Participant Information Sheet

Short Title	The Melanoma Margins Trial II (MelMarT-II)
Full Title	A Phase III, Multi-centre Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma
Protocol Number	Lead Group Protocol Number: 02.18 MelMarT-II Version 4.0 dated 08 Nov 2024 & Study Operations Manual
Project Sponsor	Melanoma and Skin Cancer Trials (MASC Trials) Limited, Australia
UK Sponsor	Norfolk & Norwich University Hospitals NHS Foundation Trust (NNUH)
UKPI/Lead	Prof Marc D Moncrieff (NNUH)
Coordinating Principal Investigator	*[Insert Coordinating Principal Investigator here]*

1 Introduction

You are invited to take part in this clinical research study, called the **Mel**anoma **Mar**gins **T**rial II (MelMarT-II). We are asking you if you would be prepared to take part because you have been diagnosed with a form of skin cancer called melanoma which develops from melanocytes (pigment cells). The study aims to further medical knowledge and may improve future treatment of melanoma. The study will investigate how much skin should be removed from around the melanoma during wider excision surgery. Currently, doctors do not know how much skin to remove from around a melanoma to reduce the chances of it coming back. Guidelines in different countries vary in their recommendations on this. This study will investigate if reducing the excision margin to 1cm is as good at reducing the risk of melanoma returning as a 2cm excision margin. The study will involve follow up visits for up to 9 years after the surgery; however this would be considered normal clinical practice.

This Participant Information Sheet/Consent Form tells you about the study. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the study. **Please read this information carefully.** It is important to ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend, or your local doctor.

Participation in this study is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the study, you will be asked to sign the Consent Form. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the study
- Consent to have the tests and treatments that are described
- Consent to obtain primary, secondary and tertiary care resource use data as well as mortality data from Clinical Practice Research Datalink, Hospital Episode Statistics and Office of National Statistics
- Consent to the use of your personal and health information as described.

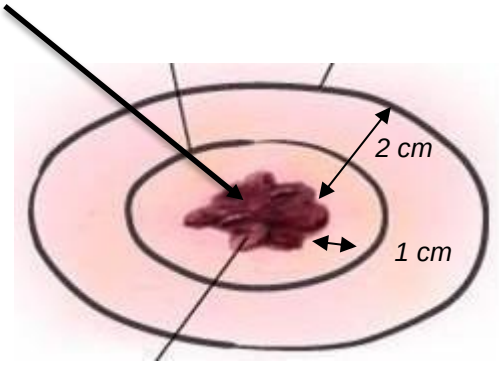
You will be given a copy of this Participant Information Sheet / Consent Form to keep.

2 What is the purpose of this study?

The purpose of this study is to investigate whether reducing the current standard 2cm excision margin to 1cm is safe and whether it changes the risk of melanoma coming back. There is currently no good evidence to prove or disprove that a 1cm margin is as safe as a 2cm margin and a clinical trial, such as this study, is the only way to investigate the safety of a 1cm margin and its possible benefits.

The standard treatment for people with early melanoma is to remove it using surgery. This usually happens in 2 stages (described in Diagram 1 below).

Step 1: *The lesion is removed to confirm what it is (called a biopsy). This usually removes the entire lesion and leaves behind a scar.*



Primary melanoma lesion

Step 2: *Once the lesion has been confirmed as melanoma, your doctor will discuss the MelMarT-II trial and, if you consent and are randomised on to the trial, you will undergo a wider excision procedure. A wide margin of the skin surrounding the lesion is excised (either 1 cm or 2cm from the border of the lesion or from your biopsy scar).*

Diagram 1: *Describes the surgical excisions when a melanoma is removed.*

In the first stage, a doctor, usually a dermatologist (skin specialist), removes some or all of the growth (a biopsy) in order to evaluate the tissue and make a diagnosis. A pathologist examines the growth to confirm that it is a melanoma and to see if the entire tumour has been removed. You may have already had this stage performed and it is most likely that there is only a scar left at the original site of your melanoma. The second stage, known as a “wider excision”, involves removing an extra “safety margin” of skin surrounding the original melanoma site to ensure the removal of any remaining scattered melanoma tumour cells that may have been left behind after the first operation. This is done to reduce the chance of the melanoma returning. Depending on the country you are living in, current guidelines recommend that a safety margin of between 1 and 3cm of skin surrounding the melanoma is removed.

