	Title	**The MARECA study – National study of management of breast cancer locoregional recurrence and oncological outcome**				
	Version	**3.0**	Date	**29.08.2021**	IRAS No	**285389**

PATIENT INFORMATION SHEET

Invitation to participate in the study

We would like to invite you to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve.

PART 1 tells you the purpose of this study and what will happen if you take part.

PART 2 gives you more detailed information about the conduct of the study including how your personal data and identify will be protected.

To allow you to make a decision about whether or not you wish to take part in this study please take time to read the following information carefully. Discuss it with your family, friends, and your GP if you wish. Please ask the study doctor or the site staff to explain any words or information that you do not fully understand. Take time to decide whether or not you wish to take part. You are free to decide whether to participate and if you choose not to take part, this will not affect your medical care you in any way.

PART 1

1. What is the background to and purpose of the study?

Breast cancer recurrence is where the cancer returns in a period of time after the cancer has been removed and treated. Locoregional recurrence is when the cancer returns within the same breast or chest wall area, and/or in the nearby lymph glands. Currently there is lack of research specifically looking at this patient group in the UK. The MARECA study has been set up across over 50 UK hospitals to address this. We plan to recruit at least 500 patients to the study.

The study will look at how patients with breast cancer locoregional recurrence are investigated and treated, as well as their treatment outcome. This information will be used to create recommendations for the best care and treatment of patients diagnosed with locoregional recurrence.

2. Why have I been invited?

You have been asked to join this study because you have recently (within the last 6 months) been diagnosed with breast cancer locoregional recurrence. Your hospital is one of the 50 centres around the UK participating in this study, which is recruiting women and men who are at least 18 years old.

3. Do I have to take part?

No. It is up to you to decide whether or not to take part. We appreciate the impact of a breast cancer recurrence diagnosis and you will receive support from experienced clinical and nursing team throughout your treatment.

If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to show you have agreed to take part. You are free to leave the study at any time, without giving a reason. This will not affect the standard of care you receive.

4. What will happen to me if I take part?

If you decide to take part in the study, you give permission for a member of your clinical team to review your medical records. Only information relevant to the study will be looked at and recorded. This will include the following information about your original and recurrent breast cancer;

-Dates of diagnosis

-General details of your medical history

-Investigations and treatments received

By consenting to participate in the study, you are also giving permission for a member of your clinical team to access your medical records for up to 5 years after your diagnosis of breast cancer locoregional recurrence. This will enable your treatment outcome to be recorded.

Study participation will not result in additional clinic visits, procedures, or tests. Furthermore, your treatment decisions or choices will not be affected by study participation.

5. What do I have to do?

Your responsibilities as a patient taking part in this study are to:

- Read and understand this information sheet.
- Agree that relevant sections of your medical notes and data collected during the study, may be looked at by individuals from NHS Trust (insert local details) participating in the study, from regulatory authorities or from Leeds Teaching Hospitals NHS Trust (study sponsor), where it is relevant to you taking part in this study.
- Agree that the information generated from your participation in the study may be processed, stored and analysed for research purposes.

6. **Optional for all participants: Tissue Sub Study**

This section describes an optional part of the study. You can take part in the main study without consenting to this additional step.

With your consent, we would like to access tissue samples from your original and recurrent breast cancer. This would allow us to perform further tests on the tissue with an aim of improving understanding of breast cancer locoregional recurrence.

If you agree to donate tissue samples, these will be a gift for future research. These tissue samples were collected as part of routine clinical care so you will not need to undergo any additional procedures. Your donated tissue samples may be transferred to another laboratory outside of your hospital where the research is being undertaken.

7. What are the possible disadvantages and risks of taking part?

There are no specific risks related to your participation in this study. Taking part in this study will not change any treatment plans or investigations recommended by your doctor.

8. What are the possible benefits of taking part?

We cannot promise the study will benefit you directly, but the information that you provide will help to improve the future management of patients diagnosed with breast cancer locoregional recurrence.

9. When would I take part?

Please let your clinical team know whether you would like to participate or if you have further questions. If you need more time to decide, please take the information sheet away and the team will arrange a time to discuss the study further. If you decide to participate, you can take part in the study at a date/time convenient to you.

10. What will happen if I do not want to carry on with the study?

You are free to withdraw from the study at any time. This will not affect the standard of clinical care you receive.

Leeds Teaching Hospitals NHS Trust, as the study sponsor, will process the data collected for the study up until the point of withdrawal. You can also request removal of your data from the study database if you wish.

11. What if there is a problem?

If you have a concern about any aspect of this study, you should first speak to your study nurse or doctor who will do their best to answer your questions. If you still have concerns, you may

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wish to contact your local Patient Advice and Liaison Service (PALS) or Patient Advice and Support Service (PASS) team at the study centre (Telephone number: insert local contact details). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Please ask your study doctor if you would like more information on this. Details can also be obtained from the Department of Health website: http://www.dh.gov.uk.

If at any point you have any questions or concerns about this study, please contact:

Principal Investigator Insert local details

Chief Investigator: Mr Baek Kim, Consultant Oncoplastic Breast Surgeon, Leeds Teaching Hospitals NHS Trust (leedsth-tr.themarecastudy@nhs.net)

If you have any concerns or queries, you are welcome to contact the local research team below:

Insert local details

12. Who is organising, funding and reviewing the research?

The study is being organised and sponsored by The Leeds Teaching Hospitals NHS Trust. This study is conducted according to all applicable national laws and guidelines. It is funded by the Association of Breast Surgery and the Leeds Hospitals Charity.

All research is looked at by an independent group of people called a Research Ethics Committee, to protect the safety, rights, wellbeing and dignity of those taking part. This study has been reviewed by the London - Brighton & Sussex Research Ethics Committee.

13. Will my taking part in this study be kept confidential?

Yes. We will make sure that the personal data collected throughout the study is kept confidential in compliance with both UK and European data protection laws. The information collected about you will be handled confidentially and strictly in accordance with relevant data protection laws, including the Data Protection Act 2018 and EU General Data Protection Regulation (GDPR).

Your medical data collected will be pseudonymised (i.e. de-identified) and securely stored in an electronic research database (REDCap; Research Electronic Data Capture). For more information about confidentiality and protection of personal data read Part 2 of this information sheet.

14. What will happen to the results of the research study?

We intend to publish the results from the MARECA study in scientific or medical journals and to present them at conferences. We will share the results with the hospitals involved in the study and with patient organisations. No individual participants will be identified in any publications/presentations. In this way, your confidentiality will be fully maintained. The MARECA study website (https://www.ibra-net.com/mareca) will have links to published papers

or conference presentations. Participants will be asked at the time of study entry if they wish to be contacted when the study results are available. If you consent to this, you will be provided with this information. We anticipate the initial study results to be available in 2024. This will describe how patients with breast cancer locoregional recurrences are being managed across the UK. Subsequent publications will describe long term treatment outcome of the participating patients.

This completes Part 1 of the Information Sheet. If the information in Part 1 has interested you and you are considering taking part, please continue to read the additional information in Part 2 before making a decision.

PART 2

15. How will we use the information about you?

We will need to use the information from you and your medical records for this research project. This information will include your initials, date of birth, NHS number in England and Wales, Community Health Index number in Scotland, and Health and Care number in Northern Ireland. These identifiers will be held by the participating study sites. 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 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.

16. 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 will stop collecting information about your health from your hospital.
- 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.
- If you agree to take part in this study, you will have the option to take part in future research (Tissue Sub Study) using your data saved from this study.

17. Where can you find out more about how your information is used?

You can find out more about how we use your information

Insert local header

- 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 (insert local details), or to Jonny.chagger@nhs.net (sponsor's data protection officer at the Leeds Teaching Hospitals NHS Trust)
- by ringing us on (insert local details)

18. Using your information for further research

If you agree to take part in a research study, the information about your health and care may be made available to other researchers, in this organisation and in other organisations. These organisations include universities, NHS organisations or companies involved in health and care research in the UK or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

19. For how long will we keep your data?

We will keep coded information about you for at least 25 years after the study has ended. By keeping this information, any future related clinical or laboratory research that gathers new information on the management of breast cancer locoregional recurrence can be linked to the coded information.

20. Complaints

If you wish to make a complaint on how we have handled your personal data, you should contact the Data Protection Officer of your hospital/ sponsor (see study contact details below). This person will investigate the issue further. Or, you can contact the Data Protection Officer of Leeds Teaching Hospitals (see contact details below). If you are not satisfied or believe Leeds Teaching Hospitals is using your personal data in a way that is not lawful, you can complain to the Data protection authority in your country.

Whom can I contact?

Sponsor's data protection officer at the Leeds Teaching Hospitals NHS Trust

Jonny.chagger@nhs.net

Data protection officer at the participating hospital Insert local details