(To be printed on hospital headed paper)

FURVA PARTICIPANT INFORMATION SHEET

FURVA: Fulvestrant with or without vandetanib in advanced aromatase inhibitor resistant breast cancer.

Invitation and brief summary

Dear _____,

We invite you to take part in our research study called "FURVA".

- We'd like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We suggest this should take about 30 minutes. Please feel free to talk to others about the study if you wish.

- The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part.

- Then we give you more detailed information about the conduct of the study.

- Do ask if anything is unclear.

Summary

- Hormone therapy is an effective treatment for breast cancer, but over time hormone therapy drugs can stop working because the cancer becomes resistant to them. This study involves research that aims to find out if adding another drug, called vandetanib, will stop the cancer becoming resistant to hormone therapy.

- Doing this research will help to improve our knowledge of how best to treat advanced breast cancer.

- The areas being studied in this research include advanced breast cancer and hormone therapy.

- If you decide to take part in this study you will need to take an oral tablet (of vandetanib, or a dummy tablet called a placebo) every day, and you will receive injections of a hormone therapy drug called fulvestrant every month.

- You are being asked to take part in this study because you have advanced breast cancer and your disease worsened while receiving treatment with one type of hormone therapy. You are therefore someone who may benefit from one or both of fulvestrant and vandetanib.

- This study will take place in approximately 19 NHS Trusts across the UK.

- The study will begin when you receive your first dose of fulvestrant and will end if you are not seen to be benefiting from the treatment. You can also decide to stop taking part in this trial at any time, without giving a reason.

What's involved?

Explanation: purpose of and background to the research and invitation

- This research aims to find out if adding vandetanib to treatment with the hormone therapy drug fulvestrant will improve treatment for advanced breast cancer.

- Some cancers are more likely to grow when a hormone called estrogen is present in the blood stream. This can be treated by drugs that stop the action of estrogen or the estrogen receptor, such as tamoxifen and aromatase inhibitors (such as anastrozole, letrozole and exemestane). These drugs are known as hormone therapy drugs. Although hormone therapy drugs are often effective for a while, cancers can become resistant and the drugs stop working.

- Studies have shown that a molecular pathway in cells, called the RET signalling pathway, is more active in cancer cells that have become resistant to hormone therapy.

- The study drug, vandetanib, blocks the action of the RET signalling pathway and has been shown in laboratory studies to prevent the growth of breast cancer cells which have become resistant to hormone therapy.

- We therefore believe that giving vandetanib in combination with hormone therapy may help prevent resistance to treatment in patients with breast cancer. This research will test whether we can reverse resistance to hormone therapy by adding vandetanib.

- To participate in the study you will need to take an oral tablet (of vandetanib or placebo) every day. You will also receive fulvestrant injections every month, which is one of the standard treatments for your condition.

- You will also need to have some extra medical checks during the course of the trial. These include an extra CT scan and ECG examinations to check on your heart.

- The researchers who have designed this trial have tried to fit the study into your normal treatment to keep any additional hospital visits to a minimum.

- There will be 160 participants in this study.

- We would like to invite you to take part in this study because you have estrogen receptor positive (ER+) breast cancer and your disease worsened while receiving treatment with an aromatase inhibitor (anastrazole, letrozole or exemestane). You are therefore someone who may benefit from one or both of fulvestrant and vandetanib.

What would taking part involve?

- On average we anticipate participants will be on the study for up to one year. However, if you continue to benefit from treatment after this time you can continue on study medication and will need to attend 12 weekly assessments. You will continue on study treatment until your cancer grows, or you or your doctor decide not to have the treatment anymore.

- When you stop taking part in the study, there will be two additional visits: one when you stop receiving vandetanib and the next approximately 30 days after that. Your Study Doctor will also decide how to continue to manage your condition.

- If you develop a new medical condition or an existing condition worsens at your final study visit or withdrawal visit then your Study Doctor may wish to contact you and ask you about this, until it has completely resolved.

- Everyone in your trial will receive fulvestrant, a hormone therapy drug which has been proven to be effective for your type of cancer and is the standard treatment.

- You will also possibly receive the experimental drug, vandetanib, which may improve the effectiveness of the fulvestrant. Half of the people in your trial will have vandetanib tablets, and the other half will have a placebo.

