# PATIENT INFORMATION SHEET

We would like to invite you to take part in a research study about a special test, called EndoPredict. We want to see if it helps you and your doctors decide whether or not you need chemotherapy after breast cancer surgery. Chemotherapy may reduce the risk of the cancer coming back, but not everyone needs it.

In the study we will compare your doctor's opinion about the need for you to have chemotherapy, before and after using the special EndoPredict test. Some of the cancer tissue, removed during your operation, is tested and predicts the likelihood of the cancer coming back. We will also compare your own thoughts about treatment plans, before and after having had the test carried out.

Before deciding whether to take part, please read this Information Sheet carefully and discuss it with other people if you wish. Please ask your doctor or nurse if there is anything you do not understand or if you want more information. Take your time to decide whether or not to take part.

## Why am I being invited to take part?

You have been diagnosed with localised breast cancer which was removed surgically. Your breast cancer was a type called oestrogen receptor positive so hormone therapy will be given to you to reduce the risk of the cancer coming back. Chemotherapy may further reduce this risk further, but sometimes doctors cannot easily tell if this chemotherapy is really necessary.

The doctors in your cancer team have discussed the results from tests done on the tissue collected during surgery. They think that the benefit of chemotherapy for you is uncertain. The EndoPredict test may help them to decide, whether or not chemotherapy is really necessary for you to have.

## What is the EndoPredict test?

The EndoPredict test estimates the risk of the cancer coming back. It looks at genes found in your breast cancer tissue. Genes are inherited from our mother and father and are like a set of instructions. For example, our eye, hair and skin color are decided by genes. Many cancers are caused by changes in our genes, but these changes are not always the same in different people. This is why cancer and treatments often behave in different ways between people.

The EndoPredict test looks at the genes in your own cancer. This may give your doctors a better idea of how your specific cancer might behave and whether hormone treatment alone is enough or if chemotherapy is needed. The test is done on a sample taken from the lump which has already been removed from your breast, so extra biopsies are not necessary. These samples will be sent to the Brighton & Sussex University Hospital research laboratory for the EndoPredict test, and then returned to your own hospital once the test has been performed.

## What is the purpose of this research study?

Doctors cannot easily predict if breast cancer will come back after surgery. Currently we look at certain characteristics, such as the size of the tumour and whether there is cancer in the lymph nodes. These things can help us estimate the benefit of chemotherapy in reducing future cancer, risk but current tests are not specific enough.

We wish to see if the EndoPredict test helps us work out if you really need chemotherapy or not. We want to see what you and your doctor together think about having chemotherapy before and after seeing the Endopredict test results.

We want to know how many doctors change their decisions about recommending chemotherapy to patients and if the test reduces uncertainty.

In the future, if the test is helpful, then it could help to identify women who would not benefit from chemotherapy and save them the side effects. It might also better identify women who are more likely to need chemotherapy

## What is involved in taking part in the trial?

At your first oncology appointment your doctor will discuss:-

- treatment options that the cancer team think are best for you
- the EndoPredict study in more detail and answers to any questions you may have. You will then be asked if you would like to consent to taking part in the study.

If you decide to take part in the study, you'll be asked:-

- to sign a consent form
- to fill out 3 short questionnaires about your feelings, and preferences for treatment

Up to 2weeks later you'll be asked to come for an extra appointment. At this, your doctor will give you the EndoPredict test result. You will have a chance to discuss this with the doctor and whether or not you should have chemotherapy.

After the appointment, you will be asked to fill out another 2 very short questionnaires about your treatment decision. No further hospital visits will be necessary for the trial, but of course you will continue to be seen at the hospital as required by your doctors.

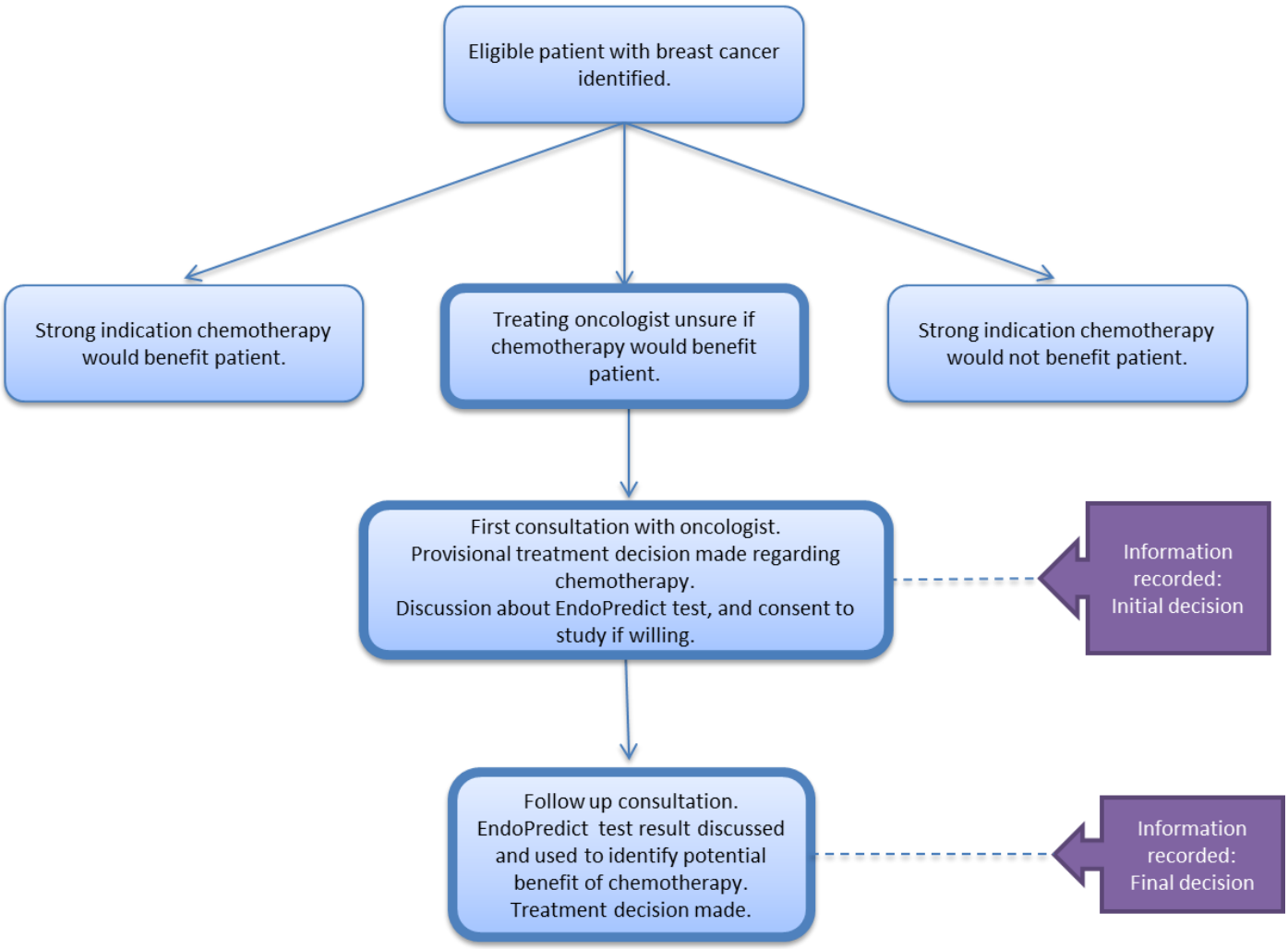
## Will this affect my treatment?

Yes, having the EndoPredict test in this study may affect your treatment plan.

After surgery, all patients have their results discussed fully by the doctors in the cancer team and a standard further treatment plan is made.

