you normally would, but let your trial team know when you are able to.

You should discuss your participation in this trial with any insurance provider you have (e.g. travel insurance, 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.

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

Standard treatment is continuing azithromycin long term treatment or a withdrawal trial of azithromycin over the summer or completely at the suggestion of your doctor or nurse. We currently have no information or evidence on these approaches, which is why we are doing this trial.

**13. Pregnancy and contraception information?**

Although this may not apply to you, we have to explain to everyone the following:

Although azithromycin is considered safe in pregnancy, women who are planning pregnancy, or are pregnant or breast feeding should not take part in the trial.

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

When the trial has stopped, you will return to standard treatment with your regular prescription of azithromycin if advised to restart this by your doctor or nurse. This prescription will be provided either by your local pharmacy or hospital pharmacy.

**15. Expenses & Payment?**

We are unable to pay you for participating but we are able to reimburse your travel expenses to and from the site for the trial-related visits. It is important that you keep any travel related receipts and request a claim form at your trial-related visit, if appropriate. Details of how and when payments will be made are available from the trial team.

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

Your trial team will contact you to discuss any new information which might affect your decision to continue in the trial. If you still 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 team may decide to stop the trial at any time. If that happens, we will tell you why the trial has been stopped and arrange for appropriate care and treatment for you.

**17. What if I decide to change or stop my participation in the trial?**

If you want to stop the study treatment or withdraw from the trial early, then you are free to do so without it affecting your future care or medical treatment. You have the options of:

* Stopping the trial treatment but you continue to have scheduled trial follow up and electronic healthcare data collected.
* Stopping treatment and scheduled trial follow up but you allow the team to continue to collect data from e-healthcare records, which would have no burden or input required from you.
* Full withdrawal from the trial, in which case no more data will be collected about you at all but data collected up to that point will still be used in trial analysis.

If you decide that you do not wish any more information to be collected about you, feel free to say so, but bear in mind that the de-identified information that has been collected up to that point will continue to be analysed by the research team.

Your trial team may also choose to withdraw you from the trial treatment if they feel it is in your best interests.

**18. 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 or nurse who will do their best to answer your questions.

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

Cambridge University Hospitals NHS Foundation Trust, as a member of the NHS Clinical Negligence Scheme for Trusts, will accept full financial liability for harm caused to participants in the study caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participating in the study, but no-one has acted negligently.

The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participating in the study.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this trial, you can do this through the NHS complaints procedure. In the first instance it may be helpful to contact the Participant Advice and Liaison Service (PALS) or equivalent service at your trial research site. Please see contact details in section 26 of this form.

**19. How will we use information about you?**

Cambridge University Hospitals NHS Foundation Trust (CUH) and The University of Cambridge are the joint Sponsors for this clinical trial based in the United Kingdom.

Cambridge University Hospitals NHS Foundation Trust is the Data Controller for the OPACE trial. This means that it is responsible for looking after your information and using it properly in a fair, lawful and secure manner. We will need to use information fromyou, your medical records and your GP for this research project. This information will include your initials, NHS number, name, date of birth, contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. It may be necessary sometimes for personal data to be transferred between trial sites in relation to participation in this trial. Any personal data will be sent or shared using appropriate secure transfer methods. With your consent, only your contact details and trial prescription will be shared securely to the trial’s central pharmacy to enable dispensing and delivery of trial medication. This pharmacy will not share any of these details provided, and will only use these for the purpose of dispensing and delivering trial medication to your chosen delivery address.

As part of your participation in the OPACE trial, in addition to the information you provide about your health, the research team in Cambridge University Hospitals NHS Foundation Trust will ask for information about your health from NHS England (including, but not limited to, NHS England, Office of National Statistics). We will send your name, date of birth, NHS number and postcode to NHS England (or other central NHS bodies) who can link this information to your centrally held records. NHS England can provide the study with relevant health information about study participants, such as those who have died, including the date and cause of death (on behalf of the Office of National Statistics) and information on your hospital attendances. Your health data information will be requested for the duration of the trial only, i.e., up to the close of the trial.

This information obtained from NHS England for the purposes of the trial will not be shared beyond designated individuals in Cambridge University Hospitals NHS Foundation Trust trial team who will manage this data from NHS England.

Other de-identified information about your health and care that are relevant to the trial may be made available for other research studies run by CUH and/or the University of Cambridge or other organisations. 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. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make automated decisions about future services available to you, such as insurance or marketing. Making information from trials available for further research helps maximise the benefit of conducting trials and allows other researchers to verify results and avoid duplicating research.

We are also asking for your permission to approach you about taking part in future research studies that are not related to OPACE. This is optional, and should you not wish to be approached about future research studies, you will still be able to participate in the OPACE trial.

If you agree, it means that you are allowing our researchers to keep your contact information and use it for the purpose of contacting you if they think you might be suitable for a particular research study. It is possible that they may not contact you at all, or they may contact you about a study that’s not directly relevant to your symptoms. If you agree to be approached, there is no commitment to take part in any particular research study and you can also let us know at any point if you change your mind and no longer want to be approached about future research. Any future research we contact you about will have received approval from an Ethics Committee.

The current regulation is that once the trial has come to an end and the anonymised analysis has been reported to the relevant authorities, essential trial documentation which may include identifiable data will be stored for a period of 5 years. Following this, the data will be securely destroyed.

### 20. What are your choices about how your information is used if you withdraw from the trial?

* You can change or stop taking part in the trial at any time, without giving a reason, but we will keep information about you that we have already collected.
* If you choose to completely stop taking part in the trial (stop treatment and visits), we would like to continue collecting information about your health from central NHS records, your hospital, your GP. If you do not want this to happen, tell us and we will stop.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

**21. Where can you find out more about how your information is used?**

You can find out more about how we use your information:

* At [www.hra.nhs.uk/information-about-participants/](http://www.hra.nhs.uk/information-about-patients/)
* Within our leaflet available from [www.hra.nhs.uk/participantdataandresearch](http://www.hra.nhs.uk/patientdataandresearch). Or please visit, for Cambridge University Hospitals NHS Foundation Trust: [https://www.cuh.nhs.uk/participant-privacy/](https://www.cuh.nhs.uk/patient-privacy/).

For University of Cambridge:

<https://www.medschl.cam.ac.uk/research/information-governance> or email The Information Governance team at: [researchgovernance@medschl.cam.ac.uk](mailto:researchgovernance@medschl.cam.ac.uk)

* By asking one of the research team (see contact details in section 26 below)
* by sending an email to [cuh.gdpr@nhs.net](mailto:cuh.gdpr@nhs.net)

**22. What will happen to my samples?**

There are no specific samples stored in this trial. If you have a blood test done it will be processed and analysed via NHS laboratories, and the results recorded in the trial. No samples will be stored for research.

**23. What will happen to the results of the trial?**

The results will be published in peer reviewed medical journals and used for medical presentations and conferences. The results of the trial will be thoroughly anonymised, and you will not be able to be identified from any of the data published. We will produce a participant leaflet which will explain the trial results once published. We will also publish results on the website. Your local trial team will be able to provide this to you.

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

The trial is being fundedby the NHS NIHR (National Institute for Health and Care Research).

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

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by the London Central 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.

**26. Further information and contact details**

**In normal office hours, please contact your OPACE Trial Team: (enter Generic email & Telephone number [delete if appropriate])**

Principal Investigator, Dr ### ######

Co-Investigator, ### ######

Research Nurse, ######

(update as applicable at local site)

Your trial Patient Advisory Liaison Service (PALs)/equivalent service/GP Practice Manager (delete as appropriate) contact is:

**In the event of a medical emergency, please contact 999 or 111**

On the next pages are Informed Consent Forms. These are provided together with this Participant Information Sheet Version ## Dated [###] to show what the consent form looks like and what it includes. Please do not fill them in yet. Two copies of the informed consent form are provided with this pack, so that if your consent consultation is conducted remotely, you will keep one signed consent form and will post back/arrange to send back the other signed consent form.

**Principal Investigator:** [Printed name to be inserted]

**Site:** [Printed name to be inserted]

**Participant ID Number:** \_\_\_\_\_\_\_\_\_

If you agree with each sentence below, please initial the box **INITIALS**

|  |  |  |
| --- | --- | --- |
| 1 | I have read and understood the Participant Information Sheet version ##, dated #### 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 by participating in this trial, I may need to stop taking the medications that I am already on. |  |
| 4 | I understand that personal information about me will be collected and used in accordance with this information sheet. This information will be kept in the strictest confidence. I will not be identifiable in any results published. |  |
| 5 | I understand that sections of my medical notes or information related directly to my participation in this trial may be looked at by research personnel, responsible individuals from the sponsor and regulatory authorities 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. |  |
| 6 | I understand that my GP will be informed of my participation in this trial and sent details of the OPACE trial. My GP may also be informed of any clinical finding from the trial that may require follow up. I will also be informed if this is the case. |  |
| 7 | I understand that you wish to access my health records held with NHS England and other central UK government bodies that collects outcomes data for linkage, and to do this you will send my NHS number, date of birth and post code to these organisations to link to relevant health data such as, hospital admissions (Hospital Episode Statistics (HES)) and mortality data.  Relevant health data for the duration of the trial will be sent to the study team. |  |
| 8 | I understand that my personal data might be transferred between the trial team at different trial sites in relation to my participation in this trial. I understand that any personal data will be sent using appropriate secure transfer methods. |  |
| 9 | I have read and understood the compensation arrangements for this trial as specified in the Participant Information Sheet. |  |
| 10 | 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. |  |
| 11 | I am happy for disclosure of my identity to the trial coordinating centre for contact (via post, email, or telephone) and follow up purposes for trial. |  |
| 12 | I am happy for disclosure of my contact details to the trial coordinating pharmacy to arrange home delivery of trial medication. |  |
| 13 | I understand that de-identified information collected about me may be used to support other research in the future, including research conducted by both commercial and non-commercial organisations in the UK and abroad. |  |
| 14 | If participant or Next of Kin contact is lost, then telephone, text, email or post methods may be used to contact. |  |

|  |  |  |
| --- | --- | --- |
| The following is OPTIONAL and is not required for OPACE trial participation.  If you agree with the sentence below, please initial each box.  If the initials box is left blank/not initialled we will consider this to mean you have declined consent for this specific statement | | **INITIALS** |
|  |
| 15 | I agree to participate in the participant experience feedback survey and be contacted by the OPACE trial coordinating centre for this. |  |
| 16 | I agree to participate in the participant experience feedback telephone interview and be contacted by the OPACE trial coordinating centre for this. |  |
| 17 | Please can we contact you about any sub-studies to this OPACE trial. |  |
| 18 | I agree to be approached to take part in future studies that may not be directly related to the OPACE trial, as outlined in the information sheet. |  |

**I agree to participate in this trial:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Full Name of participant

(First name, Surname) Date Signature

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Full Name of person

taking consent

(First name, Surname) Date Signature

If consent is taken remotely, only the participant will sign the consent form. Instead, the person taking consent will fill in a Confirmation of Consent Form.

**For the participant:** Please put your initials in this box below ONLY if this consent form is completed remotely (for example via a telephone consultation):

|  |
| --- |
| **INITIALS** |
|  |

Time of Consent (24hr clock) \_\_\_\_\_\_\_:\_\_\_\_\_\_\_

1 copy for the participant, 1 copy for the trial team, 1 copy for the patient’s medical notes.

**Principal Investigator:** [Printed name to be inserted]

**Site:** [Printed name to be inserted]

**Participant Number:** \_\_\_\_\_\_\_\_\_

If you agree with each sentence below, please initial the box **INITIALS**

|  |  |  |
| --- | --- | --- |
| 1 | I have read and understood the Participant Information Sheet version ##, dated #### 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 by participating in this trial, I may need to stop taking the medications that I am already on. |  |
| 4 | I understand that personal information about me will be collected and used in accordance with this information sheet. This information will be kept in the strictest confidence. I will not be identifiable in any results published. |  |
| 5 | I understand that sections of my medical notes or information related directly to my participation in this trial may be looked at by research personnel, responsible individuals from the sponsor and regulatory authorities 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. |  |
| 6 | I understand that my GP will be informed of my participation in this trial and sent details of the OPACE trial. My GP may also be informed of any clinical finding from the trial that may require follow up. I will also be informed if this is the case. |  |
| 7 | I understand that you wish to access my health records held with NHS England and other central UK government bodies that collects outcomes data for linkage, and to do this you will send my NHS number, date of birth and post code to these organisations to link to relevant health data such as, hospital admissions (Hospital Episode Statistics (HES)) and mortality data. Relevant health data for the duration of the trial will be sent to the study team. |  |
| 8 | I understand that my personal data might be transferred between the trial team at different trial sites in relation to my participation in this trial. I understand that any personal data will be sent using appropriate secure transfer methods. |  |
| 9 | I have read and understood the compensation arrangements for this trial as specified in the Participant Information Sheet. |  |
| 10 | 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. |  |
| 11 | I am happy for disclosure of my identity to the trial coordinating centre for contact (via post, email, or telephone) and follow up purposes for trial. |  |
| 12 | I am happy for disclosure of my contact details to the trial coordinating pharmacy to arrange home delivery of trial medication. |  |
| 13 | I understand that de-identified information collected about me may be used to support other research in the future, including research conducted by both commercial and non-commercial organisations in the UK and abroad. |  |
| 14 | If participant or Next of Kin contact is lost, then telephone, text, email or post methods may be used to contact. |  |

|  |  |  |
| --- | --- | --- |
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|  |
| 15 | I agree to participate in the participant experience feedback survey and be contacted by the OPACE trial coordinating centre for this. |  |
| 16 | I agree to participate in the participant experience feedback telephone interview and be contacted by the OPACE trial coordinating centre for this. |  |
| 17 | Please can we contact you about any sub-studies to this OPACE trial. |  |
| 18 | I agree to be approached to take part in future studies that may not be directly related to the OPACE trial, as outlined in the information sheet |  |

**I agree to participate in this trial:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Full Name of participant

(First name, Surname) Date Signature

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Full Name of person

taking consent

(First name, Surname) Date Signature

If consent is taken remotely, only the participant will sign the consent form. Instead, the person taking consent will fill in a Confirmation of Consent Form.

**For the participant:** Please put your initials in this box below ONLY if this consent form is completed remotely (for example via a telephone consultation):

|  |
| --- |
| **INITIALS** |
|  |

Time of Consent (24hr clock) \_\_\_\_\_\_\_:\_\_\_\_\_\_\_

1 copy for the participant, 1 copy for the trial team, 1 copy for the patient’s medical notes.