- We use a placebo in trials like this so we can accurately see what effects are caused by vandetanib and what effects happen by chance or are unrelated to the vandetanib drug.

- To make sure that the group of people receiving vandetanib and the group receiving the placebo are as similar as possible your treatment is decided upon by chance: a process called randomisation. This process will make sure that the treatments are compared fully and fairly.

- You will have an equal chance of being in either group. Neither you nor your doctor (except in an emergency) will be told which group you are in. This is normal for this type of study, as knowing what group you are in might affect the results of the trial.

- It is also important to remember that, regardless of the treatment group that you are allocated, you will receive the standard treatment for your disease, be monitored closely and be given the best possible care.

- Before you can take part in the study you will need to have some screening tests to confirm you are eligible to take part.

- You will be asked to sign a consent form, then you will see the doctor who will assess the following:
  - A full medical history including a list of all medication that you are taking (including over the counter medication);
  - A complete physical examination, including measurements of your vital signs such as height, weight, blood pressure, and heart rate;
  - Blood samples (approximately 4-6 teaspoons, 20-30 mls) to monitor how well your organs are functioning;
  - If the cancer has affected your skin, your doctor may record the lesions on a close-up photograph. The photograph will show only the cancer and surrounding skin. You will not be identifiable from the photo.
  - A heart trace (ECG, electrocardiogram) – You will have 3 separate ECGs taken 5 minutes apart;
  - An up to date scan of your body to assess your cancer. This will usually be with a CT (Computed Tomography) or MRI (Magnetic Resonance Imaging) scan.

- Your Study Doctor will be able to describe these assessments and exactly when they will occur in greater detail. If you have had some of these tests recently, they may not need to be repeated. Your study team will let you know which tests you need.

- Once all your screening results are available, the Study Doctor will review them and decide whether you are suitable to be included in the study. If you are suitable then trial treatment will begin:
  - You will receive two injections of 250mg fulvestrant (500mg in total), one into the muscle of each buttock on day 1 of every 28 day cycle. An additional loading dose of 500mg will be given on Cycle 1, Day 15.
  - You will start taking one 300mg tablet of vandetanib/placebo once daily every day until the end of the trial.
  - You will receive up to 16 x 28 day cycles of treatment in total, i.e. 64 weeks.
  - If you have certain kidney problems, you may still take part, but you will take two 100mg tablets of vandetanib/placebo, i.e. 200mg in total instead of 300mg.

- In addition to blood samples taken to check your health, we will also collect research blood samples from you when you start the study, after 8 weeks, and when you stop the vandetanib/placebo treatment (approximately 2 teaspoons, 10ml, at each time point). We will also arrange for a sample of cancer tissue that was previously collected from you to be sent to us for analysis. This tissue was used to diagnose your cancer. Provision of these blood and tissue research samples is optional. You will be asked to consent to the collection and genetic analysis of these samples on the main study consent form.

- If your screening assessment shows that you are not eligible for the study, the Study Doctor will explain why you are not suitable to take part, and will explain the alternatives treatments and options available for you.

- During the trial:
  - You will be reviewed by a clinician on cycle 1 day 1 and 15 and then on weeks 4, 8, 16, 24 and then every 12 weeks up to a total of 60 weeks.
  - A study nurse will review you before administering each fulvestrant dose.
  - CT scans or MRI will be performed at 8, 16 and 24 weeks after randomisation and at 12 weekly intervals thereafter.
  - Heart traces will be performed at 2, 4, 8, and 24 weeks after randomisation and at 12 weekly intervals thereafter.

<u>During the study you will have the following assessments:</u>

Assessment	**Time it will take**	**Screening**	**Treatment visits**	**Additional to standard care?**
Assessment by your hospital doctor and/or nurse	30 mins	✓	✓	No
Blood samples to monitor your health and to be stored for future research	10 mins	✓	✓	Yes. More blood will be drawn than usual.
CT scan or MRI	30 mins	✓	At Cycle 3, cycle 5, cycle 7 and then every 3 cycles.	Yes. You will have one extra scan only.
A heart trace (ECG)	20 mins	✓	At cycle 1 (day 15), cycle 2, cycle 3, cycle 7 and then every 3 cycles.	Yes

- We will use your name, NHS number, post code and date of birth to register you with the National Health Service Information Centre (NHSIC) or equivalent (e.g. Community Health Index (CHI) in Scotland) in order for us to follow up your health status (e.g. confirmation of your death if you are lost to follow up) when the trial has completed, without any input from you. You do not have to agree to this to take part in the trial. If you do agree we will collect the information on a separate form and send these to NHSIC via the WCTU. This data will be kept confidential and secure.

