PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

Study Number	**NG11-2-P1b**
IRAS No.	**1004528**
Study Title	**A Phase-1b Dose Escalation Study to Assess the Effect of NG11-2 on Radiation Induced Oral Mucositis in Patients with Head & Neck Cancer**
Sponsor Name	**VasoDynamics Ltd, Stevenage Biocatalyst Centre, Gunnels Wood Road, Stevenage, Herts, SG1 2FX**
Local Investigator	**Dr [XXX, Address]**

INVITATION

You are being invited to take part in a research study of a new formulation of a drug being developed to reduce the severity of radiation induced Oral Mucositis (**OM**), which typically appears as soreness and ulcers in the mouth during radiotherapy.

Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve.

Please take time to read this information carefully, and discuss it with friends, relatives and your General Practitioner (**GP**) if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

The study doctor, who is a member of your care team at the hospital, will talk with you about the research study and you will be given the opportunity to ask questions. Take your time to decide whether or not you wish to take part. Your decision to participate in this study is **voluntary**, and deciding not to participate will not affect your medical care.

If you need this document translated into another language, please tell your study doctor or nurse, and this will not prevent your participation.

A short video outlining the study is available here:

www.vasodynamics.co.uk/clinical-trial-patient-information

A list of the sections in this document is provided below:

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WHAT IS THE PURPOSE OF THE STUDY?

This study is being undertaken to see if the investigational drug, called **NG11-2**, can reduce or prevent the development of severe Oral Mucositis (**OM**) during radiotherapy for the treatment of Head and Neck cancer.

NG11-2 is a special liquid mixture ("formulation") of a well-known substance called Adrenaline. Adrenaline is a natural part of your body's hormone system and has been used in many patients over many years to treat a range of different conditions in various forms such as an injection, an inhaler, an eye treatment, and oral medicine in dental procedures. Thus a large number of patients have been exposed to Adrenaline as a medicine over many years.

The NG11-2 formulation of adrenaline is new and 3 clinical trial patients have been treated with this formulation containing substances very similar to adrenaline.

This study is designed to find the best dose of NG11-2 to give in order to reduce or prevent severe radiation induced OM developing during radiotherapy.

WHY HAVE I BEEN INVITED?

You are being asked to participate in this research study, because you are undergoing radiotherapy treatment for your cancer and may be at risk of developing severe radiation induced OM. Researchers want to know if giving you NG11-2 as a mouthwash before radiotherapy each day can reduce or prevent the development of severe Oral Mucositis.

Approximately 20-30 patients with Head and Neck cancer will take part this study from about 6 NHS hospitals in the UK.

DO I HAVE TO TAKE PART?

No, your participation is entirely **voluntary**, which means it is up to you to decide whether or not you want to take part.

If you do decide to take part, you will be asked to sign this consent form.

If you choose not to participate there will be no effect on your medical care, or to the treatment to which you are otherwise entitled.

You can choose to withdraw from the study at any point, or to stop study treatment, without needing to give a reason, and without this affecting your future medical care.

WHAT IS THE CURRENT STANDARD CARE FOR ORAL MUCOSITIS AND WHAT ARE MY OPTIONS?

Currently, there is no consistent Standard Care available for Oral Mucositis treatment, although there are some options which have a limited effect; as per current NHS guidelines, these are:

- Mouthwashes that clean, numb and protect your mouth
- Painkillers
- Sprays or gels to keep your mouth moist (saliva substitutes)

WHAT WILL HAPPEN TO ME IF I AGREE TO TAKE PART?

If you take part in the study, you will receive the normal Standard Care and Treatment for your cancer at your hospital, and an additional mouthwash treatment with the NG11-2 study drug.

You will also undergo some additional tests during the screening and treatment periods. These tests are detailed in Appendix 1 and include blood testing, ECGs, oral examinations and vital sign checks. During the treatment period you will also be asked to complete a simple questionnaire twice weekly.

All patients who take part in the study will receive NG11-2 study drug.

Participation in the study may take up to 13 weeks.

Before you begin the study:

If you decide to participate in this study, you will sign this consent form before any study-related procedures are performed, or you are treated with NG11-2.

The procedures and tests that you will undergo as part of the study are described below and a detailed list of all study procedures is given in **Appendix 1**.

Screening Visit (Approximately 2 hours)

Up to 14 days before you receive your first NG11-2 treatment, the study doctor will perform some tests to confirm whether or not you meet the criteria to join the study. Most of the tests are routine, for example, blood pressure, physical examination, and blood sample for lab tests (10-15mL or 2-3 teaspoons of blood).

You may have these tests as part of your usual clinic visits but if you need to make an additional visit to have some of these tests; your doctor and nurse will advise you of this, and travel expenses will be available for these additional visits.

If you meet the criteria for participating in the study, you will be enrolled to receive the NG11-2 study drug at one of the following dose levels: 0.9mg/mL, 1.8mg/mL, 3.6mg/mL and 5.5mg/mL. The dose level you receive will depend upon the time when you join the study and upon the results from previous NG11-2 dose levels received by other study participants. Your doctor will inform you which dose you are receiving.

During the study:

Each week during the study you will continue to receive your normal treatment for your cancer i.e. radiotherapy as agreed by your doctor in your individual treatment plan.

At the start of each week of your study treatment, you will undergo some tests to ensure that you can continue in the study; these will include blood tests, an ECG and physical examination.

The NG11-2 mouthwash treatment will be given to you on the same days as you receive your radiotherapy. The NG11-2 mouthwash treatment will be given as follows: -

- About 1 hour before your radiotherapy, the nurse will ask you about all medicines you are taking and whether you have had any problems ("Adverse events"). The nurse will also check your blood pressure and heart rate.
- If these checks are fine, you will be asked to rinse your mouth twice with room temperature water and then spit it out to clean out your mouth.
- You will then be asked to rinse your mouth with 12.5mL (a capful) of the NG11-2 study drug solution for between 1.5 and 2 minutes, and gargle twice if you can.
- You will then spit out the NG11-2 mouthwash.
- You should NOT swallow the NG11-2 mouthwash.

If you do accidentally swallow the mouthwash, this should not cause you any major problems because the adrenaline in the solution is inactivated very quickly by the juices in your digestive tract. Your study team will also provide advice and monitor you for up to an hour to ensure there is no discomfort and/or adverse effects.

Additionally, twice per week during treatment, your doctor or nurse will examine your mouth and you will be asked to complete a short (9 question) form about the condition of your mouth.

Your doctor and nurse are there to support you throughout the study. If you have any discomfort, abnormal feelings, anxiety or concerns, or would like some advice on continuing on the study, please feel free to talk to your doctor or nurse during your visit.

<u>At the end of the study:</u>

You will stop taking your NG11-2 study drug treatment once you have completed your radiotherapy treatment. You will then be asked to visit the hospital 4 times over the next 6 weeks, when you will have some follow-up tests to include blood tests, physical and mouth examinations.

ARE THERE ANY POSSIBLE DISADVANTAGES OR RISKS FROM TAKING PART IN THE STUDY?

If you decide to take part in the study, you will be monitored carefully and should report any problems you have at your clinic visit. You will also be given a contact number to telephone if you become concerned in any way at any time or need immediate advice on any symptoms.

Although the active ingredient (adrenaline) is a known substance which exists naturally in the body, the mixture ("formulation") and the way it is being given (i.e. as a mouthwash) are new and there is the possibility of some side-effects.

Here are important points about side effects in general & how you can help ensure they are dealt with effectively:

- The study doctors do not know who will or will not have side effects.
- Some side effects may be mild, some may be serious, some may go away quickly and some may last a long time.
- You must tell your doctor **immediately** if you experience any serious side effects. They may require hospitalisation and could even be life-threatening.
- You must tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.

Side Effects Related to the Study Drug NG11-2

Treatment with NG11-2 may cause side effects, even though the active ingredient of NG11-2 (adrenaline) is one of your body's natural hormones. Adrenaline has been used in a number of different pharmaceutical products, which have been used in humans to treat a variety of medical problems.

As NG11-2 is given as a mouthwash which is then spat out and not as an injection (which goes directly into the bloodstream), the side effects are expected to be less severe than those expected for an injection.

Although it is thought that only a small amount of adrenaline will remain in the mouth after you have spat it out, there is the possibility that some of the adrenaline in your mouthwash will get into your bloodstream and you may have some level of some of the side effects listed below (which are associated with a direct injection).

In some circumstances, the NG11-2 study drug may lead to local effects in the mouth including increased whitening of the tissue and potential ulceration in your mouth mucosa. This will be monitored very carefully by your doctor and nurse and treatment with NG11-2 study drug will be stopped if you experience repeated significant discomfort and if significant side-effects become evident due to the NG11-2 treatment.

If any side effect occurs, it is likely to happen within the first hour after rinsing your mouth with the NG11-2 study drug, and it is unlikely to cause discomfort a few hours after the NG11-2 mouthwash treatment.

In the event that some of the adrenaline does get into the bloodstream, you may get some of the side effects normally associated with a direct injection of adrenaline, although these may not be as severe. The commonly recognised side effects associated with adrenaline as an injection are listed below:

- Palpitations
- Increased heart rate ("tachycardia")

- High blood pressure (“hypertension”)
- Sweating
- Nausea and vomiting
- Breathing difficulty
- Pallor
- Dizziness
- Weakness
- Tremor
- Headache
- Anxiety
- Irregular heartbeat (“Cardiac arrhythmias”)

Interference of Your Tumour Treatment by NG11-2 Treatment

The scientific rationale and earlier laboratory studies suggest that NG11-2 treatment is unlikely to have a negative impact to your tumour treatment. At an appropriate dose level, NG11-2 may improve the condition of your mouth to better tolerate the radiotherapy treatment. In this study, we aim to identify the appropriate NG11-2 dose which will help to proceed to a larger scale study to further confirm NG11-2 safety in combination with radiotherapy.

However, before performing the larger scale study, we cannot yet exclude the possibility that treatment with NG11-2 may have a certain impact on the effect of the radiotherapy being given for your cancer, particularly if the tumour in your mouth has not been removed by surgery. Your oncology doctor and research nurse will closely monitor the effect of your NG11-2 and radiotherapy treatment; suitable actions will be taken when necessary.

At this time, it is not possible to completely exclude the risk of a negative impact to your anticancer therapy when treated with NG11-2.

Side Effects Related to Radiotherapy

As your doctor will explain, or has already explained to you, when you start your Standard Care treatment for your cancer, there are some side effects that can occur associated with the radiotherapy. You may wish to discuss these with your doctor.

You are undergoing Radiotherapy as part of your Standard Care and if you take part in this study you will have dental X-rays and a Radiotherapy planning CT scan. These procedures use ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information.

The radiation dose from the diagnostic scans will be very small compared to the dose from the radiotherapy treatment you are receiving. Ionising radiation may cause cancer many years or decades after the exposure. Taking part in this study will not significantly alter the chances of this happening to you.

Side Effects Related to Study Procedures

As part of the study you will undergo some study procedures; these may have side-effects:

Blood Samples

The most common risks associated with taking blood samples from the arm include pain where the needle is introduced, bruising, light-headedness and on rare occasions, infections.

Electrocardiogram (ECG)

The ECG test is a recording of the electrical activity of your heart. ECG patches are adhesive (like tape) and will be gently stuck on your chest skin at various places. The ECG patches may cause a skin irritation reaction such as redness or itching, localised skin discomforts, hair loss from placement and removal of the ECG patches.

Reproductive Risks and Contraception

The effects that NG11-2 may have on an unborn baby are not known. As you should not become pregnant or father a baby while being treated with radiotherapy, you should not become pregnant or father a baby while participating this study. It is important you understand that you need to use a medically approved method of birth control (contraception) during the treatment period and for 3 months (men) or 6 months (women) after you finish receiving radiotherapy. Check with your study doctor about what kind of birth control methods to use and how long to use them.

If you are pregnant or breast feeding you may not take part in this study. If you are able to have children (i.e., not post-menopausal or surgically sterilised), you must have a negative blood or urine pregnancy test before joining the study.

What if I become pregnant during the study?

Females

If you become pregnant or think you are pregnant during this study, please tell the study doctor and staff right away. The study doctor will notify VasoDynamics of the pregnancy, discuss any follow-up with you, and ask you for information until the end of the pregnancy.

Males

If your partner becomes pregnant during this study, please tell the study doctor and staff right away. The study doctor will notify VasoDynamics of the pregnancy and discuss any follow-up with you and

your partner. Your partner will need to give her informed consent to be followed-up during her pregnancy.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Taking part in this study may or may not help in the prevention or reduction of radiation induced OM during your radiotherapy treatment.

While taking part of this study, you will be closely monitored by your doctor and nurse to assess your responses to the NG11-2 throughout your radiotherapy treatment.

Your participation in this study will allow doctors to learn more about NG11-2 for the reduction or prevention of radiation induced OM in patients undergoing radiotherapy for Head and Neck cancer.

WHAT WILL HAPPEN IF I WANT TO STOP TAKING THE NG11-2 STUDY DRUG OR WITHDRAW FROM THE STUDY?

You can stop taking the NG11-2 study drug at any time or stop being in the research study. Please tell the study doctor if you are thinking about stopping or decide to stop participation. He or she will advise you how to stop.

If you choose not to participate, or withdraw from the research study, this will not affect your present or future medical care outside of the research study.

It is important to tell the study doctor if you are thinking about stopping so your study doctor can discuss what follow-up care and testing could be most useful for you.

The study doctor, the study Sponsor, or the Regulatory Authorities may stop you continuing the study at any time, without your consent, for the following reasons:

- If the study doctor believes it is in your best interest, medically or otherwise
- If we find out you should not be in the study
- If you do not follow the study rules
- If the study is stopped, even if you want to continue

The Sponsor and the study doctor are not obliged to provide you with study drug after the study is complete or has been stopped or after your participation in the study has ended.

If you leave the study or if you are taken out of the study, you will be asked to return for a final study visit to have some end of study evaluations or tests (See **Appendix 1**).

If you leave the study, no more information about you will be collected for this study. However, all of the information already collected before you left the study will still be used.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will not be paid for taking part in this study. However, you will be reimbursed for travel-related expenses which are specifically due to the study or study related inconvenience. For further information, please consult your study doctor or their staff.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you for taking part in the study. VasoDynamics (the Sponsor) is providing funding to the hospital to cover the study related aspects of the treatment.

WILL MY GENERAL PRACTITIONER(GP)/FAMILY DOCTOR BE INFORMED OF MY PARTICIPATION?

Your hospital will inform your GP of your participation in this study and may contact him/her of any findings from this study that require follow-up.

WHAT WILL HAPPEN TO THE BLOOD SAMPLES I GIVE?

Your blood samples will be processed through the hospital's standard system and be analysed by the hospital laboratory only and then disposed of in accordance with HTA 2004; the samples will not be shared with anyone. The results provided for the study will only reference your study code number, not any personal identifiable data. We will not retain any of your blood samples after the study ends.

WHAT HAPPENS IF THERE ARE NEW FINDINGS?

Sometimes, during the course of a research project, new information becomes available on the study drug. If this happens, your doctor will tell you about it and discuss with you whether you want to stay on the study. If you decide to stay on the study, you may be asked to sign an updated informed consent form.

On receiving new information, your study doctor might think it is in your best interests to stop your participation in the study. If so, he or she will explain the reasons for his or her decision and arrange for your care to continue.

WHAT HAPPENS IF THERE IS A PROBLEM OR IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

The Sponsor has taken out standard Association of the British Pharmaceutical Industry ("ABPI") insurance which offers no-fault compensation Clinical Trials insurance for the study.

The Sponsor will pay for the reasonable costs of necessary and appropriate care you receive to treat an illness or injury that is determined by your Doctor and the Sponsor to be directly caused by the study medicine NG11-2 or a procedure required by the Protocol, to the extent those costs are not covered by your insurance or third party. The Sponsor will not pay for injury caused by treatments or procedures

that are standard of care or for illness or injury due to your failure to comply with instructions provided in this consent form and from your study doctor. The Sponsor also will not pay for injuries due to your previous or existing medical condition, including progression of your disease or pre-existing medical condition. The Sponsor has no plans to provide any other compensation for illness or injury as a result of your participation in this study, including compensation for such things as lost wages, disability, or discomfort.

You are not waiving any rights by signing this form.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Your records of being in this study will be kept securely and all information retained by the Sponsor company will be anonymised using a study code. If information from this study is published in a medical journal or presented at scientific meetings, you will not be identified by name, picture, or other personally identifying information.

The following people will have access to your study records:

- Study doctor
- Sponsor's study team, authorised representatives and collaborators
- Government Regulatory Authorities such as the UK Medicines Healthcare Research Authority
- The Ethics Committee responsible for approving the study

A description of this clinical trial will be available on public websites (such as https://www.clinicaltrials.gov); this website will **not** include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT WILL HAPPEN TO MY DATA?

The data collected during this study will be stored for at least 15 years after completion or termination of the study. After that, your personal data will be deleted unless it needs to be retained due to regulatory requirements.

Individuals and entities that may receive your information as part of this study

Information about you and your health which might identify you may be given to:

- Physicians and staff at the hospital/clinic
- Those who oversee the study including the Ethics Committees that monitor the study
- Government agencies that have oversight of the study or to whom access is required under the law such as the UK MHRA and Department of Health
- The research sponsor, and its authorised team and companies that provide support to the Sponsor in the conduct of the study

Any personal health information will be anonymised if it leaves the hospital where you are getting your care and is, for example, provided to the research Sponsor or groups working with them.

HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from you and from your medical records for this research project.

This information will include your:

- NHS number
- name/ contact details
- medical history
- treatment of your cancer

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 NHS number, name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. 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.

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-patients/**

our leaflet available from **www.hra.nhs.uk/patientdataandresearch**

by asking one of the research team

by sending an email to data.protection@vasodynamics.co.uk, or

by ringing us on 01438-300880

WHAT HAPPENS TO THE RESULTS OF THIS STUDY?

The results of this study will be presented in academic and professional journals, and conferences to inform other professionals of the work we have been doing. Neither your individual data nor you would be identified in any report or publication. It is intended that a summary of the results of the study will be made available to participants via a website, their study doctor or GP.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This study is being organised and funded by VasoDynamics Ltd (the Sponsor), the company that is developing **NG11-2** (the study drug).

The costs of conducting this research study at your hospital are being covered by VasoDynamics Ltd.

WHO HAS REVIEWED THE STUDY?

All research in the UK is reviewed by an independent group of people, called a Research Ethics Committee, to protect participants' interests, in addition to the UK Medicines Healthcare Regulatory Agency.

This study has been reviewed and given favourable opinion by Coventry & Warwick Research Ethics Committee.

PATIENT AND PUBLIC INVOLVEMENT IN THIS STUDY

Patient representatives who have previously been treated for Head and Neck Cancer have been involved in (a) reviewing this Participant Information Sheet and (b) discussions with the Sponsor regarding the study in general, the proposed visits and tests. Their comments have been taken into account in designing the study and this document.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

Participating in clinical trials can be stressful and challenging both physically and mentally. Your doctor and nurse are there to support you throughout the study. If you have any questions, feelings of uncertainty or require support to help you make your decision about whether to participate, please feel free to talk to your study doctor and nurse.

In addition, if you have any questions, concerns or complaints about this study, or if you have had a research related injury, please inform your study doctor.

Further general information on taking part in clinical trials can be found using the following link:-

www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/

You will be given a copy of this signed consent form and this information sheet to keep

Thank you for reading this Patient Information Leaflet and for considering participation in this study.