Evidence from previous research suggests that a 1cm excision is enough to reduce a patient's risk of the melanoma coming back in the same area; however, a trial is needed to prove this theory. Other advantages of a reduced surgical margin include:

- Less surgery, which means a smaller scar and potentially less scar tissue.
- Extra surgery to repair the wound, such as a skin graft or other reconstruction, is less likely.
- Reducing the time, it takes for recovery from surgery, possibly resulting in a reduced stay in hospital after the operation. Less time in hospital may make it easier for patients to return to their normal routine, as well as being more affordable overall.
- Reducing the pain that patients may feel immediately after their operation and in the longer term.
- Reducing the length of time, it takes surgeons to perform the surgery, allowing them to see more patients in a day and increasing the availability of the surgeons so they can treat more people.

This study will also look at the costs and effects of having surgery for both patients and the health system. In addition, it will look at the financial impact of melanoma on patients' households. Finding out if patients and their families are experiencing financial hardship will help policy makers to address out-of-pocket costs for future melanoma patients.

3. What does participation in this study involve?

You will be participating in a randomised controlled clinical trial. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (randomly). In this way, we will be able to compare the results of the different margins and therefore determine which is the more effective in preventing melanoma recurrence. This study has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to wrong conclusions. Randomisation means that you are put into a group by chance. Neither you nor your doctor can choose the group you will be in. In this study you will have a 50% chance of having a 1cm or a 2cm margin, as if you flipped a coin.

Screening: You will be asked to read though this information sheet and will be given the chance to ask questions. This process is known as informed consent. If you agree to participate and sign the Consent Form, you will be asked to:

- Undergo a complete physical examination, i.e. your physician will examine you and record your height, weight, etc.
- Review your medical history with your treating physician.
- Have a photograph taken of the site of your primary melanoma lesion.
- Complete quality of life questionnaires (known as the FACT-M and EQ-5D-5L questionnaires). These questionnaires ask how you feel about your treatment, disease and how it affects you and your daily life.
- Complete a pain assessment questionnaire (known as the PainDetect questionnaire).
- Complete a questionnaire (known as the resource use questionnaire) to ask about your healthcare use, health insurance, general employment and income
- Complete a health and social care questionnaire to ask about any charity or community based services you may use.

The questionnaires can be completed either on paper or electronically.

They may be completed during your visit or you may have the option of receiving them by email and completing them at home. They will take no longer than 30 minutes to complete in total and are multiple choice. To enable you to receive the questionnaires by email, the study team will provide the sponsor (MASC Trials) with your email address. This information will be stored securely and only used for the purpose of contacting you for this study.

In order to allow researchers in SITU, based at the University of Oxford, to send paper versions to you in the post, and to contact you if we need to remind you to complete any of the questionnaires, we will ask for your consent to provide your address, email address, and telephone contact details. This information will be kept securely, separately to your clinical information, and accessible only to the study team.

Treatment: You will be assigned to receive either a:

- 1cm Wide Excision of your primary melanoma lesion
- 2cm Wide Excision of your primary melanoma lesion

At the same time, you will have a special test called a Sentinel Lymph Node Biopsy (SLNB). This is a staging procedure and your physician will discuss this with you further. Every patient will be offered this because it is a routine part of treatment and information about the SLNB result will also be collected by the study team. There is a small radiation dose administered as part of the SLNB (which is only performed once in the study), which is equivalent to 2 or 4 chest x-rays or several weeks exposure to natural background radiation.

If you decide to participate in this study, the study doctor will inform your local doctor.

What do I have to do?

For this trial you will be asked to attend regular visits with a doctor involved in this research. These visits are normal for patients with your condition; are recommended by your doctor and align with the national treatment guidelines.

MelMarT-II Study Visit schedule: During the first Year (Year 1): You will attend the first study visit (called the baseline visit) and subsequently visits at 3, 6 and 12 months (called follow up visits).
During Year 2: You will attend follow up visits at 18 and 24 months.
During Years 3 to 9: Regular follow up visits will be performed once per year for up to 9 years; this is considered to be routine clinical care. However, there is no reason why you should not see your doctor more frequently if you need to. These follow-up visits are normal for patients with your condition, are recommended by your doctor and align with national treatment guidelines.

At all of these visits you will have a physical examination to check that your melanoma has not returned and to see if your health and skin have changed.

X-Rays and Imaging: If, as part of your standard care, your physician would like you to have any imaging procedures (including but not limited to the following), we would like to include copies of the reports and images in the study:

- X-Rays
- Computed Tomography Scans (CT)
- Magnetic resonance imaging (MRI)
- Positron emission tomography (PET)
- Ultrasound

It is not required as part of this study that you have any of the above procedures; we only wish to collect copies if they form part of your routine care.

4. Other relevant information about the study

This is an international study with many doctors sharing the findings from their patients. It has been initiated by Professor Marc Moncrieff, who is based at the Norfolk & Norwich University Hospitals NHS Trust; who are also the UK sponsor. The study is being conducted by MASC Trials and the UK collaboration will be managed by an established team at the Surgical Intervention Trials Unit (SITU), based at the University of Oxford.

This research is funded by the National Institute for Health Research (NIHR). MASC Trials does not make any profit from its work. It exists to further knowledge about melanoma, and works with doctors in other countries.

The study in which you are being asked to participate may include patients from the following countries:

- Australia and New Zealand
- United Kingdom (UK)
- Brazil
- Canada
- Denmark
- Italy
- The Netherlands
- Norway
- Slovenia
- Sweden
- United States of America (USA)

It is envisaged that a total of 2,998 people will take part. This is a large study, which is why so many different countries, doctors, hospitals and people with melanoma will be involved. Recruitment will take place over 5 years and those included will be monitored for up to 9 years. Therefore, this phase of the study will take 10 years to complete.

5. Do I have to take part in this study?

Participation in any study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. Your decision on whether or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you, or your relationship with your institute, *[Insert Institution here]*.

If you decide to discontinue the study treatment, please notify a member of the study team beforehand. You will be asked to attend follow-up visits to allow collection of information regarding your health. Alternatively, the investigator/sponsor will request your permission to access your medical records for collection of follow-up information for research and analysis.

6. What are the alternatives to participation?

Surgery is considered standard treatment for people with this diagnosis; however, the surgery can be performed outside of a study setting.

This would mean that you would undergo the standard 2 cm wide excision margin, or as determined by standard UK treatment guidelines. If you decide not to be part of the study, you will be treated and monitored as per your local institution's standard care guidelines.

In most cases this is a 2cm surgical wide excision procedure. You will be monitored afterwards in the same way as you would be if you were part of the study.

Participation in this study is voluntary. If you choose not to participate in this study, you and your doctor can discuss and agree on the most appropriate treatment for you. Whatever your decision, it will not affect your relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time. You do not have to give a reason.

7. What are the possible benefits of taking part?

The results of the study may not directly benefit you. If you are allocated to the group receiving the 2cm excision, then you will receive no direct benefit as this is the same as the standard procedure. However, you will be contributing to the study and the results may benefit those in the future with melanoma. Possible benefits if you are allocated to the 1cm margin include:

- Having less surgery to remove the primary melanoma lesion
- A smaller scar
- Less pain at the site of your surgery
- Reduced chance of requiring a skin graft to repair removed skin, which means a less complex procedure
- A shorter hospital stay after surgery
- A reduced time for recovery. This may have cost implications for you, your family, industry and the health system. We will ask you about the costs associated with your disease and treatment, and correlate the data with national government healthcare databases, so that we can help inform policy makers about the costs associated with treating melanoma.

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

Surgery may cause side effects and all patients in the study will undergo a wide excision. So, irrespective of the treatment arm to which you are allocated (1 or 2 cm excision margin), you may experience none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will be monitoring you for side effects throughout the whole study.

Common Side Effects:

- Having a tissue sample taken may cause some discomfort, bruising, minor infection or bleeding (short term)
- Pain at the surgical site (short and long term)
- Scarring at the surgical site (long term)

Rare Side Effects:

- Reduced mobility in some locations on the body (face, hands, areas surrounding joints, etc.) (short and long term)
- Infection at the surgical site (short term)
- Minor bleeding (short term)
- Swelling at the surgical site or in a limb (called lymphoedema) (long term)
- Reopening of the wound (short term)
- Tingling or numbness relating to damage to nerves (short and long term)

Many side effects disappear shortly after the end of treatment. However, sometimes side effects can be serious, long lasting, or permanent.

Your study doctor will discuss the best way of managing any side effects with you. There may be other side effects that the researchers do not expect or do not know about and that may be serious. Please tell your study doctor immediately if you experience any new or unusual symptoms.

We believe that there will be no difference in the chance of the melanoma coming back between the patients who have a 2cm margin and those who have a 1cm margin. However, it is possible that a 1cm margin will be less effective and therefore you may be at an increased risk of your melanoma coming back if you are allocated to this treatment group. We do not know if this is the case and that is why we are conducting this study. There is a potential risk that, in a small number of patients, the 1cm margin may not be wide enough to completely remove all of the melanoma that can be seen under the microscope. The risk is very small but, if this happens, then you may need to have yet more surgery to ensure no melanoma has been left behind. This will be inconvenient and delay your recovery. We also believe that, for patients who have the bigger, 2cm margin, there is an increased risk of experiencing any of the side effects listed above, though this is the standard treatment that patients with melanoma would normally be offered by their doctor. In order to manage this risk, your doctor will be monitoring you regularly as part of this study.

If you take part in this study, you will have a sentinel node biopsy. You may have a SPECT scan or a CT scan if these are already considered to be standard practice at your site. Some of these scans may be extra to those that you would have if you did not take part and some may contribute additional radiation exposure. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.
The chance of this happening to you as a consequence of taking part in this study is extremely small.

9. Can I have other treatments during this study?

Yes, while you are participating in this study, you will be able to continue taking any of the medications or treatments you have been taking for your condition or for other reasons. However, it is important to tell your study doctor and the study staff about any treatments or medications, including over-the-counter medications, vitamins, herbal remedies, acupuncture, or other alternative treatments, that you are using. You should also tell your study doctor about any changes to these during your participation in the study. The study doctor and study team will closely monitor treatments or medications which might affect your health during the study.

10. What if I withdraw from this study?

If you decide to withdraw from the study, please notify a member of the study team before you withdraw. If you do withdraw during the study, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the study can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdrew will form part of the study results. If you do not want them to do this, you must tell them before you join the study.

11. What if I am withdrawn from the study because I am ineligible and have had surgery?

Occasionally, a patient may be incorrectly enrolled onto the study. If this is the case, you would be notified immediately by the research team, and the reason for withdrawal would be explained to you. At this time, you would have the opportunity to discuss your ongoing care with your medical team outside of the study. Withdrawal from the study like this will not affect the standard of care you receive. Your relationship with the clinical care team and with your hospital will not change.

If you are withdrawn for reasons of ineligibility, your care will be transferred to your local clinical team and you will not be required to complete any further participant questionnaires. However, the Research Ethics Committee has advised that anonymised safety data should be collected about you, including any surgical site problems, any resections, or any local, regional and distant disease recurrence that may occur. For this we are proposing passive follow up from the NHS Electronic Medical Records system. The above-mentioned safety data will be extracted from your NHS Medical Record, yearly from the date of your withdrawal and carried out locally by staff with a direct care role and with legitimate access to your sensitive personal identifiers. The file, linking your anonymised data to your identity, will be held securely and accessed **only** by staff in a direct-care role. The Research Study Team and the Research Ethics Committee will be sent your anonymised safety data for review. You would be aware of any safety concerns as a result of continuing to see your local clinical team, per standard of care. Any relevant findings will be included in the final published results.

This is voluntary and you have the option to opt out without giving a reason and without it affecting your ongoing care.