- There will be no cost to you for participating in this study. You will not be paid for participating in this study.

- During the trial you must:
  - Carry a trial card that shows you are taking part in this study and show it to any doctors you visit.
  - Ask your GP to give you a list of your regular medication and bring this list to your first study appointment. In most cases you should continue to take your regular medication as instructed by your GP. Your GP may prescribe an alternative medication for your condition.
  - Record your treatment, other medications that you take and side-effects that you may experience in the patient diary we will provide.
  - Attend scheduled visits as directed by your Study Doctor.
  - Tell your Study Doctor/Nurse if you experience any side-effects.
  - Tell your Study Doctor if you have taken part in any other clinical trials.

- It is important that you take the vandetanib medication as directed:
  - When you start to take the medication regularly you must take vandetanib once daily, and if possible at the same time each day with or without food.
  - Please swallow tablets whole with water, not chewed or crushed.
  - If you cannot swallow the tablets whole, drop the vandetanib tablet(s) into a glass of non-carbonated water, do not crush, and stir until dispersed (approximately 10 minutes). Swallow the mixture immediately. Mix any leftover residue with half a glass of water and swallow. Wherever possible, you should not miss a dose. If you do miss a dose, please ensure that you report this to the medical staff at your next visit to the clinic.
  - If you miss a dose of vandetanib in the morning, you may take that day's dose any time up to 10 p.m. the same day. If you are unable to take the missed dose before 10pm, you must not take another dose the same day.
  - If you vomit within 30 minutes of taking the vandetanib you may take a replacement dose. If vomiting occurs after 30 minutes of taking your vandetanib you must not take another dose the same day.If you take more vandetanib tablets than you have been prescribed, talk to a doctor or go to a hospital straight away.
  - Any leftover study medication that you do not take (and the container, even if it is empty) must be returned at each of your visits.
  - You must avoid the use of drugs and herbal supplements, such as St John's Wort, that may have an interaction with vandetanib. Please report the use of all medications, including herbal medications, to your Study Doctor or study staff.

- You must avoid excessive sun exposure and if you do have to go in the sun, use sunglasses, where additional clothing, and apply sun blocker (with SPF 50 to UVB rays and a high degree of protection against UVA rays), for the whole time you are on study and until 3-4 weeks after your last dose of vandetanib. You must also avoid using sun beds or tanning booths. The aim of these sun protective measures is to reduce the risk of you developing a skin rash that may occur if you are exposed to too much sun whilst taking vandetanib.

- There are some more restrictions regarding other medications you may be taking. Your Study Doctor will discuss these restrictions with you.

What are the possible benefits of taking part?

- We hope that the study treatments will help you. However, the outcome of all treatments is uncertain.

- Everyone who participates in this study will receive fulvestrant which has proven activity in patients with your type of cancer. This does not guarantee benefit, but by entering you in the study your Doctor believes this drug alone would be appropriate for you.

- Whether vandetanib is effective against your cancer or helps fulvestrant to be more effective in your case is not known. Therefore, you may not get any extra beneficial effect by participation in this study than you would by treatment with fulvestrant on its own.

- If you complete all 16 cycles of study treatment without your cancer getting worse you may continue treatment. If you require treatment beyond April 2019 and you received vandetanib you will have the option to continue on vandetanib supplied for free by AstraZeneca until May 2020. If you require treatment beyond April 2019 and you received placebo you will have the option to continue on fulvestrant alone supplied by AstraZeneca indefinitely.

- The information that we get from this study may help us to treat future patients.

What are the possible disadvantages and risks of taking part?

