LOCAL HEADED PAPER

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Title of study: A prospective study of breast cancer treatment outcomes – tumour samples

SUPPLEMENTARY INFORMATION SHEET FOR PATIENTS

We are very grateful to you for agreeing to take part in the POSH study. You will be having an operation in the near future to remove the breast tumour. When you have your operation the tumour will be placed in a preservative fluid to "fix" the tissue and then processed for examination by the pathologist. If you have consented to it, we will routinely be requesting these fixed samples once they are no longer needed for your care so that we can compare the appearances and characteristics of tumours from everyone in the study.

In patients in the study with a family history of breast cancer, we are keen to make an extra effort to freeze a small piece of tumour tissue. This would be taken once you are asleep for your operation, before the tumour is removed and processed in the usual way. This allows us to do some additional studies over and above those we can do with the routine tissue samples.

In order to do this, once you are asleep for your operation and if you agree, we would ask your surgeon to take a small piece of tissue and transfer it as soon as possible to a special preservative or a very cold freezer depending on which is most convenient. The simplest way to do this is for your surgeon to take a small needle biopsy from the tumour (you may have had this done in order to make the diagnosis in the first place).

This procedure would be done once you have had your anaesthetic and immediately before you have the operation to remove the whole tumour and it will take only a few minutes to do. Taking needle biopsies has been shown to have no serious adverse effects and you will feel no different than if you just had the tumour removed without the biopsy being done. The tissue is the size of a short (1cm) piece of string and is called a "core biopsy".

The tissue will be used to examine the way tumours develop and behave in a very detailed way which cannot be achieved using fixed material at present. The results are unlikely to be of any individual benefit and as in the main study any information from analysing your tumour core biopsy will not be disclosed to you or your doctor or surgeon.

Please discuss this with your surgeon if you would like more information. If you are happy to participate in this part of the study, please sign the attached consent form. A copy of this will be sent to the study co-ordinator in Southampton and a copy will be kept on your hospital file. Thank you for reading this information sheet.

<Local clinician>

Diana M Eccles MD FRCP
Principal Investigator POSH study

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Centre Number:
Study Number: MREC/00/6/69
Patient Identification Number for this trial (**Hospital number**)

SUPPLEMENTARY CONSENT FORM

Prospective study of breast cancer treatment outcomes

Principal investigator for your centre:

☐	I consent to my surgeon taking a core biopsy once I am asleep ready for my operation and before the surgery is undertaken.
☐	I understand this tissue will be sent to Southampton for storage and analysis as part of the Prospective Study in treatment outcomes for Sporadic versus Hereditary breast cancer.
☐	I understand there will be no specific results from studying my sample that would be relevant to my current care and that results will not be made available to me or my doctor

Name: Date:
Signature

Name of clinician: Date
Signature of clinician: