Appendix B1 Participant Information Sheet

PLEASE READ THIS INFORMATION SHEET

Title: REGRESSION TESTING NOMELA® ON IMAGES OF SKIN LESIONS CONFIRMED AS CUTANEOUS MELANOMA

NOMELA® C7-1

We would like to invite you to take part in a research study being carried out by Dr Frances Gallagher, Consultant Pathologist and Dr Girish Gupta, Consultant Dermatologist, University Hospital Monklands.

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

Background and purpose of the study Most moles are not serious but an important small number are serious and malignant (melanoma). The clinical load on health services from moles which may be suspicious of malignancy is substantial but a large number of those referred to hospital are considered by the specialist dermatologist to be benign.

This study will evaluate a novel photographic image analysis test, **nomela®**, using iOS technology from Moletest Ltd., which may reduce the need for referral to a specialist by earlier exclusion of moles which are not likely to be melanoma.

The study is to test images of known melanoma.

Why have I been invited? You have been invited to take part because your pigmented mole has been confirmed as melanoma by the specialist dermatologist and pathologist.

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. We will then ask you to sign a consent form to show you have agreed to take part.

If you to agree to participate you are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I agree to take part? **You will not be involved in any additional procedures or tests.** This is to ask for your consent to use the photo images which were previously taken of your skin lesions (moles) which were then shown to be melanoma. These photographs will be tested by nomela®.

Your routine care will not be affected.

Benefits There will be no direct benefit to you at present. If this technology is found to be useful then it enables specialist dermatologists and general practitioners to support its wider use in primary care.

Risks None.

Confidentiality Any information about you collected for the duration of this study will be kept strictly confidential. None of the information you provide will

be directly associated with your identifiable personal information. The security of the information held has been approved by the NHS IT security authorities.

Results The results of this study will be published in suitable medical journals and presentations may be made at relevant medical conferences. Your name and personal details will never be revealed. You will be able to request a summary of the results of the study from the Dermatology Department in Lanarkshire if you wish.

Follow-up None

Research team, Sponsor and funders

- Dr. Frances Gallagher Consultant Pathologist, NHS Lanarkshire is the Principal Investigator, with Dr. Girish Gupta, Consultant Dermatologist and Lead for Skin Cancer, NHS Lanarkshire Co-Principal Investigator.
- The study Sponsor is 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 in the first instance who will make every effort to answer your questions.

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 Sponsor and/or NHS Lanarkshire, 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 see Contact for further information below.

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, University Hospital Monklands *or* Dr Girish Gupta, Consultant Dermatologist, University Hospital Monklands t: 01236 712349

e: girish.gupta@lanarkshire.scot.nhs.uk

16 January 2018

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Appendix B2 Consent Form

Participant Consent Form: nomela® C7-1

Title: REGRESSION TESTING NOMELA® ON IMAGES OF SKIN LESIONS CONFIRMED AS CUTANEOUS MELANOMA

Principal Investigators: Dr Frances Gallagher, Consultant Pathologist and Dr. Girish Gupta, Consultant Dermatologist, University Hospital Monklands, NHS Lanarkshire

please initial all 5 boxes below

1) I confirm that I have read and understand the Participant Information Sheet dated **16 January 2018** for the above named study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2) I understand that there are no extra procedures or tests on me. The photographs of my skin lesions (moles) which were found to be melanoma will be labelled with a unique number tested by nomela®. No additional personal information will be requested for the study. The photographs and related study data will be stored securely on an NHS approved computer. ☐

3) I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected. If I choose to withdraw the additional nomela® photographs of my mole(s) and study data will be destroyed. ☐

4) I understand that relevant sections of my medical notes and data collected during the study may be looked at by authorised individuals from NHS Lanarkshire, the University of Aberdeen, the Sponsor [Moletest (Scotland) Ltd.] , authorised persons conducting audit of the study and regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

5) I agree to take part in the above named study: ☐

_____

Name of Participant Date Signature

_____

Person taking Consent Date Signature

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Appendix C

(i) List of items for source data spreadsheet

per provisional Case

Pathology Report Date

Pathology Reference

Lesion site

Melanoma type
- melanoma superficial spreading
- nodular melanoma
- lentigo maligna melanoma
- acral lentiginous melanoma
- indeterminate

CHI

Medical Illustration images for known melanoma: present No/Yes

Medical Illustration references

Reason (poor image) for exclusion

Consent obtained: No/Yes

(ii) List of items for transfer on secure data stick for Regression Testing

per confirmed Case
(i.e. confirmed diagnosis of melanoma
plus usable medical illustration images
plus consent to use)

Medical Illustration references and images (only)

Appendix D
Information technology: statements re security of transmission and storage

Statement by Moletest (Scotland) Ltd. on the handling of Data (2017).

The Moletest nomela® technology is a professional medical device. Patient identifiable information is minimised to use of the Community Health Index (CHI). Except for a brief period before upload, no information is retained on the hand-held iOS device.

i) The images obtained using nomela® ensures accurate identification of the location of the lesion by capture of a regional image (the overview) without ambiguity linked to a close-up focused image that is then cropped circularly, typically to around 1.5cm diameter.

ii) Certain lesions are not considered suitable for nomela®, including moles in the mouth, eyelid, nailbed, genital and perianal areas, thereby obviating confidentiality concerns in this respect.
(see section 4.3.3.2 of nomela® C5 study protocol).

iii) Image capture by nomela® does not use the iOS embedded Camera App nor link with Camera Roll or Photo Stream.

iv) The nomela® technology stores and analyses the images within a temporary secure cache on the iPad until a secure WiFi or 4G link is established leading to immediate and complete upload as a ZIP File using HTTPS to a secure NHS approved Moletest server. The memory cache is then cleared so that no images or data are retained on the iPad.

v) nomela® generates a universally unique identifier (UUID) for each lesion which is linked to the CHI/NHSnumber for accurate linkage to the nomela® report output which in turn is transmitted to the approved NHS EPR system and shown on reports by use of a QR code.

vi) The patient id, which is itself encrypted, and the nomela® reference are linked in a separate store.

vii) The statistical analysis of the results will not include any patient identifiable information.

viii) Moletest (Scotland) Ltd uses Amazon Web Services (AWS) servers which are all based in the London region. AWS and Moletest (Scotland) Ltd provide assurance that data remains in the UK.

The AWS infrastructure used is compliant with the 17 requirements for a Commercial Third Party as described in the NHS Digital (HSCIC) Information Governance Toolkit. This also applies to the server software built by Moletest (Scotland) Ltd on-top of the AWS infrastructure.

https://aws.amazon.com/compliance/eu-data-protection/

https://d0.awsstatic.com/whitepapers/compliance/Using_AWS_in_the_context_of_UK_Healthcare_IG_SoC_process.pdf

ix) Connectivity to NHS electronic patient records is via the NHS N3 portal.

APPENDIX E Schedule of Events

nomela® C7-1 L18002 SCHEDULE OF EVENTS-1

	in secondary care		
visits	**none**		
search melanoma diagnosis (histopathology) eg by EPR/monthly reports	*		
add to List of Provisional Cases	*		
use CHI to search for Medical Illustration images	*		
check suitable for nomela® test	*		
send Patient Information Sheet and Consent Form	*		
collate Consent Forms	*		
load images (with Medical Illustration refs) to data stick	*		
complete List of confirmed cases	*		
despatch data stick with List of confirmed cases		*	