If you have any questions on the study please contact _____

APPENDIX 1 STUDY SCHEDULE

The table below shows what will happen to you at each visit before, during and after you stop NG11-2 study treatment.

Before NG11-2 Study Treatment Begins	**Tests you will receive**	**Other Information we will collect from you**
Screening Visit (Up to 14 days prior to starting Study Drug.)	• Physical Examination • Blood Pressure and Heart Rate Check • ECG • Blood test (10-15mL- 2-3 teaspoons of blood) • Mouth examination • Pregnancy Test for women of childbearing age	• Medical History • Other medication you are receiving • Questionnaire on mouth health
During the Study	**Tests and Study Treatment you will receive**	**Other Information we will collect from you**
Days 1-5 of each week of Radiotherapy Treatment (for up to 7 weeks maximum)	Before Study Drug Given • Physical Examination (Day 1 only) • ECG, Blood test 10-15mL -2-3 teaspoons of blood. (Day 1 on weeks 2, 4 & 6 only) • Mouth examination for Oral Mucositis (Twice weekly on Days 1 and 4, or on Days 2 and 5)	Before Study Drug Given • A check of your mouth condition • A check of any adverse events • Other medication you are receiving • Questionnaire on mouth health (twice weekly)
	~10 minutes before Study Mouthwash completed • Blood Pressure and Heart Rate check	
	~5 minutes before Study Mouthwash completed • Rinse mouth twice with room temperature water	
	2 minutes before Study Mouthwash completed • Start Mouthwash Treatment	
	5-10 Minutes after Study Mouthwash completion • Blood pressure and Heart Rate checks	
	Within 60 minutes after Study Mouthwash Completion • Complete Radiotherapy	

	Within 30 Minutes <u>after</u> Completion of Radiotherapy • Blood Pressure and Heart Rate check	
At the End of Study Treatment	**Tests you will receive**	**Other Information we will collect from you**
Visit (approx. 30 mins) at 7 days after the end of treatment	• Mouth examination for Oral Mucositis	• A check of any adverse events • Other medication you are receiving • Questionnaire on mouth health
Visit (approx 1 hour) at 14 days after the end of treatment	• Physical Examination • Blood Pressure and Heart rate Check • ECG • Blood test (10-15mL, 2-3 teaspoons of blood) • Mouth examination for Oral Mucositis	• A check of any adverse events • Other medication you are receiving • Questionnaire on mouth health
Visit (approx. 30 mins) at 28 days after the end of treatment	• Mouth examination for Oral Mucositis	• A check of any adverse events • Other medication you are receiving • Questionnaire on mouth health
Visit (approx 1 hour) at 42 days after the end of treatment	• Physical Examination • Blood Pressure and Heart rate Check • ECG • Blood test (10-15mL, 2-3 teaspoons of blood) • Mouth examination for Oral Mucositis	• A check of any adverse events • Other medication you are receiving • Questionnaire on mouth health

INFORMED CONSENT FORM

Protocol/Study Number	**NG11-2-P1b**
Study Title	**A Phase-1b Dose Escalation Study to Assess the Effect of NG11-2 on Radiation Induced Oral Mucositis in Patients with Head & Neck Cancer**
Sponsor Name	**VasoDynamics Ltd**
Local Investigator	**Dr XXX, Address**

Please Initial Box

I confirm that I have read and understood the Patient Information Sheet (dated 11-Jan-23, Version 1.2), for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.	
I understand that my personal data will be collected, processed, reported and transferred, within the UK, for healthcare and/or medical research purposes.	
I give permission for my General Practitioner /physician being informed of my participation in this study.	
I understand that relevant sections of my medical records and data collected during the study may be looked at by individuals from the Sponsor and their representatives, from regulatory authorities, and from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my medical records.	
I agree to take part in the above study, to follow the study procedures and to provide necessary information to the study doctor or other study team members, as requested	

Patient Name			
Signature		**Date**	

Person Taking Consent			
Signature		**Date**	

One copy of this ICF-PIL for participant; one copy for Investigator Study File, one copy to be kept with hospital notes.