Participant Information Sheet

(Final version 1.0: 17 Jan 2013)

Title of Study: Participant acceptability of a proposed future skin cancer trial

Name of Lead Researcher: Dr Louise Lansbury

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish. If anything is not clear after reading this information sheet, one of our team will be happy to go through it with you and answer any questions you may have (contact details are given at the end of this sheet).

What is the purpose of the study?

We are conducting exploratory work to assess whether a future skin cancer trial which we are currently developing would be acceptable to potential participants and what sort of barriers may prevent recruitment into such a trial. This study also forms part of the PhD work of Louise Lansbury, the lead researcher.

Squamous cell carcinoma of the skin (SCC) is a common type of 'non-melanoma skin cancer', the vast majority of which are successfully treated. Usually this involves cutting out the cancer with a margin of normal looking skin (the excision margin). Other types of treatment are sometimes used, and occasionally a group of skin cancer specialists may decide to treat an SCC that has already been surgically excised with some additional radiotherapy.

Occasionally, SCCs that appear to have been treated successfully come back, either in the same area as the original SCC, or they may spread to lymph nodes or a distant organ. This is called 'recurrence' and some SCCs have particular features which makes the chances of this happening more likely. These are called 'higher-risk' SCCs.

Although there are professional UK guidelines which suggest how large the excision margin size should be for SCCs, the evidence upon which these guidelines are based is limited. Similarly, there is uncertainty as to whether some patients are more likely than others to benefit from extra radiotherapy after their surgery. Therefore we are developing a trial to see if we can reduce the risk of recurrence of SCC by comparing recurrence of SCCs that have been cut out with a 6mm margin of normal looking skin with those that have been cut out with a 10mm margin, and then further examining whether patients who have had surgery and who have SCCs with particular high-risk features would benefit by having additional radiotherapy.

We would like patients who have recently been diagnosed with this type of skin cancer to help us make sure that we get the best trial possible by finding out what is important to them about their treatment and whether they would in principle be prepared to take part in such a trial themselves and if not, why not. This will help us to decide if the proposed future trial is feasible to do and whether to pursue our idea further.

The current study involves completing a questionnaire which will be sent by post and returned to the research team. For participants who would like to help us further, we will also run a follow-up focus group to explore issues in greater depth. Please note that if you take part in our current study, you will NOT take part in the trial itself, which is currently only in the early stages of development.

Why have I been invited?

You are being invited to take part because you were recently treated for this particular kind of skin cancer. We will be approaching about 20 people like you who have experienced this condition, asking them to answer some questions about the trial we are proposing and, if they are interested, to take part in a focus group to discuss issues in greater depth.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and your consent to take part will be implied by returning the completed questionnaire. People who complete the questionnaire are under no obligation to take part in the follow-up

focus group if they do not wish to, and those who do take part in the focus group will be asked to sign a separate consent form.

If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

The chart below summarises each stage of your involvement in our study if you agree to take part:

Invitation
The consultant dermatologist who treated you will send you a **letter of invitation** to take part, along with this Participant Information Sheet. ***The research team will only send you the questionnaire after you have given permission for them to have your contact details by returning the enclosed reply slip.***
Postal Questionnaire
Details of the proposed trial and the **questionnaire** itself will be sent by post for you to complete in your own time. *Time to complete questionnaire*: 45 minutes to 1 hour
Focus Group
People expressing interest on the questionnaire will be invited to take part in a follow-up focus group with other participants (anticipated 6 or 7) and two researchers. This will take place at Kings' Meadow Campus at the University of Nottingham. Potential participants will be telephoned with further details of the focus group upon receipt of their completed questionnaire, with written confirmation and final details being sent to those able to take part in the week before the meeting. Prior to the discussion written consent will be obtained from each participant. An audio-recording of the discussion will be made to assist with analysis. *Duration:* Approx 1-2 hours

If you agree to take part, we would only ask that you are completely honest in response to the questions you are asked. We would rather learn about possible barriers which may prevent people from wanting to take part in the actual study at this early stage rather than when the study is up and running.

You are very welcome to discuss the questionnaire with relatives and friends, but please note that it is only **your** views in which we are interested. Please also note that by taking part in this work you are providing valuable input into the development of a future trial, and that you will not be taking part in the final trial itself.

Expenses and payments

Participants will not be paid to participate in the study. Focus group participants will be reimbursed all out-of-pocket expenses and will also receive £25 in high-street vouchers in recognition of the time given up to attend the group.

What are the possible disadvantages and risks of taking part?

There are no foreseeable risks if you agree to take part. Your clinical care will not be affected in any way if you agree to participate in our research. Please note that the research team will not be able to answer questions about your clinical care. It is important that you keep all other appointments that have been arranged with the doctors involved in your care.

What are the possible benefits of taking part?

Although you will not directly benefit from this study, the information we get from those who take part will help us to understand whether our proposed trial will be acceptable to future skin cancer patients who may be asked to take part, and may raise issues which we will need to take account of when we are designing the trial.

What happens when the research study stops?

Your participation in this study will end when you have completed the questionnaire, or after the focus group if you decide to also take part in this. You will be asked if you would like to receive a summary of the results of this work after all the data has been analysed.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Complaints. Details can be obtained from the Patient Advice and Liaison Service (PALS) at Nottingham University Hospitals NHS Trust, Freepost, NEA 14614, Nottingham NG7 1BR (tel: 0115 9249924 ext 65412)

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for 6 to 12 months after the end of the study so that we are able to contact you about the findings of the study and future related work (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the focus group is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be notified of your participation in this study**.**

What will happen to the results of the research study?

The results of this phase of the research will be used to assess the feasibility of doing a study of excision margins and radiotherapy for SCC in the future. This research will be incorporated into a chapter of the researcher's PhD thesis which will eventually be accessible via the University of Nottingham's on-line thesis repository and may also be published in a peer-reviewed journal or presented at a dermatology conference. You will not be identified in any report or publication resulting form this work.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the National Institute for Health Research as part of a programme grant award (RP-PG-0407-10177) awarded to the Centre of Evidence Based Dermatology.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Coventry and Warwickshire Research Ethics Committee Proportionate Review Sub-Committee.

Further information and contact details

Further information can be obtained from the Centre of Evidence Based Dermatology website: www.nottingham.ac.uk/scs/divisions/evidencebaseddermatology/research/nihrprogrammegrant/skincancer.aspx

Contact: Dr Louise Lansbury (Research Associate)

Tel: 0115 8468721

E-mail: Louise.Lansbury@nottingham.ac.uk

Chief Investigator: Dr Fiona Bath-Hextall (Reader and Associate Professor of Evidence Based Healthcare)

Tel: 0115 8230883

Address: Centre of Evidence Based Dermatology, University of Nottingham, King's Meadow Campus, Lenton Lane, Nottingham NG7 2NR