- If you have insurance cover, such as medical or travel insurance, you should contact your provider before you agree to take part in the study. This is to make sure that taking part in this study will not affect your cover.

- Study checks could reveal a medical condition that you are not currently aware of. If this occurs the Study Doctor will ensure that you are treated appropriately. This may mean being withdrawn from the study.

- You will also be required to attend hospital more frequently than you would if you were receiving standard care. This may cause some disruption to your normal activities and home life, and this should be discussed with your family and friends if this will impact on them.

- Risks associated with the study assessments:
  - Additional blood tests: Blood tests can cause pain, bruising, infection or inflammation at the sampling site, and may make you feel faint.
  - Dye injections for scans: As part of the normal CT scan or MRI scan you will also be given an injection of a dye to help show up your organs and any tumours that might be present. Rarely, these injections can cause an allergic reaction or damage to the kidneys but precautions are routinely taken to minimise this risk.
  - Radiation: MRI scans do not involve the use of radiation. The CT Scans involve exposure to x-rays to produce images of the inside of your body. Only one of the CT scans is additional to the ones that you would receive as part of normal routine care. As a consequence you will be exposed to slightly more radiation. However, the overall level radiation exposure is still negligible and you will not notice any

changes to your health because of it. You will receive a dose of radiation from each CT scan which is equivalent to about 10 years' natural background radiation. The risks from the radiation are considered to be acceptable in relation to the advantages of the examination.

- All drugs have potential side-effects. However, not all patients will experience them. Your doctor may give you additional supportive medications to prevent or treat some of the side-effects.

- Tell your Study Doctor/Nurse if you experience any of the side-effects listed below, or any changes in general health (whether you think it is related to the study or not). You are encouraged to report anything that is troubling you.

- If you experience any side-effects, you may be asked to return to the clinic for more assessments, which may include more blood tests. Your doctor will explain these tests to you if they are needed. You may also need to take a lower dose of the drug, or stop taking one or both of the study drugs, after talking with your Study Doctor and/or take additional medication to control the side-effect.

- The possible side effects of vandetanib include:
  - Very common (more than 10 patients out of every 100 treated); diarrhoea, rash, feeling and being sick, fatigue, increased blood pressure, loss of appetite, headache, constipation, insomnia, dry skin, weakness.
  - Common (between 5 and 10 patients out of every 100 treated); itch, heart trace changes not associated with symptoms, weight loss, protein or blood in urine, abdominal pain, sore mouth, acne, loss of appetite, increased sensitivity to the sun.
  - Rare (between 1 and 5 patients out of every 100 treated); low blood pressure, low blood potassium, altered liver blood tests, dry mouth, depression, anxiety, hair loss, altered sense of taste, blurred vision, dehydration, conjunctivitis, dry eyes, reduced thyroid hormones, low blood magnesium, sore hands and feet, low blood calcium, changes to the fingernail beds, kidney stones, nose bleeds, blood in urine.
  - Very rare (less than 1 patient out of every 100 treated); eye damage, angina heart pump damage, stroke.

- The possible side effects of fulvestrant include:
  - Commonly reported side effects (10 or more out of every 100 patients); feeling sick, increase in liver enzymes, weakness and lack of energy and strength, and injection site pain.
  - Less common side effects (less than 10 out of every 100 patients) include:elevated bilirubin, vomiting, diarrhoea, hot flushes, headache, anorexia, rash, urinary tract infection (UTI) and hypersensitivity reactions.

- If your cancer gets worse while you are on the study treatment your Study Doctor will stop your treatment with vandetanib/placebo and fulvestrant and will discuss other treatment options with you.

Supporting information

What will happen to the samples I give?

- Your hospital will analyse any blood samples taken to monitor your health.

- The research blood and tissue samples you provide will be used in future research to assess whether the genetic make-up of cancer can predict whether patients will benefit from the drugs used in this study. At this stage we do not know what the research will involve but some of it could include genetic research (for example the identification of genes or disease that run in families). Your samples will not be sold and will not be used for animal research or in the commercial sector. We will not use individual results, but will draw conclusions based on data from all participants.

- Your research blood and tissue samples may be transferred to, stored at, processed by, and tested by research laboratories approved by the Sponsor.

