Study Protocol Front Page

FULL PROTOCOL TITLE OF THE STUDY

Assessing the feasibility, acceptability, and effectiveness of using a hand dermatitis self-assessment screening questionnaire in a workplace health surveillance programme.

SHORT STUDY TITLE and ACRONYM

Digital skin surveillance of healthcare workers in the NHS

Chief Investigator:

Dr Vaughan Parsons, Guy's and St Thomas NHS Foundation Trust

Sponsored by:

Guy's and St Thomas' NHS Foundation Trust (GSTT)

Funded by:

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V1.0, 15.05.2025

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PROTOCOL VERSION NUMBER AND DATE

Version Stage	Versions No	Version Date	Protocol updated & finalised by;	Detail the key protocol update
Current	*1.0*	*15.05.2025*	*Vaughan Parsons*	*Original application*
Previous				

SIGNATURE PAGE

The Chief Investigator and the R&D (sponsor office) have reviewed this protocol. The investigators agree to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the trial in compliance with the approved protocol, EU GCP, the UK Data Protection Act (2018), the Trust Information Governance Policy (or other local equivalent), the UK policy Framework for Health and Social Care research, the Sponsor's SOPs, and other regulatory requirements as amended.

Chief investigator

[Insert name of CI]

Signature Date

This Protocol template is intended for use with UK sites only.

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1 LIST OF ABBREVIATIONS AND DEFINITIONS

AWS	Amazon Web Services
CI	Chief Investigator - The overall lead researcher for a research project (Outside the UK the term Coordinating Investigator or Investigator may be used). Chief investigator is responsible for the overall conduct of a research project.
COSHH	Control of Substances Hazardous to Health
CRF	Case Report Form
CRN	Clinical Research Network
GDPR	General Data Protection Regulation
GP	General Practitioner
GSTT	Guy's and St Thomas NHS Foundation Trust
HRA	Health Research Authority
HSE	Health and Safety Executive
ICF	Informed Consent Form
ICU	Intensive Care Unit
IGA	Investigator Global Scale
IPC	Infection Prevention Control
NOSQ	Nordic Occupational Skin Questionnaire
NHS R&D	National Health Service Research & Development
OSF	Open Science Framework
PI	Principal Investigator- An individual responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person.
PIN	Participant Identification Number
PIS	Participant Information Sheet
PPI	Patient and public involvement
Participant	An individual who takes part in a clinical trial
PPI	Patient Public Involvement
SAE	Serious Adverse Event
SCIN	Skin Care Intervention in Nurses
SOP	Standard Operating Procedure
Sponsor	The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.

SSA	Site Specific Assessment
TMF	Trial Management File
UK	United Kingdom
WHO	World Health Organisation

SUMMARY/SYNOPSIS

Title	Assessing the feasibility, acceptability, and effectiveness of using a hand dermatitis self-assessment screening questionnaire in a workplace health surveillance programme
Protocol Short Title/Acronym	Digital skin surveillance of healthcare workers in National Health Service
IRAS Number	284234
REC Reference	
EDGE reference	176025
Study Duration	12 months
Health condition(s) or problem(s) studied	Dermatitis
Primary objective	1. Can a self-assessed hand dermatitis screening questionnaire for at-risk healthcare workers reliably be used as part of a health surveillance programme? 2. What is the sensitivity and specificity of the hand dermatitis self-assessment screening questionnaire in identifying early hand dermatitis, and is it similar across all Fitzpatrick skin phototypes and occupational (clinical vs non-clinical) groups? 3. Is the self-assessment screening questionnaire and photographic method acceptable and feasible to use in healthcare staff in a busy NHS setting?
Secondary objective (s)	n/a
End of study definition	All data collected, all queries are resolved and database locked
Number of Participants	1386 (462 per site)
Study Type	Cross-sectional questionnaire with follow-up tele-dermatology
Human Tissue Samples (if applicable)	n/a
Data collected/storage (if applicable)	During the study, study data will be collected and stored on the REDCap database and data files will be pseudonymised at the point of download so only participants study ID number and no other identifying information is on the file. This pseudonymised file will form the main dataset for analysis and will be sent to Stefania D'angelo (statistician: email: sd@mrc.soton.ac.uk) and stored locally at the University of Southampton during the data analyses phase. Additionally, the separate personal data extracted at the time of download will be removed from the main data file. Included in this contact information data file will be each participant unique study ID, and this will be used to link participant's contact information back to their response. Personal data will be deleted within 2 years of the end of the study.

	All digital records will be kept in a secure Guy's and St Thomas NHS Foundation Trust shared computer drive which is restricted to authorised research staff only. At the end of the study, the data files will be downloaded on to two encrypted USB sticks and will be held in a secure location (i.e. locked and restricted access) within the OH department. for a period of two years.