12. Could this study be stopped unexpectedly?

This study may be stopped unexpectedly for a variety of reasons which will be reviewed by the study management committee and your study doctor will be immediately notified of any decision to stop the study; reasons may include:

- Feasibility and recruitment issues
- Unacceptable side effects
- The 1cm margin is shown not to be as safe as the 2cm margin

13. What happens when the study ends?

Once you have completed the study, the study team will collate and publish the results to the medical community through journal publications and conference presentations. The final published results will be shared with you by your study doctor, and will be publicly accessible for the benefit of all patients diagnosed with melanoma, doctors, and researchers.

Furthermore, you will be monitored as per your local healthcare provider's standard of care. If your melanoma returns, you will be offered the choice of the best treatment available by your treating doctor.

14. What will happen to information about me?

What is patient data?
When you go to your GP or hospital, the doctors and others looking after you will record information about your health. This will include your health problems, and the tests and treatment you have had. They might want to know about family history, if you smoke or what work you do. All this information that is recorded about you is called patient data or patient information.

When information about your health care joins together with information that can show who you are (like your name or NHS number) it is called identifiable patient information. It's important to all of us that this identifiable patient information is kept confidential to the patient and the people who need to know relevant bits of that information to look after the patient. There are special rules to keep confidential patient information safe and secure.

What sort of patient data does health and care research use?
There are lots of different types of health and care research. If you take part in a clinical trial, researchers will be testing a medicine or other treatment. Or you may take part in a research study where you have some health tests or answer some questions. When you have agreed to take part in the study, the research team may look at your medical history and ask you questions to see if you are suitable for the study. During the study you may have blood tests or other health checks, and you may complete questionnaires. The research team will record this data in special forms and combine it with the information from everyone else in the study. This recorded information is research data.

In other types of research, you won't need to do anything different, but the research team will be looking at some of your health records. This sort of research may use some data from your GP, hospital or central NHS records. Some research will combine these records with information from other places, like schools or social care. The information that the researcher collects from the health records is research data.

Why does health and care research use information from patients?
In clinical trials, the researchers are collecting data that will tell them whether one treatment is better or worse than another. The information they collect will show how safe a treatment is, or whether it is making a difference to your health. Different people can respond differently to a treatment. By collecting information from lots of people, researchers can use statistics to work out what effect a treatment is having.

Other types of research will collect data from lots of health records to look for patterns. It might be looking to see if any problems happen more in patients taking a medicine. Or to see if people who have screening tests are more likely to stay healthier.

Some research will use blood tests or samples along with information about the patient's health. Researchers may be looking at changes in cells or chemicals due to a disease.

All research should only use the patient data that it really needs to do the research. You can ask what parts of your health records will be looked at.

How does research use patient data?
If you take part in some types of research, like clinical trials, some of the research team will need to know your name and contact details so they can contact you about your research appointments, or to send you questionnaires. Researchers must always make sure that as few people as possible can see this sort of information that can show who you are.

In lots of research, most of the research team will not need to know your name. In these cases, someone will remove your name from the research data and replace it with a code number. This is called coded data, or the technical term is pseudonymised data. For example, your blood test might be labelled with your code number instead of your name. It can be matched up with the rest of the data relating to you by the code number.

In other research, only the doctor copying the data from your health records will know your name. They will replace your name with a code number. They will also make sure that any other information that could show who you are is removed. For example, instead of using your date of birth they will give the research team your age. When there is no information that could show who you are, this is called anonymous data.

Where will my data go?
Sometimes your own doctor or care team will be involved in doing a research study. Often, they will be part of a bigger research team. This may involve other hospitals, or universities or companies developing new treatments. Sometimes parts of the research team will be in other countries. You can ask about where your data will go. You can also check whether the data they get will include information that could show who you are. Research teams in other countries must stick to the rules that the UK uses.

We would like to collect your email address for the purpose of sending you Quality of Life questionnaires to you via email. Your email address will be stored on our electronic database called "REDCap" and access to your identifiable information will be restricted only to members of the sponsor (MASC Trials) team. The electronic database is password protected and will send you reminders indicating when follow-up quality of life questionnaires are due.

All the computers storing patient data must meet special security arrangements.