For some patients like you, the doctors may not be sure whether chemotherapy is really necessary which is why you have been asked to take part in the study. The decision to offer you chemotherapy may or may not be changed with the result of the EndoPredict test.

## Figure 1: Patient Pathway.



## What are the potential advantages of taking part?

The result of the test may help us to understand better the risk of cancer coming back in the future. We may find that your cancer is 'low risk', and so avoid chemotherapy and any unnecessary side effects. Your cancer may be 'high risk' and if so, we would be more certain that you might benefit from extra chemotherapy treatment, despite the side effects.

We hope that the information we gain from this study will benefit you as an individual patient.

It may also help us know if the test should be offered to more patients like you in the future.

## What are the potential disadvantages and risks of taking part?

If you decide to take part:

- you will have one extra visit with your cancer doctors to discuss the results of the EndoPredict test up to 2 weeks later. This could mean that if you do decide to have chemotherapy, there may be a delay, although procedures will be put in place to minimise this.
- you will have 5 extra short questionnaires to fill out
- this would mean additional time at the hospital.
- there is also a chance that your treatment plan will be changed from that first described to you
- some patients might not like the uncertainty as to what is going to happen for an extra week
- travel expenses cannot be reimbursed for the extra hospital visit

We hope that the results of EndoPredict will help tailor your treatment to your specific type of cancer and possibly avoid further chemotherapy.

If you have private medical insurance, please check with the company before agreeing to take part that your medical insurance cover will not be affected.

## Do I have to take part?

No. It is up to you to decide whether or not to take part. If you agree and then change your mind, you can still withdraw at any time without giving a reason. What ever you decide, it will not affect the standard of care you receive. It is routine for your GP to be told if you are taking part in this research and we ask permission to be able to inform him/her on your behalf.

## What if I decide to take part in the study?

If you decide to take part you will be asked to sign the study consent form. You will be given a copy of your signed consent form to keep for your own records.

## Will my taking part in the trial be kept confidential?

Yes. If you consent to taking part in this study, relevant parts of your medical records may be seen by your doctor, authorised members of the research team at your hospital, and representatives of the study sponsor and/or regulatory bodies. The tissue samples that we send for testing will have your date of birth and a unique registration study number on them. This is because all tissue samples look exactly the same and it is vitally important that we do not get them mixed up. The sample will be returned to your hospital after the test has been performed.

The answers you give to the questionnaires will not be seen by the cancer team. They will be placed in a sealed envelope and given to the researchers at Sussex Health Outcomes Research & Education in Cancer (Shore-C) who are looking at decision-making by patients and doctors.

All information will be kept strictly confidential. No individual patients will be identified when the results of the study are published in medical journals. Your general practitioner will, however, be informed of your participation in accordance with usual practice if you consent to this.

## Has this study been reviewed?

All research in the NHS is looked at by an independent group of people called a research ethic committee to protect your interests. This study has been reviewed and given a favourable opinion by South-Central Oxford C Research Ethics Committee.

## What if I decide not to enter the trial?

If you decide not to take part, no questions will be asked and your relationship with the doctors and nurses looking after you will not be affected. Your treatment will not be affected and will proceed in line with best current practice.

## What if something goes wrong?

If you are not happy with any aspect of this research study, in the first instance please contact the research team directly. If you are not able to resolve your complaint, please then contact the Head of Research & Development at the hospital. If you still do not feel the issue has been resolved, the NHS Complaints department should be contacted.

## Is there someone I can talk to independently about research trials in general?

You can talk to any of the nursing staff in the oncology unit if you have any concerns about trials or contact Patient Advice and Liaison service (PALS).

## Who is organising and funding the research?

This study is being organised by Brighton and Sussex University Hospital NHS Trust and is being funded by Unrestricted Educational Grant from Myriad UK.

## Contact number for the research team

Thank you for taking the time to read this leaflet. If you have any further questions do not hesitate to ask. For further information please contact:

Research Nurse:

Insert address here

Tel

Email:

Principal Investigator:

Tel:

Email: