Plastic and Reconstructive Surgery
East Anglian Regional Service

	Consultant Plastic Surgeons **Direct Telephone Lines**
Head and Neck Tumour	Mr. A F Bardsley 288126
Cleft Lip and Palate	Mr. M Meyer 288543
Congenital Deformities	Ms. E M Sassoon 288105
Hand Surgery	Mr. R M Haywood 288131
Facial Reconstruction	Mr. J J Clibbon 288131
Micro Surgery	Mr. M D Moncrieff 288127
Breast Reconstruction	Miss R S Ali 288167
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Dept. of Plastic Surgery, Norfolk and Norwich University Hospital, Colney Lane, Norwich, NR4 7UY

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CONSENT TO PARTICIPATE AS A SUBJECT IN A RESEARCH PROJECT

RANDOMISATION PHASE

Title of Study: Multicenter Selective Lymphadenectomy for Melanoma Trial II: A Phase III Multicenter Randomised Trial of Sentinel Lymphadenectomy and Complete Lymph Node Dissection versus Sentinel Lymphadenectomy Alone in Cutaneous Melanoma Patients with Molecular or Histopathological Evidence of Metastases in the Sentinel Node (MSLT-II)

Investigator: Mr. Marc Moncrieff

Institutional Affiliation: Norfolk and Norwich University Hospital Foundation NHS Trust
Colney Lane
Norwich
NR4 7UY

Sponsor: John Wayne Cancer Institute (JWCI)
Funded in part by National Cancer Institute Grant Number P01 CA29605.

This is a research study. Research studies include only people who choose to take part. Please take your time to make your decision. Discuss it with your friends and family.

Subject's Initials _____

You have been asked to volunteer for this research study because you have a form of cancer called melanoma, and your doctor has found that cancer cells have spread to your lymph node(s). You might have already participated in the Screening Phase of this study.

Thank you for reading this.

WHY IS THIS STUDY BEING DONE?

The overall purpose of the research is to find out if melanoma can be treated by removing only a few lymph nodes (called "sentinel nodes") from a lymph basin (called a "sentinel node dissection"), or if all lymph nodes in a lymph basin must be removed (called a "complete lymph node dissection").

To find the answer, we will compare people who receive sentinel node dissection only with those who also receive a complete lymph node dissection. We will look at each group for ten years to see whether their melanoma spreads, whether they die from their melanoma, and other factors.

WHY HAVE I BEEN CHOSEN?

The sentinel node biopsy that you had has shown that the melanoma cells have spread to your lymph nodes. You have already had these sentinel nodes removed. We do not know if removing the rest of the lymph nodes in the same group is necessary or not. That is the purpose of the study and why you have been chosen to enter into it if you wish.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Many research sites around the world will contribute, and about 1925 subjects will be participating in this phase of the study. At our site, we plan to randomise about 50 subjects.

DO I HAVE TO TAKE PART?

It is up to you whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving reason. A decision to withdraw at anytime, or a decision not to take part, will not affect the standard of care you receive.

WHAT IS INVOLVED IN THIS STUDY?

If you agree to be a part of this study, you will be "randomised" into one of two treatment groups. The first group receives a complete lymph node dissection. The second group receives regular ultrasound tests of their lymph node basin. Randomisation means that you are put into a group by chance. It is like flipping a coin, but it is done using a computer. Neither you nor the doctor will be able to choose which group you will be in. You will have an equal chance of being placed in either group.

If you agree to take part in this study, the following procedures will be done as a part of the study:

Subject's Initials _____

Chest X-ray or a computerized tomography (CT) of the Chest. You do not need one if you have had a Chest x-ray in the last 60 days, or a CT of the Chest in the last 90 days. This will help us be sure that your cancer has not spread.

You must have a complete medical history and physical exam if you have not had one within the past 60 days.

You must complete a Quality of Life Questionnaire and a Medical Outcomes Study (MOS).

Node(s) removed during your lymph node dissection as well as your melanoma biopsy will be sent to the University of California, Los Angeles (UCLA) for further examination under a microscope.

You will be randomised to one of the two treatment groups.

1) You may be randomised to receive a complete lymph node dissection. If so, you will see your doctor every four months for two years after randomisation. Then it will be every six months for the next three years. Then it will be once a year for five more years. You will have a physical exam each time you see your doctor. You will fill out a Quality of Life Questionnaire 4 months and 12 months after you randomise and then annually thereafter until the end of your fifth year. You will also fill it out if your melanoma comes back, and three months after that. You will have radiology tests (X-Rays, CTs, MRIs) for safety according to your doctor's standard of care.

2) You may be randomised to observation. If so, you will have all of the procedures noted above. Additionally, you will have a nodal ultrasound at every visit until the end of your fifth year.

HOW LONG WILL I BE IN THE STUDY?

You will be in the randomisation phase of the study for ten years.

The researcher may decide to take you off this study if it is in your best interest or if the study is stopped for any reason.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

WHAT DO I HAVE TO DO?

If you have been randomised to receive surgery then there will be a recovery period from this. Once this is over there are no other lifestyle restrictions or restrictions on medication. If you are randomised to Ultrasound monitoring, you will be required to have an Ultrasound of you lymph nodes every 4 months as well as your usual follow up visit.

WHAT ARE THE RISKS OF THE STUDY?

While on the study, you are at risk for the following side effects. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict.

The nodal ultrasound has no known risks or side effects except occasional minor discomfort from pressure on the skin of the nodal basin during use of the ultrasound probe.

The complete node dissection may have risks and side effects. These include early postoperative morbidity related to local side effects of the surgical procedure such as infection, bleeding, pain and discomfort at the site of surgical excision, more systemic side effects such as pneumonia, heart attack, blood clots traveling to the lungs which could lead to prolongation of hospitalization and rarely death. Long term side effects consist of swelling or lymphedema of the legs or arm when the surgery involves the groin or the armpit.

In addition, there may be other risks that are currently unforeseeable.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other patients with melanoma in the future. The possible benefits of taking part in this study are the same as receiving a complete lymph node dissection without being in the study.

WHAT OTHER OPTIONS ARE THERE?

You may have a complete lymph node dissection even if you do not take part in the study. Please talk to your regular doctor about this and other options. Take the opportunity to ask questions.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

You will not be compensated for your participation in this study.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study.

If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. Also on receiving new information, your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

WHAT IF SOMETHING GOES WRONG?

Subject's Initials _____

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms should be available to you. If you believe that you have experienced a research-related illness or injury, you must contact Mr. Marc Moncrieff immediately.

WHAT ABOUT CONFIDENTIALITY?

The doctor will take all reasonable measures to protect the confidentiality of your records. The only people who will know that you are a research subject are members of the research team and, if appropriate, your doctors and nurses. No information about you, or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights and welfare (for example, if you are injured and need emergency care); or
- if required by law.

The information in this study may be published in medical journals or presented at professional meetings; at no time will it be possible to identify you as a participant of the study.

Authorized representatives of the National Institutes of Health (NIH), John Wayne Cancer Institute, and the ethics committee may need to review records of individual subjects. As a result, they may see your name, but they are bound by the rules of confidentiality not to reveal your identity to others.

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. However, information by which you can be identified will not be otherwise released or published without your separate written consent except as may be required by law.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Your participation is voluntary. You have the right to refuse to participate in this study or to withdraw at any time for any reason. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

If any significant new information about treatment therapy develops, your doctor will inform you, and your options concerning therapy will be discussed at that time. If new information is provided to you, your consent to continue participating will be re-obtained.

Circumstances may arise which may cause the doctor to terminate your participation before completion of this study and that this would be discussed with you in advance of such an occurrence. Your doctor will be informed of your progress.

Subject's Initials _____

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The information in this study may be published in medical journals or presented at professional meetings; at no time will it be possible to identify you as a participant of the study.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The John Wayne Cancer Centre
To Doctors conducting the research are not being paid for this study, although the costs of the tests will be covered.

WHO HAS REVIEWED THIS STUDY?

The St. Thomas' Hospital Research Ethics committee has reviewed this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

Mr. Marc Moncrieff who can be reached at **Department of Plastic and reconstructive surgery, Norfolk and Norwich University hospital, Colney Lane, Norwich, NR4 7UY, 01603 288127.**

Alternatively you can contact the Melanoma Research Specialist Nurse Kelly Almand-Chinn who can be reached at **Department of Plastic and reconstructive surgery, Norfolk and Norwich University hospital, Colney Lane, Norwich, NR4 7UY, 01603 288161.**

You will get a copy of this form.

Thank you for taking part in this study.

Subject's Initials _____

Centre Number:
Study Number: 06/Q0702/22
Patient Identification Number for this trial:

CONSENT FORM

Title of Project: **MSLT II – A randomised comparison of SLNB only versus SLNB and Completion Lymph Node dissection**

Name of Researcher: **Mr. Marc Moncrieff**

Please Initial Box

1. I confirm that I have read and understood the information sheet dated…… (Version……) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at anytime, without giving reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of any of my medical notes may be looked at by responsible individuals or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent (If different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

1 for patient, 1 for researcher, 1 to be kept with hospital notes
Patient Consent form Version 3 December 2011