What are my choices about my patient data?
You can stop being part of a research study at any time, without giving a reason, but the research team will keep the research data about you that they already have. You can find out what would happen with your data before you agree to take part in a study.
In some studies, once you have finished treatment the research team will continue to collect some information from your doctor or from central NHS records over a few months or years so the research team can track your health. If you do not want this to happen, you can say you want to stop any more information being collected.
Researchers need to manage your records in specific ways for the research to be reliable. This means that they won't be able to let you see or change the data they hold about you. Research could go wrong if data is removed or changed.

What happens to my research data after the study?
Researchers must make sure they write the reports about the study in a way that no-one can work out that you took part in the study.

Once they have finished the study, the research team will keep the research data for several years, in case they need to check it. You can ask about who will keep it, whether it includes your name, and how long they will keep it.

Usually your hospital or GP where you are taking part in the study will keep a copy of the research data along with your name. The organisation running the research will usually only keep a coded copy of your research data, without your name included. This is kept so the results can be checked.

If you agree to take part in a research study, you may get the choice to give your research data from this study for future research. Sometimes this future research may use research data that has had your name and NHS number removed. Or it may use research data that could show who you are. You will be told what options there are. You will get details if your research data will be joined up with other information about you or your health, such as from your GP or social services.

Once your details like your name or NHS number have been removed, other researchers won't be able to contact you to ask you about future research.

Any information that could show who you are will be held safely with strict limits on who can access it.

You may also have the choice for the hospital or researchers to keep your contact details and some of your health information, so they can invite you to take part in future clinical trials or other studies. Your data will not be used to sell you anything. It will not be given to other organisations or companies except for research.

Will the use of my data meet GDPR rules?
GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If they could do the research without using patient data they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

If you have any concerns or require any further information regarding the use of your data then please contact the lead sponsor via email at the following address: enquiries@masc.org.au
The website for the lead sponsor can be found at the following address, which has additional contact information: https://www.masc.org.au/

What if I don't want my patient data used for research?
You will have a choice about taking part in a clinical trial testing a treatment. If you choose not to take part, that is fine. In most cases you will also have a choice about your patient data being used for other types of research. There are two cases where this might not happen:

- *When the research is using anonymous information.*

Because it is anonymous, the research team doesn't know whose data it is and can't ask you.

- *When it would not be possible for the research team to ask everyone.*
  This would usually be because of the number of people who would have to be contacted. Sometimes it will be because the research could be biased if some people chose not to agree. In this case a special NHS group will check that the reasons are valid. You can opt-out of your data being used for this sort of research. You can ask your GP about opting-out, or you can find out more.

Who can I contact if I have a complaint?
If you want to complain about how researchers have handled your information, you should contact the research team, details are provided at the end of this information sheet. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer.

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Norfolk and Norwich University Hospitals NHS Foundation Trust will act as UK Data Controllers for this study. The lawful basis for processing personal data collected in this study is that it is a task in the public interest. You can find out more about how we use your information at https://www.nnuh.nhs.uk/publication/privacy-notice-v4/ or contacting the Data Protection Officers (info.gov@nnuh.nhs.uk or 01603 286286).

15. Complaints and compensation

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). By signing the consent form, you have not waived any legal or other right to seek compensation.

[Localise for participating sites]
If you wish to make a formal complaint regarding your treatment or the conduct of the study, please contact your hospital who will advise you how to do this through NHS Complaints procedure.
Alternatively, you may wish to contact the local Patient Advice & Liaison Service (PALS) in the first instance to seek advice and support. The local PALS contact details are as follows:
[Insert NHS PALS contact details here as applicable]
Telephone:

16. Who is organising and funding the study?

This is an investigator-initiated clinical trial. This means that the concept of the study has been designed by the doctors who treat melanoma. This study is being organised by Melanoma and Skin Cancer Trials (MASC Trials) and Norfolk & Norwich University Hospitals NHS Foundation Trust, UK who are the sponsor for the UK sites. The study represents an international collaboration of academic and clinical institutions.

The funding of the centralised trial management for the study is Australian and comes from a research grant from the National Health and Medical Research Council (NHMRC) Australia. There is a local study sponsor in each participating country who is also responsible for organising and funding the study at your institution. No member of the study team will receive a personal financial benefit from your involvement in this study (other than their ordinary wages).

