Study Information and Consent Form for Adults	
Study Code	D6930R00002
Version	2.0
Date	16 September 2019

Study Information and Consent Form: The CORAL study

You are invited to take part in this study because you have chronic obstructive pulmonary disease (COPD). Whether you take part or not is completely up to you. Please take the time you need to read this information sheet and ask your study doctor or nurse any questions. You can talk to your family, friends or family doctor before you decide. If you decide to take part, the study will be discussed with you in more detail and then you will be asked to sign the consent form.

Why are we doing this study?

COPD is a common condition affecting nearly 250 million people worldwide. Patients with COPD are usually treated daily with inhalers that contain either one or two long acting bronchodilators, e.g. Duaklir® (to open up the airways), and for some patients inhaled steroids (to reduce inflammation). Patients often report symptoms of breathlessness and the need to take short-acting reliever medicines as needed such as Ventolin®. In addition, patients may also experience acute worsening of symptoms, termed exacerbations (‘flare-ups‘). We know that during a flare-up, patients may require extra doses of Ventolin, but we do not understand how this relates to changes in your symptoms, breathing tests or blood and sputum cells (measures of inflammation). The reason for the study is to have a better understanding of what happens to your symptoms, breathing tests and markers of inflammation on a day-to-day and week-to-week basis. This information will increase our understanding about COPD and how we may design new treatments for COPD in the future.

Who is doing this study?

The study is being performed by Professor Mona Bafadhel, at the Oxford University Hospitals NHS Foundation Trust in collaboration with AstraZeneca AB. AstraZeneca AB are providing funding for this study.

AstraZeneca AB, 151 85 Södertälje, Sweden is responsible for your personal information and any results from research described in this document are owned by AstraZeneca AB.

Who will take part in this study?

Approximately 60 adults, current or ex-smokers, with a diagnosis of COPD will be invited to take part in this study. You have been invited to participate because you have a diagnosis of COPD and are already receiving treatment with a rescue medication (e.g. Ventolin®) in addition to your daily inhaled COPD medication.

Do I have to take part in this study?

No, your participation is entirely voluntary. If you do decide to take part you are free to withdraw at any time without providing any reasons and this will not affect your clinical care in any way.

What will happen if I take part in the study?

Before the start of the study, after you have signed the consent form, the study team will check that you are suitable to take part. If you decide to take part, your study doctor may check your medical records, ask you questions or do some tests (e.g. breathing and blood tests) first.

If you are suitable to enter the study and you wish to continue to take part, the study doctor will ask you to replace your regular and reliever COPD medication to Duaklir® and Ventolin®, if you are not already taking these medicines. These treatments are standard treatments for COPD. Duaklir is taken as 1 inhalation twice per day (once in the morning and once in the evening) for regular treatment and Ventolin is taken on an as needed basis. These medicines will be taken throughout the study period, for a total of 16 weeks. At the end of the study period, you can discuss with your GP about staying on this medicine or going back to the medicines you were taking before you started.

Details of all tests are described at the end of this information sheet.

The schedule of study visits is described below:

Screening visit 1

At the study centre, after signing the consent form, the study team will:

Ask you questions about

- your medical history and previous medical conditions
- what medications you have previously taken and are taking now
- your demographic and lifestyle details

The study team will then do the following:

- Check your pulse and temperature, breathing rate, blood pressure, height and weight
- Perform a physical examination
- Take blood samples
- Collect a sputum sample and a swab from your nose
- Ask you to perform breathing tests
- Ask questions about your COPD using questionnaires
- Collect a urine sample
- Perform a urinary pregnancy test if required. If this is positive, then a blood test will be performed to confirm. If it is confirmed that you are pregnant, then you will not be able to continue with the study.
- Dispense the inhalers
- Seek consent to obtain a separate blood sample for genetic testing.

Finally the study team will provide the 'Study Kit' and teach you how to use this at home. The 'Study Kit' contains an 'Electronic Tablet' and 5 devices which are:

- Breathing devices (Spirobank, Vivatmo me and Resmon Pro Diary)
- Inhaler sensor (SmartTouch)
- Home monitoring system (Albus Home RD) this is an optional component of the study

Training on how to use the above devices will be provided by the research team if needed.

In addition, sample collection kits (sputum and nasal) will be provided. As these tests may be new to you, you will be given detailed instructions on how to use these and will be trained by the study team on how to use the electronic tablets, the devices and sample collection kits. You will be provided with a telephone number to contact the study site in case you have any technical difficulties with the devices. A trained member of the study staff team will visit your home at a time suitable for you to ensure devices and sampling equipment are set up in your home environment.

When you finish the study, you need to return all the equipment provided (i.e. the 'Study Kit') back to the research team.

Please note that following the screening visit, you may be found not eligible for participation in this study and you will not be able to continue.

Specific for oscillometry, Resmon Pro Diary:
Once you have consented to take part, your personal details (Name, Address, Telephone Number) will be passed on to the Engineering Team (Dolby Vivisol) to allow arrangements to be made for the delivery and then collection of the oscillometry device (Resmon Pro Diary). The Dolby Vivisol team will contact you directly to arrange a convenient time for their visits. Your details will be held securely and will only be used for the purpose of arranging the visits or technical support for the device during the study. When your involvement in the study finishes, Dolby Vivisol will be instructed to destroy your contact details.

Home assessments and using the 'Study Kit':

Using your 'Study Kit', you will perform measurements daily at home. The measurements are described in detail at the end of this information sheet and include measures of your health using questionnaires and breathing levels using 2 different devices and symptoms. This will initially be performed for a duration of 4 weeks between visit 1 and 2. Following review at visit 2, you may then be suitable to continue the study and will then be asked to complete the 'Study Kit' measures at home for the rest of the study duration (every day for the remaining 12 weeks).

All details about the 'Study Kit' are at the end of this information sheet.

Study centre visits 2-8:

You are asked to bring the 'Study Kit' with you to all visits to the study centre. At these visits, the following will happen:

We will ask you questions about:

- Your suitability to continue the study and confirm whether you wish to continue
- What medications you are taking now and whether there have been any changes
- Whether you have noticed any changes to your COPD symptoms
- Whether you have needed any extra medications for your COPD and if so, when were these taken

The study team will then do the following:

- Check your pulse and temperature, breathing rate, blood pressure, height and weight
- Perform a physical examination
- Take blood samples
- Collect a sputum sample and a swab from your nose
- Ask you to perform breathing tests
- Perform questionnaires
- Collect a urine sample
- Dispense inhalers every other visit
- Ask for any adverse events
- Provide additional training, if required, about the use of the 'Study Kit'

You will be considered to have completed the study when you complete the 12-week observational period and Visit 8.

Unscheduled visits:

If you experience any worsening of your COPD, you may contact the study team for a medical review. They may give advice over the telephone or ask you to come to the study centre for an assessment. If possible, you should continue to perform your morning assessments at home as usual. If you are asked to attend the study centre for a medical review, the following clinical assessments as part of usual clinical practice may be performed:

- Physical examination
- Vital sign checks, such as blood pressure, temperature and oxygen levels
- Chest x-ray
- Blood and sputum tests

The study team may then, if appropriate, prescribe medication to treat the worsening of the COPD as per usual practice (e.g. a course of steroids and/or antibiotics).

Genetic blood sample:

As part of this study, we would like to take an extra blood sample from you to look at your DNA. It is entirely up to you whether you donate this extra sample or not. You can still take part in this study, even if you do not agree to donate this extra sample.

Each person has genetic material (called DNA) in the cells of his/her body. The DNA contains genetic information (called genes) that determines a person's traits such as body structure and

function. Some of this genetic information is different from person to person (e.g. eye colour and blood type). Some of these differences in genes may make certain people more vulnerable to certain diseases than others. There is growing evidence that such genetic variations may also affect people's response to medicines. This DNA blood test will look at the effects of a person's genes on how medicines may work for that specific person. DNA genetic testing in this study is for research purposes only. We will not have results related to any potential genetic conditions that you may have as these results are all anonymised to us as the researchers. This optional blood sample will be used to study whether your genes have an effect on how proteins are broken down or moved through your body. The taking of this blood sample is entirely optional and will not directly benefit you; however, this additional information may help patients in the future. This additional, optional blood sample will be anonymised just like the other blood samples that will be taken. Your privacy is very important to the researchers and they will make every reasonable effort to protect it.

Unused parts of samples for further research

We might also like to use any unused parts of samples for further research (by Astra Zeneca AB and/or collaborators) to find out more about possible side effects, or how the medication works, or to find out more about any disease.

You can still take part in the study, even if you do not agree to the use of unused parts of sample(s) for further research. If you decide to stop taking part in the study please tell the study doctor if you want to change your mind about using extra sample(s) for further research.

Unused parts of samples for further genetic testing

We would also like you to agree to let us and/or other collaborators do further genetic testing on unused parts of samples you donate. Right now it is not known what the exact questions might be in this further testing. Possible questions might be to find out more about for example possible side effects, or about how the medication works, or to find out more about diseases, by looking at specific genes.

It is entirely up to you whether you agree to allow us to use the unused parts of your samples.

You can still take part in this study, even if you do not agree to the use of unused parts of sample(s) for genetic testing. If you decide to stop taking part in the study please tell the study doctor if you want to change your mind about using donated sample(s) for further genetic testing.

In case of pregnancy

If at any time during the study you suspect that you may be pregnant, please inform the study doctor immediately. If the pregnancy is confirmed, the study doctor will ask for information

about the pregnancy. To ensure that any risks to the unborn child are detected as early as possible, we will review relevant medical records. The outcome of all pregnancies will be followed up and documented even if you have discontinued from the study.

What will I have to do?

- If you agree to be in this study, you will be asked to sign this informed consent and you will be asked to attend your study appointments and have all the tests and examinations described above.
- It is also important that you tell the study staff about any other medication you are taking before and during the study.
- You will be expected to attend all visits listed in the study schedule and any others that may be deemed necessary. Please inform the study doctor if you will not be able to go to a visit.
- You should be able to read, speak, and understand English; and be able to, in the study doctor's judgment, comply with the study requirements.
- Women who are of childbearing potential should have a negative urine pregnancy test at Visit 1 to participate in the study.
- You are not allowed to take part in any other research study with any approved or experimental medical interventions while you are in this research study. You study doctor will explain in detail regarding the restricted medications. If you have any health care contact such as with a doctor or a dentist, tell them that you are in this research study.

What are the possible side effects, risks and discomforts?

None of the COPD medications that will be used are new. All of them have been approved for use in clinical practice by European and UK Health Authorities, based on their proven safety and efficacy profile. Therefore, the risks involved in taking any of these medications is the same as if they were prescribed to you by your family doctor outside of the study.

As with all research studies, the tests and medicines may involve unknown risks. Duaklir/Ventolin can have side effects and can cause unforeseen adverse reactions. If you have any side effects or are worried about them, please talk with the study doctor. Your study doctor will discuss the best way of managing any side effect with you. If you experience any side effects that in the opinion of the study doctor requires you to be discontinued from the study, you will be followed up until your condition is stabilised. If you do not understand what some of the side effects or risks mean, ask the study doctor or the study staff to explain them to you.

How will my personal information and study samples be handled and used?

To get the answers we need from the study described in this study information and consent form, we have to collect personal information about you and your health. This includes

information collected at your hospital during this study and also information that is already in your medical records. As well as information about your health we need information such as your age, sex, and race. The study team will also collect personal identifiable data for purposes of study contact, e.g. your address, to be able to visit your home to set up devices. Results from the tests and examinations mentioned in the section "What will happen if I take part in the study?" are also included as part of your personal information.

We will do everything we can to make sure that no one, except your study team and study inspectors, know who you are. We do this by using a code instead of your name and only these people will have the key to the code. We will make sure your personal information is protected. Health authorities and people helping AstraZeneca AB to run the study, including members of the AstraZeneca group of companies, contractors, sub-contractors and any company that AstraZeneca AB goes into business with, or sells all or part of its business to, will be allowed to see your personal information but they will not know who you are unless they are study inspectors.

The personal information from this study may be kept for 15 years. You can find out more about how AstraZeneca group of companies keeps personal information at www.astrazenecapersonaldataretention.com. Results will be used to learn about COPD.

The use of your personal information for the purpose of conducting the research study as described above is based on Sponsor's legitimate interest of conducting research studies and public interest.

Results from this study will be published for example in medical journals or online, but you will not be mentioned in a way that would let people find out who you are. Researchers from for example AstraZeneca AB, other health related companies, and universities might ask to use information from this study, including your information and samples for other medical, healthcare or scientific related research. The researchers may combine the results from this study with results from other studies. If AstraZeneca AB shares your information, AstraZeneca AB will make sure that they cannot find out who you are and that such research is in line with this study information and consent form. The use of your coded personal information for these scientific research purposes is based on your agreement.

Your personal information may be sent to other country(ies)/outside the European Economic Area (EEA) since some of the recipients are based outside of your country. When we send your personal information to another country, the way we do it is either controlled by a contract approved by data privacy authorities or by AstraZeneca AB's own privacy rules which have been approved by privacy authorities (called Binding Corporate Rules). Your personal information will still be kept completely private, no matter which country it goes to,

even if that country does not have the same level of protection for personal information as United Kingdom.

You can ask your study doctor to see the information that has been collected about you. If you think any of it is wrong, you can ask your study doctor in writing if it can be changed or removed. You can also ask that we restrict the use of your personal information. If you change your mind about taking part, we cannot remove the personal information that was collected for this study before you stopped.

If you have questions about how we use your personal information or want a copy of the Binding Corporate Rules, please ask your study doctor first. You may also ask the Sponsor Data Protection Officer at privacy@astrazeneca.com or c/o the Chief Privacy Officer, AstraZeneca, Academy House, 136 Hills Road, Cambridge CB2 8PA, England. If you are not happy with the answers you get, you can complain via the NHS Complaints Procedure. Tel: 01865 235855 Email: PALS@ouh.nhs.uk.

The blood/nasal/sputum samples that you donate will be analysed for the purposes of this study. You will not get copies of the results. If you decide to stop taking part in this study your personal information and samples that we have already collected will still be used in the ways that you agreed to when you started in the study. You can discuss with your study doctor if you do not want this to happen. We will try to destroy samples, but if the samples are no longer linked to you, this might not be possible.

Your samples may be analysed or safely stored in another country but will always be coded. Some samples will be destroyed when they have been used for the purpose of the study or be kept longer than required, up to 15 years if you agree.

Will it cost me anything to take part?

We recognise that this is a demanding study requiring daily commitment from you if you take part. You will be reimbursed £10 per day for your time taken at home to complete all the assessments during the study. We will also reimburse reasonable travel expenses. Reimbursement will be paid after your last study visit.

What happens if I am injured while I am in the study?

If you have medical insurance, please check with your insurance company that taking part in this study will not affect your cover.

AstraZeneca AB may also compensate you in accordance with the law of United Kingdom and by signing this study information sheet and consent form you do not give up any legal right you may have.

If you become ill or are injured while you are in this study, you must tell your study doctor straight away. Injuries that have been caused by the tests or procedures are called 'research injuries'. Injuries caused by your usual medical care or your COPD, are not research injuries.

AstraZeneca AB has insurance to cover the costs of research injuries as long as you have followed your study doctor´s instructions. AstraZeneca AB will pay the costs of medical treatment for research injuries, provided that the costs are reasonable, and you did not cause the injury yourself.

Can the study be stopped, or can I be taken out of it?

You may be taken out of the study even if you are willing to carry on. Possible reasons for this are: your study doctor thinks it is better for you to stop; you do not follow the study instructions; AstraZeneca AB; health authorities, the ethics or regulatory agencies decides that the study must be stopped.

Who can I contact for information and help?

A Research Ethics Committee (REC) has reviewed the plans for this study to make sure that people who take part in this study are protected from harm.

If you have any questions about your rights when you take part in this study, you can contact:

PATIENT ADVICE AND LIAISON SERVICE (PALS) at PALS@ouh.nhs.uk or Tel: 01865 221473 or Tel: 01865 235855.

If you have any questions about the study, please contact:

Study doctor Prof Mona Bafadhel Dr Sanjay Ramakrishnan	Study Coordinator (e.g. nurse appointed to the study) Christine Mwasuku Karolina Krassowska
Phone No. 01865 612898	Phone No. 01865 227242
Address Respiratory Department Churchill Hospital Old Road Oxford OX3 7LE	Address Respiratory Medicine NDM-Experimental Medicine Division Level 5, Room 5061 John Radcliffe Hospital Headley Way OX3 9DU
Coral@ndm.ox.ac.uk or sanjay.ramakrishnan@ndm.ox.ac.uk	christine.mwasuku@ndm.ox.ac.uk karolina.krassowska@ndm.ox.ac.uk

Information about this study will be posted on http://astrazenecaclinicaltrials.com and http://www.clinicaltrials.gov. These websites do not contain any information about you.

Study Assessments *performed at the site*

Blood Pressure: An inflatable cuff will be placed on your arm and a machine will measure your blood pressure, 5 minutes after you have been lying on your back or after sitting on a bed/couch. You may experience mild discomfort in your arm while the cuff is inflated.

Spirometry: This is used to measure how well your lungs are functioning. This test measures the airflow in and out of your lungs. To take a spirometry test, you sit and breathe into a device called a spirometer, which records the amount of air you breathe in and out and the speed of your breath. We may ask you to do this test a maximum of 3 times.

Exhaled nitric oxide: This test will allow us to detect any inflammation in your lungs. You will be asked to blow into a machine at steady speeds for approximately 10 seconds. We will usually only ask you to do this once.

Blood Tests: Blood samples will be taken from a vein, in a fully sterile method, from your arm. This may cause some discomfort and bruising. The maximum amount of blood to be taken at each visit is 65 mL (no more than 5 tablespoons). Part of the blood sample will be sent to the hospital laboratory, which will include personal identifiable data, such as name, age and NHS number. The remainder will be sent to the university laboratory, in a fully anonymised format, with no personal identifiable information.

Sputum samples: We will ask you to produce a sputum sample at the study site visits by asking you to cough. On occasion if you have been able to, a sputum sample collected at home within 2 hours of attending the site is also appropriate (as long as it is not the first sputum sample of the day). Sometimes, if you are unable to produce a sputum sample by coughing, we prepare a sputum induction procedure. We will ask you to inhale different strengths of salty water via a nebuliser until we can produce a sputum sample. We will carefully watch you during this procedure tests to make sure that we can continue doing this test. On occasion a sputum sample may not be produced. The inhalation of salty water may cause some irritation leading to cough. On rare occasions you may experience some chest tightness, which is promptly treated by taking some extra puffs of your reliever medication such as Ventolin. Part of the sputum sample will be sent to the hospital laboratory, which will include personal identifiable data, such as name, age and NHS number. The remainder will be sent to the university laboratory, in fully anonymised format, with no personal identifiable information.

Nose swabs: We will ask you to blow your nose first and then test which nostril is ‘open’ by asking you to slowly breath in through each nostril one at a time. The nostril at which it appears easier to breathe will be the one we take the test from. We will then ask you to pass a small probe, which has attached on it a collecting sponge, into the ‘open’ nostril. We will then

ask you to hold this in place against the side of the nostril for a maximum of 60 seconds. The samples will be sent to the university laboratory, in fully anonymised format, with no personal identifiable information.