- All tissue will be supplied anonymously to researchers; only your local hospital staff will be able to identify which samples you donated. Minimum information will be supplied to each laboratory. Only your study number, initials and date of birth will be used to identify your research blood samples. Only your study number, initials, date of birth, the date your biopsy was taken, and the histology block reference number will be used to identify your research tissue sample.

- Any tests being done on your stored samples (and derivatives thereof), other than those related to the FURVA trial, will require separate ethical approval. We will not need to contact you about this as the consent you give in this study will cover these tests.

- You will be told the results of your monitoring blood tests, but you will not be told of any specific results about any other research on your samples (and derivatives thereof). Individual results will not be passed on to other parties outside of this study.

- The Sponsor shall endeavour to return specific diagnostic samples to your hospital if required for your continued care.

- At the end of the study we will store your research blood (and derivatives thereof) and tissue samples for a period of at 5 years. After this period the WCTU and Sponsor may apply for additional funding for continued storage and/or analysis. If additional funding is not sourced, any remaining research samples may be returned to your local hospital or destroyed at the discretion of the Sponsor and according to locally approved practices.

What happens if something goes wrong?

- Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. In the event that something does go wrong and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for legal action against the organisations involved including the Sponsor (Velindre NHS Trust) or the National Health Service (NHS) trust. However, you may have to

pay your legal costs. The NHS complaints mechanisms will still be available to you (if appropriate).. Details can be obtained from your hospital.

- If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can do this by contacting [insert details e.g. NHS Complaints Procedure]. Details can be obtained from [insert details].

What will happen if I don't want to carry on with the study?

- Taking part is voluntary. You may withdraw your consent to take part in the study at any time. You do not have to give a reason and you will still receive the same level of medical treatment as you would in standard care.

- Depending on how much you wish to withdraw we will know what treatment we can give you, what information and research samples we can keep, and whether we can still collect information on your progress. You may withdraw at one of these levels:

  Level 1: Stop taking study treatment but remain in follow-up and continue to take part in the translational study.
  Level 2: Stop taking part in the translational study but continue taking study treatment and remain in follow-up.
  Level 3: Stop taking study treatment and stop taking part in the translational study, but remain in follow-up.
  Level 4: Stop taking study treatment, stop taking part in the translational study, do not remain in follow-up, i.e. completely withdraw from the study.

Withdrawal Level	Study Treatment	Translational study	Follow-up
1	X		
2		X	
3	X	X	
4	X	X	X

- If you withdraw from study treatment you will stop taking both vandetanib and fulvestrant and your doctor will discuss alternative treatment options with you.

- If you continue to take part in the translational study we will collect and test your research blood and tissue samples.

- If you remain in follow-up we will still collect information on your progress.

- Data and samples collected before the date you withdraw will be kept and analysed by the WCTU irrespective of withdrawal level.

- If you initially consented to be registered with NHSIC or equivalent, and subsequently withdraw, you will remain on the system so that important research information on date and cause of death can be requested from NHSIC by the WCTU.

What are the alternatives for treatment?

- You can talk to your doctor about your choices before you decide if you will take part in this study. Your other choices may include treatments available outside this study such as other hormone therapies or chemotherapy, taking part in another study, no treatment or comfort care, also called palliative care.

Will my information be kept confidential?

- All information collected about you during the study will be confidential, and will be handled, stored and destroyed in accordance with the Data Protection Act 1998. By signing the consent formyou only allow people working on the study, or working to ensure the study is being run correctly, to have access to your data. With your permission your GP will be notified that you are taking part in the study.

- Records identifying you will be kept confidential and will never be made publically available. If the results of the trial are published, your identity will remain confidential.

What will happen to the results of the study?

- A summary of the study results will be sent to each participating hospital, where it will then be forwarded to participating patients and their families. The results may be shown at medical meetings and submitted to major research journals for publication. You will not be identified in any way in any report or publication arising from the study. Where possible, publications will be made available to the general public on the Wales Cancer Trials Unit (WCTU) website (www.WCTU.org.uk). They will also be brought to the attention of Macmillan Cancer Support.

Who is organising and funding this study?

- The study is being sponsored by Velindre NHS Trust, the organisation responsible for the conduct of the study within the UK. The study is being organised by the WCTU on behalf of the Sponsor and the Chief Investigators, Dr Mark Beresford, who is based at Royal United Hospital, Bath, and Dr Robert Jones, who is based in Velindre Cancer Centre, Cardiff.

- The study has been funded by an AstraZeneca-National Cancer Research Network (AZ-NCRN) collaborative award, and is endorsed by the Cancer Research UK Feasibility Study Committee.

- AstraZeneca, which makes fulvestrant, has provided the drug for free. AstraZeneca sold its vandetanib business to Genzyme in July 2015 after the start of the FURVA study. AstraZeneca will continue to provide vandetanib for this study for free up to May 2020, and placebo up to April 2019.

- Separate funding will be sourced for the analysis of research blood and tissue samples.

How have patients and the public been involved in this study?

- The WCTU have recruited research partners to this study. The research partners have previously experienced breast cancer and have reviewed this patient information sheet.

Who has reviewed this study?

- This study has been approved by a Research Ethics Committee and the Medicines and Healthcare Products Regulatory Authority (MHRA). It has also received independent peer review by the Clinical Trials Awards and Advisory Service (CTAAC) and the National Cancer Research Network (NCRN) Chemotherapy and Pharmacy Advisory Service (CPAS) group.

What if new information becomes available?

- Sometimes, during the course of a research study, new information becomes available about the drug that is being studied. If this happens, your hospital doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your hospital doctor will make arrangements for your care to continue. If you decide to continue in the study you may be asked to sign an updated consent form. Also, on receiving new information your doctor might consider it to be in your best interests to withdraw you from the study. If this happens he/she will explain the reasons and arrange for your care to continue.

Further information and contact details:

If you have any further questions concerning this study, please contact your **Consultant:**

Name:…… Tel:……..

Or your **research/specialist nurse:**

Name: …… Tel: ……..

Information on all aspects of cancer care is also available on **Macmillan Cancer Support's** patient website (www.macmillan.org.uk) or contact their specialist cancer nurses on **0808 800 1234**.
Thank you for taking the time to consider participating in the study.

(To be printed on hospital headed paper)

FURVA: Fulvestrant +/- vandetanib in advanced aromatase inhibitor resistant breast cancer

FURVA PARTICIPANT CONSENT FORM
Version: 2.0 **Date:** 09 December 2016

Centre Number: | | | |

Participant Trial Number: | | | | | | | | |

Name of Principal Investigator: | |

Please **initial** boxes:

1.	I confirm that I have read and understand the FURVA Participant Information Sheet (Version 2.0 dated 16 December 2016) for the above study and have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time from part or all of the study, without giving any reason, and without my medical care or legal rights being affected.	
3.	I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from the Sponsor, the Wales Cancer Trials Unit or from regulatory authorities or from the NHS trust, where it is relevant to my taking part in research. I give permission for these individuals to have access to my records	
4.	I consent to the storage of personal information (including electronic), for the purposes of the study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication.	
5.	I agree to provide my diagnostic biopsy to the FURVA study for use in laboratory research studies including genetic analysis. My biopsy may be transferred to, stored at, processed by, and tested by research laboratories approved by the Sponsor for this purpose.	

6.	I consent to give research blood sample(s) for use in laboratory research studies including genetic analysis. My samples may be transferred to, stored at, processed by, and tested by research laboratories approved by the Sponsor for this purpose.	
7.	I give permission for my GP to be informed of my inclusion in this study.	
8.	I agree for my details to be registered with the National Health Service Information Centre (NHSIC) or equivalent (e.g. Community Health Index (CHI) number in Scotland) for which my name, postcode, date of birth, and NHS number or equivalent must be used in order for my health status to be followed up. If I subsequently withdraw from the study, I will remain on the system so that important research information on date and cause of death can be requested from NHSIC by the WCTU.	
9.	I agree to take part in the above study.	

…….....	……	……
Name of participant	**Date**	**Signature**

.....	.....	.....
Name of person taking consent (if different from Principal Investigator)	**Date**	**Signature**

.....	.....	.....
Name of Principal Investigator	**Date**	**Signature**

Copies: 1 for Participant; 1 for Centre file; 1 to be kept with hospital notes