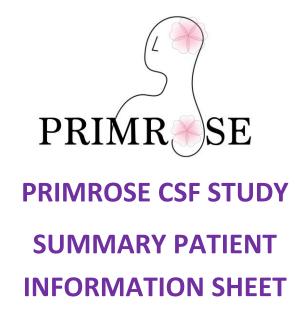
# **THANK YOU**

Thank you for taking the time to read this summary information sheet. If this study interests you and you think that you might like to take part, please read the full Patient Information Sheet provided by the research staff.











We would like to invite you to take part in the PRIMROSE CSF study. Before you decide, it is important that you understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. If this summary interests you, and you think that you might like to take part please read the detailed Patient Information Sheet provided by the research staff.

Please ask if there is anything that is not clear or if you would like more information. If you decide you would like to take part in this study, your participation will be voluntary, and you will be free to withdraw at any time.

### PURPOSE OF THIS STUDY

The PRIMROSE CSF Study aims to study **cerebrospinal fluid (CSF)** in patients with breast cancer that has spread to the brain (brain **metastasis**) or the lining surrounding the brain (leptomeningeal disease).

### What is CerebroSpinal Fluid (CSF)?

This is the liquid that surrounds and protects the brain and spinal cord. CSF is constantly produced by our body and small amounts removed during extraction procedures are rapidly replaced.

#### What is a metastasis?

This is when cancer cells break off from the main tumour (in this case – in the breast), enters the blood stream and spreads to another part of the body such as the brain (so called brain metastasis or the thin lining over the brain (so called leptomeningeal disease).

Research into understanding more about breast cancer that has spread to the brain or lining of the brain is limited. This is because it is difficult to get brain tissue contacting cancer cells for research. This is normally only obtained if tumours are removed which does not happen in all patients. Research shows that more and more patients with breast cancer are developing disease that spreads to the brain or the lining of the brain as treatments for breast cancer improves. The PRIMROSE CSF Study aims to improve our understanding of breast cancers spreading that spread to the brain/brain lining by collecting and studying the fluid that circulates around the brain and comparing the sample to other cancer samples and blood samples.

### **CONTACT DETAILS**

Contact details can be found on the full Patient Information Sheet once you have given a verbal consent that you would like to participate. Please ask the study team as many questions as you wish and read through the entire full Patient Information Sheet very carefully. Before you agree to take part, you must fully understand what the study involves, taking as much time as you need. Please feel free to discuss the study with your family, friends, study doctor and GP if you wish.

### RISKS

All procedures will be carried out by trained medical professionals.

Diagnostic/Routine Tissue Collection - This will only occur as part of procedures that are medically advised for you and thus there are no additional risks introduced as part of the PRIMROSE CSF study.

**Lumbar Puncture** - There may be risk of the following after the procedure:

- Back Pain at the time of injection (Bleeding, swelling and bruising may occur)
- Post-procedure headache (can be associated with nausea and vomiting)
- Nerve root irritation (tingling or pain down the back of your legs)
- There is a rare risk of increased pressure within the skull (intracranial), due to a brain tumour or other spaceoccupying lesion, which can lead to compression of the brainstem after a sample of cerebrospinal fluid is removed.

Prior to doing a lumbar puncture, your clinician will make a decision using all available information to ensure risks are minimized.

Ommaya Reservoir – There is a risk of infections, but these are rare. Assessments to ensure your safety will always occur before CSF extraction. If you are deemed to be at high risk of infection, the CSF extraction procedure will not occur.

Once you have healed from the procedure, you can return to all of your normal activities. Ommaya reservoirs do not require any care or maintenance.

Cancer cells that have spread to the brain or the lining of the brain shed their genetic material into the fluid that surrounds the brain. Therefore, by collecting the fluid around the brain we will be able to purify this genetic material that is floating in the fluid from the breast cancer cells. By doing this we will be able to examine the genetic make of the breast cancer cells affecting the brain/lining of the brain without to operate. We will compare the differences in the original cancer and the new cancers in the brain.

This research will help us understand of why some breast cancers spread to the brain as well as helping to develop new treatments to be to treat breast cancers that have spread to the brain or lining of the brain.

If you wish to withdraw from the study, you will be able to do so at any time. If you wish to withdraw from the study your permission will be sought retaining and use any samples already collected for the study.

### WHAT IS INVOLVED?

If you agree to take part, we will also check with your doctor/nurse that it is safe and appropriate for you to have samples taken, we will ask for consent to the following:

- 1) Collection of 10ml 15ml CSF sample (CSF extraction) via lumbar puncture or aspiration from Ommaya Reservoir
- 2) Collection of 20ml Blood sample
- 3) Collection of Tissue

Further information regarding study procedures and visits can be found within the full Patient Information Sheet.

### PROCEDURE

CSF can be obtained by any of two procedures – Lumbar Puncture or Ommaya Reservoir. They are described below

#### **Lumbar Puncture**

Lumbar puncture is performed in your lower back, in the lumbar region. During the procedure, a needle is inserted between two lumbar bones (vertebrae) to remove a sample of cerebrospinal fluid.

The following steps will occur:

The doctor will usually position you on the left side with your knees curled up to your stomach, but this can be done sitting up.

The skin of your lower back will be cleaned with an antiseptic – please let us know if you are allergic to chlorhexidine. The antiseptic may feel wet and cold. A local anaesthetic is then used to numb the skin.

You may feel a stinging sensation before the local anaesthetic begins to work. You may then feel a pushing sensation as the needle is inserted, and sometimes a brief, sharp pain when the needle is moved forward. This pain should stop in a few seconds.

Overall, discomfort is minimal to moderate, but it is important to lie still. Once the needle is correctly positioned, the doctor will measure the pressure (if required) and collect the samples.

The entire procedure usually takes approximately 20 minutes.

### **Ommaya Reservoir Tap**

If you have an Ommaya reservoir in place already the CSF will be collected by inserting a needle into the soft plastic dome. You may have previously had samples collected in this way. This entire process usually takes 20 minutes.