Urine tests: We will ask for a urine test at the study centre. We will test this for glucose, protein and cell count. If you are a female of child bearing age, we will also test this for signs of pregnancy. All urine samples will be discarded.

Questionnaires: You will be asked to complete up to 5 questionnaires at the study centre. These questionnaires have been previously tested and will require no more than 15 minutes of your time to complete.

Genetic blood sample: An optional blood samples may be taken, if you agree, from a vein in your arm during the study using either a needle for this testing (approximately 6 mL or a teaspoon). This will be sent to the university laboratory, in fully anonymised format, with no personal identifiable information.

‘Study Kit’ *assessments at home*

The ‘study kit’ will be provided to you packaged in a study bag with instructions for how to take each measurement, when to take each measurement, and who to contact if there is a problem. We would request that you bring the ‘Study Kit’ with you to each of the study visits for checks.

The ‘Study Kit’ contains the following:

Electronic tablet: You will be provided with an electronic tablet in order to collect and record the questionnaires and symptoms for the study. Each day you will need to complete several online questionnaires and use the **CORAL App** - an application with instructions on how and when to perform each breathing test and record additional symptoms, such as how you are feeling and how many times you have taken your Ventolin inhaler. At the study centre, on your first visit, you will be set up on this device, with a special email address and registration details. The study team will also show you how to navigate each part of the programs and the use of the other devices used in this study.

Exhaled nitric oxide (Vivatmo me): This test will allow us to detect any inflammation in your lungs. At steady state, you will have to blow into the

Vivatmo me device for less than 10 seconds. You will need to follow these instructions:

1. This test should be done first thing in the morning when you wake up.
2. You should not smoke, eat, drink, or take your inhalers for 1 hour before this test.
3. You record on the CORAL APP what time you last smoked, ate and drank before taking this test.

Inhaler sensor (SMART-TOUCH): At the first visit, we will attach this inhaler sensor to the Ventolin inhaler for you. This records the number of times that the inhaler is used in a day, automatically. If you finish the inhaler before you are next seen at the study centre, we would like you to replace the new Ventolin inhaler into the **SMART-TOUCH**, so that we get recordings throughout the study. If you usually use 2 inhalers, we will ensure that we provide you with 2 **SMART-TOUCH** devices. The study team will show you how to switch these at home.

Spirometry (Spirobank): This is a test you will be familiar with and should take no more than 2 minutes to perform. After you have taken your Duaklir inhaler, you will need to take a big breath in and then to blow out as hard and as fast as you can in the **Spirobank** device. We would like you to repeat this up to 3 times if you can and to do the test in the morning and in the evening.

Oscillometer (Resmon Pro Diary): This is a device for the assessment of lung function. In this test you will breathe into the oscillometer for 2 minutes at steady normal breathing, whilst you are holding your cheeks with your hands. The device will be set-up at home at the start of the study. At the end of the set time, the recording will automatically terminate, the data will be stored on the internal memory and sent to a data server and the device will switch off.

Home monitoring system (Albus home RD): If you consent to this, one of the research staff members will come to the home to set up this device. It is placed in your bedroom in order to measure your symptoms, by using

motion and audio sensors. The device is the size of an alarm clock and measures breathing patterns, records cough and wheeze (audio capture) and information about the local environment such as temperature. All the recordings, of motion and audio sensors are analysed such that speech or recognisable sounds are removed electronically at the outset. However, in order to provide you with further privacy from the audio recordings, we have put in place the following:

1. Set the audio recording to start after your usual bedtime

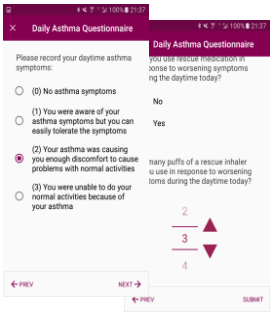
2. Allow a 'snooze' action, where a button can be pressed to stop the device for 1 hour (pressed once) or for the whole night (press and hold for 3 seconds)

3. Contact the research team to let us know (without reason required) if you want any recordings to be deleted.

We would ask you to

I. Keep the device plugged in at all times. It uses the same amount of electricity as a mobile phone charger and costs approximately 1.5 pence per day.

II. Bring along the device to each of the site visits so that the study staff can remove the storage card and provide a new one.



Questionnaires: Each morning you will be asked to rate how much five symptoms related to your COPD are currently affecting you on a scale of 0 (not affecting you) to 100 (the worst you've ever experienced). Each evening you will be asked to complete two questionnaires (BCSS and EXACT-RS) which also relate to your symptoms on that day. You will receive a message on your tablet device reminding you to complete these questionnaires.

Sample collection (*white polystyrene box)*

We would like you to send a sputum and nose swab sample at the same time once every two weeks. These will alternate with the study site visits. Sputum and nose swab samples will be collected as shown at the study centre and are as described here again:

Sputum: To produce a sputum sample, you need to cough into the provided sputum pot. You should avoid using the 1st sputum sample of the day as this often doesn't contain useable cells or material.

Nose swab: To perform the nose swab, blow your nose first and then test which nostril is 'open' by slowly breathing in through each nostril one at a time. The nostril at which it appears easier to breathe will be the one you use. Then take the small probe, which has attached on it a collecting sponge, into the 'open' nostril. Hold this in place against the side of the nostril for a maximum of 60 seconds. Take this probe and place it in the nose pot provided.

As soon as you have produced these samples, we request that you to contact the research team on the agreed number. A courier will then be arranged to come and pick up the sample from you in the sample collection box (white polystyrene box). We will aim to arrange this for collection within 60 minutes of you contacting the study team.

The order of the testing and use of the 'Study Kit' are as follows:

Morning:

1. Collect sputum and nose samples and contact research team for courier to pick up
2. Turn on Electronic tablet
3. Vivatmo me
4. Resmon Pro Diary
5. Take Duaklir inhaler
6. Spirobank

Evening:

1. Take Duaklir inhaler
2. Spirobank
3. Evening questionnaires

Detailed instructions on how to use the devices will be provided with the Study Kit.

Signature consent form

Study Code:	D6930R00002	Centre No:	
Sponsor:	AstraZeneca AB	Investigator:	
Study Title:	A 12-week Exploratory Study to Characterise the Relationship Between Changes in Inflammatory Markers, Lung Function, Symptoms And Reliever Use in Chronic Obstructive Pulmonary Disease Patients (CORAL)		

- By signing this study information and consent form you confirm the following:
- I have had time to read this information and think about the study and my questions have been answered properly.
- I agree to take part in this research study and provide samples as explained in the information sheet.
- I have been informed on the way my coded personal information and samples may be collected used and shared as described in this document
- I agree to my contact details (Name, Telephone Number and Address) being passed on to the Engineering Team (Dolby Vivisol) to allow arrangements to be made for the delivery and collection of the oscillometry device.

Please **initial** the 'Yes' or 'No' boxes below:

1. I agree that my GP can be told I am in this research study.	Yes	☐	No	☐
2. I agree that my coded personal data can be used for other medical, healthcare or scientific related research purposes.	Yes	☐	No	☐
3. I agree that the unused parts of my samples can be used for further research.	Yes	☐	No	☐
4. I agree that the unused parts of my samples can be used for further genetic testing.	Yes	☐	No	☐
5. I agree to donate an extra sample to look at my DNA.	Yes	☐	No	☐
6. I agree to take part in the Home Monitoring (Albus Health RD) assessment.	Yes	☐	No	☐

Oxford University Hospitals NHS Foundation Trust

Signature consent form

Signature of participant	Date and time of Signature
Printed name of participant	
Signature of person conducting the informed consent discussion	Date and time of Signature
Printed name of person conducting the informed consent discussion	

When signed and dated, we will give you a copy of this form and the original will be kept in the study site file.

Version history

Document Owner MICF Responsibility	Revision Date	Comments