2 INTRODUCTION

Occupational hand dermatitis is the most frequently recognized occupational skin disease in the United Kingdom, with an estimated 84,000 people experiencing dermatitis caused or made worse by their work. (1-3) It is a particularly important occupational disease in healthcare workers. The 1-year prevalence of self-reported hand dermatitis in healthcare workers in Sweden (9051 workers) and in Norway (2274 workers) was estimated to be 21%. This compares with <10% in the general population. (4) The point prevalence of hand dermatitis (as diagnosed by hand photography) in a sample of 1599 nurses in the UK, was estimated to be 15% (13% in student nurses and 17% in ICU nurses). (5) Once an individual has developed irritant contact hand dermatitis the prognosis is poor. In a 15-year follow-up study of a Swedish general population sample, about a third of those with hand dermatitis needed on-going medical treatment and 5% experienced long periods of sickness absence, loss or change of job, or retirement from ill-health, as well as adverse economic implications. (6-7) Affected individuals may also experience negative psychosocial consequences, such as sleep disturbance and interference with leisure activities. (8)

There is a statutory responsibility under the COSHH Regulations 2002 for employers to carry out health surveillance for hand dermatitis in workers exposed to a known hazard in the workplace and where there is potential for significant exposure.(9) As many healthcare workers are unavoidably exposed to frequent wet work in their roles due to frequent or prolonged contact with water, the Health and Safety Executive considers that they should be under regular high-level health surveillance.(10) The reality of introducing such a programme in the healthcare setting is a challenge, not least because it raises practical and logistical issues which need to be carefully considered; for example which questionnaire should be used for health surveillance or, who should do the visual inspection of a worker's skin if dermatitis is suspected? The Nordic Occupational Skin Questionnaire (NOSQ)(11) is a validated tool but even its short form is four pages long, rendering it impractical for use in a large health surveillance programme in the National Health Service. Consequently, the statutory requirement is frequently not enforced in the health service and hand dermatitis is often not picked up until relatively late in the disease, making it harder to treat and increasing the risk of them being unable to continue to work.

The single-item questionnaire has been used before. As a component of a large randomised trial (SCIN trial: Skin care intervention in nurses) of an intervention to prevent hand dermatitis in intensive care and student nurses, we tested the accuracy of NHS nurses' self-assessment of hand dermatitis, using a simple question screening tool *('In your opinion do you have hand/wrist dermatitis?'* with answer options of *yes/no or unsure);* if they reported having dermatitis they were asked to state where on the hand / wrist the dermatitis was. We compared their self-assessment with assessment by dermatologists using hand photographs. (5) The method was feasible and acceptable, as was that employed by the Danish study of hairdressers' dermatitis who self-assessed hand dermatitis when using a screening questionnaire adapted from NOSQ. (12)

During the course of the SCIN trial we developed a standardised validated method of screening for hand dermatitis using photographic images.(13) Several other studies have indicated that diagnostic decisions based on photographic images of localized skin regions are comparable with face-to-face assessments by dermatologists, since it allows clinicians to zoom in on distinct skin areas where early signs of disease are present.(14,15) Previous

teledermatology studies have also shown them to be flexible and feasible to deliver in large, geographically dispersed occupational groups with noteworthy cost-benefits.(16,17) It is important that we now test our screening tools in clinical staff other than intensive care nurses, and in non-clinical staff for example laboratory workers. We also need to ensure that our screening tools are equally effective when applied to all Fitzpatrick skin phototypes as there are challenges in recognising the typical clinical features of dermatitis in skin of colour, especially given that a high proportion of NHS workers have darker skin type. For the purpose of this study, we will use a slightly modified Fitzpatrick Skin-Type Chart tool.

We postulate that screening by a single-item questionnaire with follow-up of those reporting possible hand dermatitis by teledermatology using selfie hand photographs taken with a mobile phone camera, would be a novel, and time- and cost-effective, approach to optimise and improve health surveillance for hand dermatitis in healthcare staff. If our suggested method is found to be feasible, acceptable, and effective, it has the potential to revolutionise the early detection and management of hand dermatitis in the healthcare sector.

3 PATIENT AND PUBLIC INVOLVEMENT

During development and conduct of the former SCIN trial, we appointed, as our PPI co-investigator, an experienced NHS midwife (Wendy Taylor) who had a history of occupational hand dermatitis on the study. In this role, Ms Taylor assisted the study team with developing the new digital hand photographic method and self-assessment questionnaire used in the SCIN trial.

During conduct of the present study, we sought feedback from several nurses when developing the study document (participant information sheet) to ensure it was suitably worded and their feedback comments were incorporated.

During preparation of the present study, we sought feedback from several nurses when developing the study document (participant information sheet) to ensure it was suitably worded and their feedback comments were incorporated. Additionally, during conduct of the present study we will request guidance and practical assistance from wider PPI members (i.e. NHS staff: matrons and department managers) to support delivery of the study within each participating department. In addition, the proposed study was present to our trust's Occupational Health Clinical Governance and Risk Management committee which comprises OH nurses, service managers and matrons and clinical director for their review and feedback.

At the end of the present study, we will convene a one-off stakeholder forum involving representatives from infection, prevention and control (IPC), occupational health, NHS Employers, and the regulatory body (Health and Safety Executive) to consider the findings of the study and recommendations for the wider adoption of the screening tool across the NHS if the results are favourable.

Additionally, during conduct of the present study, it is possible we will request support and assistance from wider PPI members (i.e. NHS staff: matrons and department managers) to support delivery of the study within each participating department.

At the end of the present study, we will convene a one-off stakeholder forum involving representatives from infection, prevention and control (IPC), occupational health, NHS

Employers, and the regulatory body (Health and Safety Executive) to consider the findings of the study and recommendations for the wider adoption of the screening tool across the NHS if the results are favourable.

4 TRIAL OBJECTIVES AND PURPOSE

4.1 Research Questions

1. Can a self-assessed hand dermatitis screening questionnaire for at-risk healthcare workers reliably be used as part of a health surveillance programme?

2. What is the sensitivity and specificity of the hand dermatitis self-assessment screening questionnaire in identifying early hand dermatitis, and is it similar across all Fitzpatrick skin phototypes and occupational (clinical vs non-clinical) groups?

3. Is the self-assessment screening questionnaire and photographic method acceptable and feasible to use in healthcare staff in a busy NHS setting?

5 STUDY DESIGN & FLOWCHART

5.1 Study Design and Methods

This is a cross-sectional questionnaire of workers at risk of developing occupational hand dermatitis, with teledermatology using selfie hand photographs taken with a mobile phone camera.

6 PARTICIPANT SELECTION

6.1 Setting

We have selected three NHS Trusts in different geographical regions of the UK and where staff are from a diverse range of ethnic origins and are likely to have a spread of Fitzpatrick skin phototypes: Aneurin Bevan University Health Board (Wales), Guy's and St Thomas' NHS Foundation Trust (England), and University Hospital of Leicester NHS Trust.

6.2 Participant inclusion criteria

NHS staff (clinical and non-clinical) who are at increased risk of developing occupational hand dermatitis, here defined as staff who on average wash their hands with soap and water for a minimum of 10 times a day at work.(18) Examples of staff we will include are nurses (with the exception of ICU nurses - as this occupational group were part of the original SCIN study) (19), operating department practitioners, mortuary staff, clinical scientists and bench staff working in laboratories. We will aim at recruiting participants representing different skin phototypes.

Additionally, to be eligible participants will need to employed by the participating NHS organisation, have access to a smart phone or tablet device for the purpose of taking and sending in hand photographs AND have a valid NHS email address.

Participants must be aged between 16 and 80 years.

6.3 Participant exclusion criteria

Individuals with current dermatitis as diagnosed by a medical practitioner, individuals who have used topical steroid cream to their hands in the past six weeks, visiting or temporary personnel who are undertaking duties on NHS premises including students on placements,

contractors and anyone not directly employed by the participating NHS organisation. Individuals on long term sick leave (4 weeks or longer)

7 STUDY PROCEDURES

7.1 Screening Procedures

With the assistance of Trust departmental managers and occupational health services, we will identify a minimum of six departments at each site where staff are known to engage in frequent hand washing and therefore have an increased occupational risk of dermatitis. As above, these departments will comprise a mix of patient-facing areas (wards) and other clinical settings (laboratories and mortuary).

In collaboration with departmental managers and with the support from local occupational health departments and Clinical Research Network (CRN) research delivery staff, we will distribute an information flyer (poster) to promote the study to eligible staff working in the selected departments. The study manager will work with clinical leads (department/ward managers) to develop a targeted approach to ensure participants' engagement with the study. This will include promotion of the study at team meetings, in the OH department and in communal staff rooms followed by provision (sent by the clinical leads via email) of an electronic participant information sheet (PIS) which will contain a link (including QR code) to the secure REDCap (eCRF) data collection portal.

A non-probability (convenience) sampling approach will be used to screen and recruit participants to the study. Accordingly, the study will be promoted to all staff from each participating department/unit.

No personal information will be reviewed or screened during the process of promoting the study to staff. If staff are interested in taking part, they will be encouraged to access study material (additional copy of the participant information sheet and consent form) via the online questionnaire platform using the link in the PIS or by using the study's QR code printed on posters and flyers. Note: Study documents (PIS, consent form and questionnaire) will be made available in Welsh upon request.

7.2 Participant recruitment

We aim to recruit 1386 participants across our three participating sites (~460 at each site). Staff interested in taking part will simply need to follow the link which will invite them to complete the online study screening for eligibly questions to ascertain their eligibility for inclusion into the study. To motivate staff to participate in the study, especially those concerned about job security if problems with hand dermatitis are identified, we will emphasize the potential benefits of our questionnaire, and guarantee the confidentiality of participants' information received.

We have followed the HRA guidance on 'Proportionate approach to seeking consent' when devised the following e-consent method. Those screened as eligible for the entry into the study will be asked to complete an online e-consent form via the eCRF (REDCap) portal before completing the self-assessment skin surveillance screening questionnaire. Importantly, prospective participants will be free to access the study Redcap portal at a time of their

choosing during the recruitment period. Participants will not be able to access their questionnaire once completed.

In addition, with the participants' consent we will collect NHS email addresses of participants and their line manager, to enable notification of assessment outcome.

At the end of the e-consent participants will be required to tick a box to confirm that *"I certify that all of my information in the document is correct. I understand that clicking 'submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document"*.

After completing and electronically signing the e-consent form (form 1), participants will be given the option to click on a hyperlink which takes them directly to the Part 2 (form 2) of the questionnaire.

Participants will then be assigned a unique participant identification number (PIN) when logging into the portal.

Based on our previous work (5, 13,19) we anticipate that the recruitment period will need run for up to nine months.

By taking part in this study, participants will be provided with a remote digital assessment of hand dermatitis based on the data they provide (i.e. hand photographs). Therefore, if this assessment indicates that they may have hand dermatitis then we will recommend that they self-refer for follow-up advice and support from either their local occupational health, GP or pharmacist. Conversely, where applicable, participants may also benefit by receiving confirmation that they do not have hand dermatitis.

At the end of the questionnaire, participants will have the option to enter a prize draw to win a gift voucher. In total, there will be twenty £50 shopping vouchers available to win. Winners will be chosen at random. To be eligible to win this prize, participants will need to have completed the questionnaire, provided their hand photographs and a valid NHS email details.

Since we are testing digital methods for skin surveillance, paper-based study documentation will not be included in this study.

7.3 Schedule of assessments for each visit

Completion of the questionnaire and the taking and uploading or sending of hand photographs should take no longer than five minutes to complete and will comprise separate forms.

On form 2, all eligible participants will be given a self-assessment screening questionnaire consisting of demographic information (including rating of Fitzpatrick skin type based on two domains; 'genetic disposition' and 'reaction to sun exposure'), dermatitis-related symptoms, hand washing frequency, and a single self-assessment screening question: *'In your opinion do you have hand/wrist dermatitis/eczema)?'* with answer options of *yes/no or unsure.* Those who answer 'yes', or 'unsure' will then be asked the question: (ii) *'where is your hand/wrist dermatitis or skin condition located?*'. The participants will be given eight options

and will be asked to tick all those that apply. The options will be left (or right) hand palm; left (or right) hand back; left (or right) wrist (front or back); between the fingers; and other part of hand/wrist (e.g. side of hand), with a request to specify the site if this category is selected. Participants will also be asked whether they have been told by a doctor that they have skin dermatitis or eczema (if so, how long ago) .

Once form 2 is complete, all participants (whether they consider that they have hand dermatitis or not) will be instructed on how to take photographs of their hands and wrists and upload the photographs on to form 3 of the REDCap portal within 3 days of completing the questionnaire. Ideally, all participants will complete the upload of their hand photographs (on form 3) immediately after completing the self-assessment screening questionnaire (form 2). At the time of the upload, they will be asked whether any new changes to skincare or treatments have been used between completing the questionnaire and taking the photos, to ensure that the photos are representative of the questionnaire. They will be asked to take one photo each of the front and backs of their hands and wrists using a smartphone following the standardised protocol which was developed and evaluated as part of the SCIN trial (13). As outlined in Part 2 of participant questionnaire (Taking and submitting hand photographs), participants will have the option to contact (via email) their local principal investigator should they require practical 1-2-1 assistance with taking and uploading selfie hand photographs.

After participants have submitted their data on the REDCap portal, an automatic standard email will be sent to participants to confirm their recruitment into the study and to encourage them to continue to monitor their hand for skin problems and to seek follow-up advice from their local OH department, GP or pharmacy.

Hand photographs (form 3 only) will be accessible to the study nurse via the REDcap portal and the study nurse will assess the presence of dermatitis using the Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) tool (20). Within the portal, the study nurse will then assign and score the photographs to five categories as per IGA score (Category 1: 'Clear'; Category 2: 'Almost clear'; Category 3: 'Mild'; Category 4: 'Moderate'; Category 5: 'Severe') with the first indicating 'absence of dermatitis' and any of the categories 2-5 indicating 'presence of dermatitis'. The dermatology nurse will also keep a separate category for the photographs for which they are unsure and another category for photographs which are insufficiently clear for assessment and which participants will be invited by the research team to resubmit new hand photographs. For the unsure cases, the photographs will be assessed by the dermatologist via the REDcap portal (form 3 only). Information on whether participants' hand photographs require further assessment by the study dermatologist (i.e. categorised as 'Unsure' by the study nurse) will also be recorded in REDcap, as it is relevant for future application of surveillance method.

Participants who provide photographs that are not sufficiently clear for assessment will be re-contacted by a member of the central study team (not the study dermatologists or dermatology nurse) and invited on one occasion only to provide an additional set of hand photographs. In order to ensure that the photograph is taken within 3 days of the time as they are being assessed for presence of hand dermatitis, we will require them to re-answer the question *'In your opinion do you have hand/wrist dermatitis/eczema)?'* with answer options of *yes/no or unsure.* Those who answer 'yes', or 'unsure' will then be asked the question:

'*where is your hand/wrist dermatitis or skin condition located?*'. A separate form (form 6) will be used to collect re-submitted hand photographs. Photographs that the dermatology nurse deems to be of too poor quality to assess will not be included in the final analysis.

Prior to assessing the presence of dermatitis, to ensure appropriate use of the vIGA-AD tool, the dermatologist nurse will be required to complete a training consisting of a video on best practices for using the scale to rate the severity of the disease and subsequently complete a certification examination as described by Simpson et al. (20)

Once the study nurse is fully trained, they will independently assess all hand photographs. After nurse's assessment has been completed, the presence or absence of dermatitis (vIGA score Categories 2-5 and Category 1, respectively) will be compared with participants' self-responses.

Photographs on discordant pairs (outcomes 2 and 3 described below) will be further assessed by the two study dermatologists who will assess presence of dermatitis. The dermatologist will independently assess the hand photographs for presence of hand dermatitis and score 1-5 on the vIGA scale. If the dermatologists' scores differ they will agree a score by discussion. The original nurse's assessment using the vIGA tool will be corrected for the dermatologists' expert opinion where needed.

The nurse's assessment of the hand photographs and any back up required by the study dermatologist with correction of the assessment on the vIGA scale where needed, will be considered the gold standard against which the questionnaire-based self-assessed presence of dermatitis (new proposed screening tool) will be compared. We will assess the acceptability of the self-assessment screening tool by incorporating several short questions into the study questionnaires.

The questionnaire we will also include several questions to capture participants views on the study material, and the instructions they have to follow to complete the self-assessment screening questionnaire and for taking and submitting hand photographs. Response options will be set out in Likert scale format to aid analyses of results. We will further ask their willingness to involve their line-managers in the skin surveillance. The questionnaire will also include the option for participants to provide further qualitative (free text) feedback on a) concerns about completing the questionnaires and/or uploading photos, b) on obstacles and facilitators to implementation of the proposed methods, and c) anything not covered by the questions above.

In addition to the staff questionnaire, we will administer a case report form to capture feedback from the clinical leads and service managers from the participating departments on the acceptability and feasibility of delivering the skin surveillance method in the clinical setting. We will also enquire about barriers/facilitators of implementing the proposed surveillance method and future practical strategies to optimise its use if this skin health surveillance activity was delegated to them. We will also enquire about existing skin surveillance approaches (if any) at each participating site. This data will be collected electronically using separate REDCap database under GSTT licence or Microsoft Forms and no personal identifiable data will be collected.

7.4 Follow up Procedures

The outcome of the health surveillance will be shared via standard email with each participant and (if they consent) their line manager. The study manager or chief investigator will send the email correspondence (outlined below) to participants as soon as practicable following

the assessment, ideally this will be within a 1-3 week timeframe. There are four possible outcomes:

1. Questionnaire negative, nurse's photograph assessment of absent dermatitis (true negative): hand dermatitis absent. Participant will be informed.

2. Questionnaire negative, nurse's photograph assessment of hand dermatitis present (discordant case). Photographs will be sent to dermatologists. If dermatologists agree that dermatitis is present, this will be considered a false negative case and the participant will be encouraged to use the standard email as supporting evidence in which to self-refer themselves to their local occupational health team for further management or to follow local arrangements. If dermatologists agree no dermatitis is present, this will be noted as a true negative case, and the participant will be informed.

3. Questionnaire positive, nurse's photograph assessment of absent dermatitis (discordant case). Photographs will be sent to dermatologists. If dermatologists agree dermatitis is present, this will be noted as a true positive case, and the participant will be encouraged to use the standard email as supporting evidence in which to self-refer themselves to their local occupational health team for further management If dermatologists agree dermatitis is not present, this will be considered a false positive case, and the participant will be informed.

4. Questionnaire positive and nurse's photograph assessment of present dermatitis (true positive): hand dermatitis present. The participant will be encouraged to self-refer themselves to their local occupational health team for further management or to follow other local arrangements.

No other follow-up procedures relating this study will be delivered beyond notification of the assessment outcome.

8 END OF STUDY DEFINITION

We define the end of study as occurring when all data is entered, queries resolved and database locked.

9 ASSESSMENT OF SAFETY

This study is deemed low risk and no serious adverse events (SAEs) or safety issues are expected to arise during conduct of this study.

While the participants assessed as having hand dermatitis (positive case) will be strongly recommended to seek follow-up confidential advice and management from their local occupational health department, general practitioner (GP) or pharmacy as soon as possible, the researchers are unable to mandate that such action is taken by participants. However, as per existing NHS staff policy and statutory regulation, if staff suspect they may have hand dermatitis then they are expected to report it to their employer, therefore the onus is on the participants to fulfil this requirement.

9.1 Ethics & Regulatory Approvals

This study is exempt from the requirement to obtain research ethics approval since it is recruiting NHS staff as participants by virtue of their professional role. However, the study requires NHS Health Research Authority HRA approval. Before any site can enroll participants

into the study, the Chief Investigator/Principal Investigator or designee will ensure that NHS Confirmations of Capacity and Capability and Sponsor green lights are in place.

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor and HRA will be retained. The Chief Investigator will notify the Sponsor and HRA of the end of the study.

The final approved study protocol will be registered on OSF Registry (Centre for Open Science).

10 COMPLIANCE AND WITHDRAWAL

10.1 Participant compliance

All participants (whether they consider that they have hand dermatitis or not) will be instructed on how to take photographs of their hands and wrists and upload the photographs on to the REDCap portal within 3 days using a step-by-step instruction guide. Participants who provide photographs that are not sufficiently clear for assessment will be re-contacted and invited to provide an additional set of hand photographs and in order to ensure that the photograph is taken within 3 days of the time as they are being assessed for presence of hand dermatitis, we will require them to re-answer the question *'In your opinion do you have hand/wrist dermatitis/eczema)?'* with answer options of *yes/no or unsure.* Those who answer 'yes', or 'unsure' will then be asked the question: '*where is your hand/wrist dermatitis or skin condition located?*'.

We deem this to be a low-risk study, and we do not anticipate any serious risks by completing the questionnaire. As we have mentioned, by taking part in this study we will collect data from participants including hand photographs and when assessing these, we may detect the presence of hand dermatitis. If this occurs, we will contact participants directly and advise them to self-refer to their local occupational health team as per local arrangements for further management such as advice on suitable work adjustments. In cases where hand dermatitis is detected, the research team will not have the authority to provide any treatment advice and products. Instead, participants will be encouraged to seek treatment advice from your general practitioner or local pharmacy.

10.2 Withdrawal / dropout of participants

Participants will have the option to withdraw from the study at any time without giving a reason. Their data will be retained and used in the study unless they express the wish that their responses should be destroyed.

As the data collected by the questionnaire will be identifiable prior to final download from the REDcap database, we can allow participants to withdraw their data after they have submitted the questionnaire, should they desire. Participants will be made aware that they should contact the research team if they would like to withdraw their data. If this occurs, we will use their contact information to identify responses. If an individual did not provide their contact information but would like to withdraw their data, we will use their date of birth and demographic information to identify their record. Participants who did not provide sufficient data required to undoubtedly identify their response will be told that it is not possible to

withdraw their data. Participants will be informed in the PIS that they will not be able to amend their data once their questionnaire has been submitted.

If participants ask to withdraw their data after their data has been analysed and included in the final analyses, they will then be informed that it will not be possible to remove their data from the study.

10.3 Protocol Compliance

We consider this to be a low risk study and do not foresee anticipated protocol deviations arising during conduct of this study. Nevertheless, the CI will monitor protocol deviations and list them in a deviation log /include a file note in the TMF/Site file where applicable.

11 DATA

11.1 Data to be collected

Pre-consent screening for eligibility questions and participant contact information and questionnaire data will be collected using sponsor approved REDCap software database and access to the source data within the software portal will be password protected and only accessible by authorised persons (i.e. central study team only). This personal identifiable data will be stored on the REDCap software for the duration of the study. However, all downloaded data files from REDCap will have personal identifiable data removed at the point of data extraction and at this point the data file will then become fully pseudonymised and kept in a secure, password file, and only accessible by the study team responsible for conducting the study.

Additionally, the separate personal data extracted at the time of download will be removed from the main data file. Included in this contact information data file will be each participant unique study ID, and this will be used to link participant's contact information back to their response. This will mean that the survey will be pseudonymized for the duration of data analysis and storage. If it is necessary to email data files among research team member, this will be done by sending securely via email in encrypted and password protected data files. Passwords will be sent to the recipient in a separate email.

The following baseline data only will be collected from participants using online tool (REDCap) only. Local managers and research delivery staff will be available to provide practical 1-2-1 assistance with taking and uploading hand photographs in the unlikely event that this should be required.

1. Questionnaire

PART 1

- a) Screening for eligibility (no personal data collected)
- b) Participant Consent Form (Name, email address, preferred telephone number)

PART 2

- c) Self-assessment questionnaire (Demographic (age in years, gender, ethnicity, skin phototype, occupational group, frequency of hand washing) and self-assessment of hand dermatitis: a single question item about presence/absence of the disease (*'In your opinion do you have hand/wrist dermatitis/eczema)?'* with answer options of *yes/no or unsure*), location of symptoms (tick box of any the options that apply: left (or right) hand palm; left (or right) hand back; left (or right) wrist (front or back); between the fingers; and other part of hand/wrist (e.g. side of hand), with a request to specify the site if this category is selected), duration of symptoms, and level of impact on work, views on the study material and study processes).

PART 3

- Viewing on the study materials and methods (self-assessment of hand dermatitis and taking and sending hand photographs)
- e): Contact details for entry into prize draw (Name, email address and phone number Note: the online questionnaire will be set up such that participants will be required to complete each question before proceeding to the next question.

2. Collection of hand photographs

- All participants (whether they consider that they have hand dermatitis or not) will be instructed on how to take photographs of their hands and wrists and upload the photographs on to the REDCap portal. Participants will be asked to take one photo each of the front and backs of their hands and wrists using a smartphone following the standardised protocol which was developed and evaluated as part of the SCIN trial. (13) Participants will also be given the option to submit hand photographs to the study team via email.

No follow-up data will be collected from participants.

11.2 Data handling and record keeping

To facilitate data collection, data (completion of the questionnaire and upload of the hand photographs) will be collected using sponsor approved REDCap software database. Access to the source data within the software portal will be password protected and only accessible by authorised members of the study team to aid screening, assessment and scoring of hand photographs and other analyses.

All electronic data will be held securely on Guy's and St Thomas NHS Foundation Trust (GSTT) servers via the REDCap software. The completed REDCap project will be hosted on Amazon Web Services (AWS), a GSTT research and development contracted General Data Protection Regulation (GDPR) compliant third-party storage provider within the Europe (London) region. The pseudonymised research data files will be retained and stored for two years after the completion of the study before being destroyed.

Authorised members of the study team (dermatology nurse and study dermatologists based external to Guy's and St Thomas NHS Foundation Trust 'as sponsor') will have access the password-protected secure online database when undertaking the assessment of the hand photographs. At the end of the study, the pseudonymised data files will be downloaded from REDCap, password protected and securely sent (via email) to Stefania D'angelo the statistician (based at the University of Southampton) to aid final data analyses.

The downloaded data files will be kept in a secure, password file, and only accessible by the study team responsible for conducting the study. Data files will be encrypted and password protected if it is necessary to email data files among research team members e.g. when conducting the data analyses. Passwords will be sent to the recipient in a separate email. Study data will be pseudonymised. Personal data collect in consent form and 'section E: Entry into the prize' of the questionnaire will be stored separate to the study data at the point of download from the REDCap database. Personal data will be deleted within two years of completion of the study.

After site closure, each participating site and collaborating organisation will archive their research data in accordance with instructions from the Sponsor for a period of two years. The process of destroying documents will be in accordance with the standard procedures of the Sponsor.

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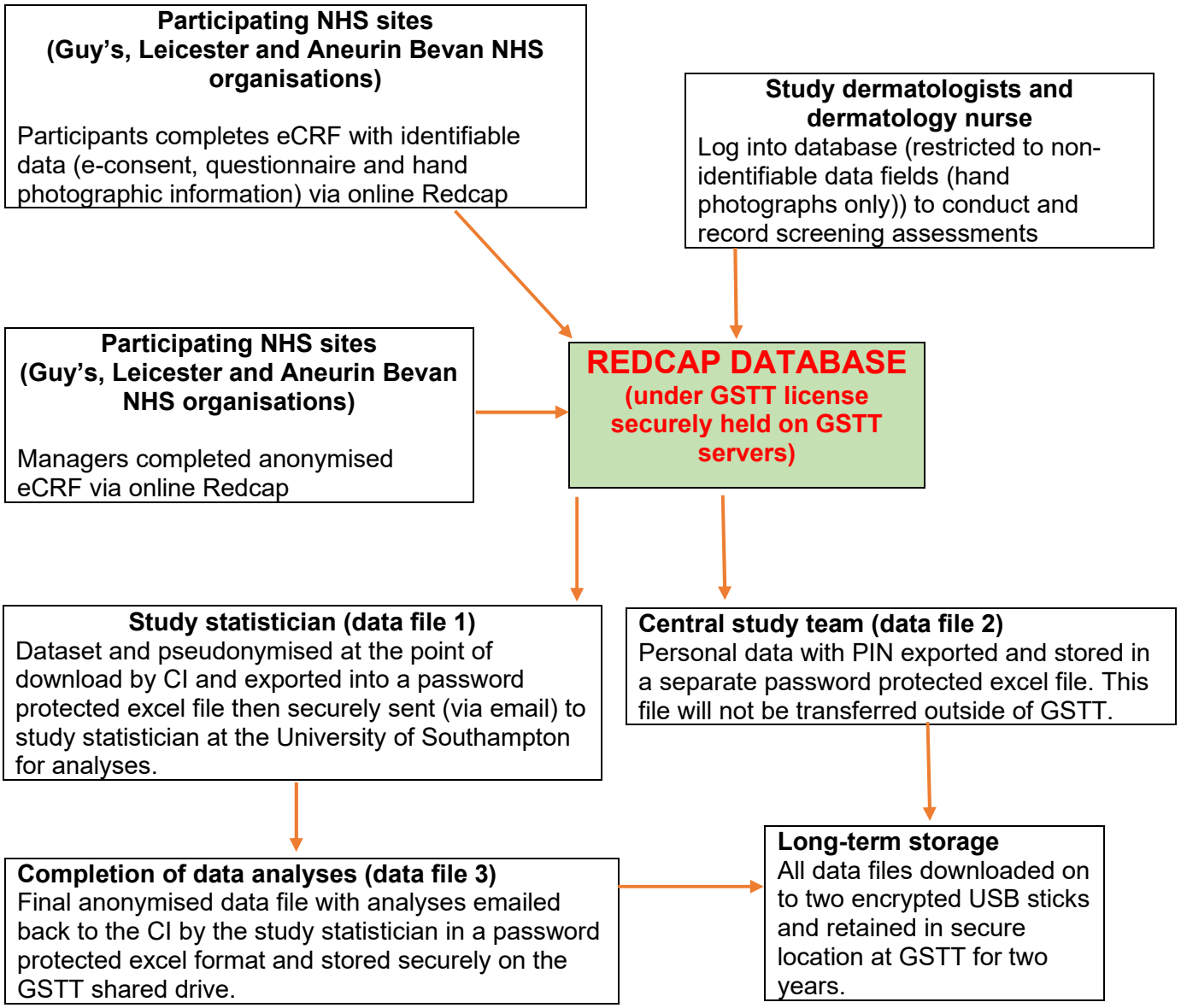
11.3 Data sharing