Funding for the UK part of the study is provided by the National Institute for Health Research (NIHR) and the Surgical Trials Intervention Unit (SITU) based at the University of Oxford will be responsible for managing the study.

17. Who has reviewed the study?

All research in the UK involving humans is reviewed by an independent group of people called a Research Ethics Committee (REC). This study has been reviewed and approved by the Cambridge East REC reference number: 19/EE/0369, IRAS ID 257226.

The conduct of this study at the *[Insert name of hospital here]* has been authorised by the Health Research Authority (HRA). Any person with concerns or complaints about the conduct of this study may also contact the HRA (www.HRA.nhs.uk) and quote protocol number IRAS ID:257226.

This study will be carried out according to the principles agreed at the International Conference on Harmonisation Good Clinical Practice. In the UK this is governed by the Health Research Authority (www.hra.nhs.uk) & the UK Policy Framework for Health and Social Care Research.

18. Further information and whom to contact

If you want any further information concerning this study, or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact the following: *[Insert hospital specific details]*

Principal Investigator

Name	
Position	
Telephone	
Email	

Clinical Research Nurse

Name	
Position	
Telephone	
Email	

Complaints

Name	
Position	
Telephone	
Email	

Informed Consent Form

Short Title	Melanoma Margins Trial II (MelMarT-II)
Full Title	A Phase III, Multi-centre Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma
Protocol Number	Lead Group Protocol Number: 02.18 MelMarT-II Version 4.0 dated 08 Nov 2024 & Study Operations Manual
Project Sponsor	Melanoma and Skin Cancer Trials (MASC Trials) Limited, Australia
UK Sponsor	Norfolk & Norwich University Hospitals NHS Foundation Trust (NNUH)
UKPI/Lead	Prof Marc D Moncrieff (NNUH)
Coordinating Principal Investigator	*[Insert Coordinating Principal Investigator here]*

Declaration by Participant

Participant initials

I have read the Participant Information Sheet dated ___/___/_____ (version ____)
I have had an opportunity to ask questions and I am satisfied with the answers I have received. ☐

I understand the purposes, procedures and risks of the research described in the Participant Information Sheet. ☐

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Insert name of Institution here]* concerning my disease and treatment for the purposes of this study. I understand that such information will remain confidential. ☐

I consent to donate blood and/or tissue samples for use in other/or future ethically approved research. These samples will be de-identified and may be stored in a biorepository. ☐ *Optional*

I freely agree to participate in this study as described and understand that I am free to withdraw at any time during the study without affecting my future health care. ☐

I understand that I will be given a signed copy of this document to keep. ☐

I understand that, if I decide to withdraw from the study, I may be asked to attend follow-up visits to allow collection of information regarding my health. ☐

I understand that, if I am withdrawn from the study, a member of the study team may request my permission to obtain access to my anonymised medical records for collection of follow-up information for the purposes of research and analysis. ☐

I understand that the information collected about me may be used in an anonymous form to support other research in the future. It will not be possible for me to be identified by it. ☐

I give consent for information on primary, secondary and tertiary care resource use to be obtained via The Clinical Practice Research Datalink, NHS England for Hospital Episode Database (HES) and the Office of National Statistics, if necessary, and for this information to be accessible for at least 9 years for the purposes of the study. ☐

I give permission for my doctors to notify my GP that I have been enrolled onto this study. ☐

I understand that the SITU study team may need to contact me to send paper versions of questionnaires through the post and reminders for questionnaire completion. I give permission for my postal address, email address, and telephone contact details to be kept and used for this purpose, on the understanding that they will be kept securely, separately to my clinical information, and accessible only to the SITU study team. ☐

I understand that MASC Trials Limited will need to contact me via email to administer the questionnaires and reminders for questionnaire completion. I give permission for my email address to be kept and used for this purpose, on the understanding that it will be kept securely, separately to my clinical information, and accessible only to the MASC Trials Limited team. ☐

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher

I have given a verbal explanation of the study, its procedures and risks and I believe that the patient has understood that explanation.

Name of Study Doctor/
Senior Researcher (please print) _____

Signature _____ Date _____

University of Oxford SITU Surgical Intervention Trials Unit
SUPPORTED BY NIHR National Institute for Health Research