PARTICIPANT INFORMATION SHEET
28 Mar 2019 v2.0
Study: nomela® C8 IRAS 254451

PLEASE READ THIS INFORMATION SHEET

Study Title: TESTING nomela® ON SUSPICIOUS PIGMENTED NAEVI (MOLES): a hospital-based study

This is to invite you to take part in a research study which Dr Nigel Burrows, Consultant Dermatologist, of Addenbrooke's Hospital, Cambridge University Hospitals NHS Trust and specialist colleagues are carrying out.

Before you decide, you need to understand why the research is being done and how you would be involved. Please take time to read the following information.

Background Most skin moles are not serious but an important small number are serious (melanoma). The load on health services from moles with a suspicion of malignancy is substantial yet many moles referred to hospital are considered benign on inspection by the specialist. However some moles require a skin biopsy to clarify the diagnosis.

Purpose of the study This study will check the performance of nomela®, a photographic image analysis test using tablet software technology, which aims to assist in the exclusion of melanoma. If nomela® is shown to work well it would be used to reduce the need for referral for a skin biopsy.

Why have I been invited? You have been invited to take part because you have a pigmented mole which the specialist has decided on routine clinical grounds to have removed for a specialist pathology opinion.

Do I have to take part? You do not have to take part. It is up to you to decide. This Information Sheet describes the study. You can ask further questions if you need to clarify anything or have any other concerns (see Contact below). You will then be asked to sign a Consent Form on the nomela® device to show you have agreed to take part.

If you agree to participate you are free to withdraw at any time without giving a reason and this will not affect the standard of care you receive. All information about you that has been collected for the study will be deleted and not used in any way.

What will happen to me if I agree to take part? When the specialist has decided to arrange for a biopsy of your mole or for your mole to be removed the routine practice is to have photographs taken of the mole(s) by the Media Studio photographers. The only extra activity over the routine is that you will have nomela® test photographs taken of your mole in this clinic by the nurse using a specially prepared iPad: this lasts a few minutes.

Your routine care will not be affected.

Benefits There will be no direct benefit to you at present. However if the nomela® test is found to be fit for purpose then specialist dermatologists/plastic surgeons and general practitioners will support its wider use.

Risks There is very little risk associated with taking part in the study.

1 Whether you take part or not in the study, the specialist has considered that biopsy or removal of the mole is needed. This will be explained separately and a separate consent will be requested. 2 The risk of exposure of your personal data is minimised as follows: Your hospital number is only shown on the electronic consent form which you complete. This is immediately transferred securely from the device to a dedicated research NHS email which is only available to your specialist doctor and the dedicated

clinical research team. No personal or test information of any kind is kept on the nomela® device on completion of the test and its transfer. Your hospital number is encrypted securely on the Moletest server only for linkage to the diagnosis of your skin biopsy by the clinical research team but cannot be discovered by anyone other than the specialist doctor and dedicated clinical research team.

For the avoidance of doubt:

- Your hospital number is only available to your doctor/nurse.
- Your hospital number is not available to Moletest.
- Your hospital number is not available to access by others.

Confidentiality Any personal information about you collected for this study will be kept strictly confidential by the NHS. The information you provide to be used by Moletest (Scotland) Ltd will not be directly associated with your identifiable personal information. The security and nature of the information held has been approved by the NHS IT security authorities and NHS Clinical Information Governance.

Results The results of this study will be published in suitable medical journals and presentations may be made at relevant medical conferences. Under no circumstances will your name or other personal details be revealed. You will be able to request a summary of the results of the study from the Dermatology Department, Addenbrooke's Hospital if you wish.

Follow-up None

Research team, Sponsor and funders

- Dr. Nigel Burrows, Consultant Dermatologist, is the Principal Investigator; Dr. Ed Rytina, Consultant Histopathologist, is Co-Investigator. (Cambridge University Hospitals NHS Foundation Trust)

- The Study Sponsor is Moletest (Scotland) Ltd.

- The data (anonymised) will be analysed by medical statisticians at the University of Aberdeen.

- The Study is funded by Moletest (Scotland) Ltd.

Who has reviewed this study? This study has been reviewed and approved by an independent NHS Research Ethics Committee in the UK.

Concerns If you have a concern about any aspect of this study please discuss this with the clinical research nurse/dermatology nurse in the first instance who will do her/his best to answer your questions.

If the problem is not resolved you may seek help from the Patient Advice and Liaison Service (PALS) - tel: 01223 216756 email: pals@addenbrookes.nhs.uk

In the unlikely event that something goes wrong and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for legal action for compensation against the Cambridge University Hospitals NHS Trust and/or Moletest (Scotland) Ltd., but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Withdrawal If you wish to withdraw from the study at any time, you may do so without giving a reason. The nomela® photographs of your mole and any data collected specifically for the study will be destroyed and removed from the analysis.

PLEASE KEEP YOUR COPY OF THIS INFORMATION SHEET

Contact for further information: If you have any further questions or concerns about the study please contact: Clinical Research Nurse, Dept. of Dermatology, Clinic 7, Addenbrooke's Hospital. tel: 07340 619965