The data flow diagram sets out the arrangements for data sharing.



At the end of the study and with consent from participants, the final anonymised dataset will be uploaded to OSF data repository for future ethnically approved research. This has been highlighted on the PIS and the ICF, and participants will have the option to with-hold their anonymised data if they desire.

11.4 Personal Data Breaches

The CI and study team will comply with the requirements of the UK's data protection law and all data collected as part of this study will strictly be within the terms of the UK GDPR and Data Protection Act 2018. The CI and study team will also adhere, where appropriate, to the current version of the NHS England Code of Practice (Confidentiality). Access to collated participant data will be restricted to the CI and appropriate members of the study team. Computers used to collate the data will have limited access measures via usernames and passwords. Recorded consent will be stored as a datafile on a Guy's and St Thomas NHS Foundation Trust secured shared drive, separate from study data.

Research data will be stored securely in the Occupational Health Service at Guy's and St Thomas NHS Foundation Trust during the study. At the end of the study, data will be archived following the Sponsor's archive standard operating procedure for a period of two year.

Only members of the research team will have access to the personal data details collected using the REDCap database during the study. Access to this database is password restricted. The download file from the REDCap database will be secured stored in access restricted OH Research files on the GSTT servers.

To facilitate the long-term storage of electronic data, data files will be converted to 'read only' before being downloaded onto two encrypted USB sticks. These will be retained in a sealed archive box along with other study documents.

All personal data will be handled and securely stored during the study as outlined above. If there is a data breach/breach of confidentiality (as per GDPR definitions), GSTT Trust incidence reporting mechanisms will be followed. The data subject(s) would also be informed promptly. GSTT Information Governance team will also be immediately informed.

The CI will determine whether the breach meets the definition of a serious breach and warrants reporting to the regulators including the ICO https://ico.org.uk/for-organisations/report-a-breach/personal-data-breach-assessment/.

MONITORING AND AUDITING

The study will be monitored by the project team which consists of the main study personnel. The CI will oversee the study in collaboration with the study manager with regular input and day-to-day coordination and conduct of the study by remaining members of the study team.

A study-specific Delegation Log will be prepared, detailing the responsibilities of personnel supporting conduct of the study.

The study team will permit study-related monitoring and audit reviews as required. The CI agrees to allow, or representatives (authorised personnel) of the sponsor and external

parties (e.g. regulator) , direct access to all study records and source documentation for auditing and compliance purposes where appropriate delegated authority exists.

12 STATISTICAL CONSIDERATIONS

The following outlines the proposed statistical analyses methods planned as they relate to each research question (RQ).

- *RQ1 Can a self-assessed hand dermatitis screening questionnaire for at-risk health care workers reliably be used as part of a health surveillance programme?*

As the primary study outcome, we will calculate the sensitivity of the proposed self-assessment screening tool (single-item self-reported dermatitis) along with its 95% confidence intervals when compared with the gold standard (nurse's dermatitis assessment from the hand photographs). We will further assess its specificity, positive and negative predictive value. The analysis will be conducted for all participants and then separately by medium and high risk of hand dermatitis, determined by frequency of hand washing 10-20 times per day (medium risk), and more than 20 times per day (high risk).

- *RQ2 What is the sensitivity and specificity of the hand dermatitis self-assessment screening questionnaire in identifying early hand dermatitis, and is it similar across all Fitzpatrick skin phototypes and occupational (clinical vs non-clinical) groups?*

The accuracy of hand dermatitis self-assessment screening questionnaire will further be explored in sub- groups of our sample participants. Primarily sensitivity, and specificity, and further positive and negative predictive values, as indicators of the accuracy of the screening test will be estimated for clinical and non-clinical staff and their differences will be compared statistically. Due to the high number of NHS staff of non-white ethnic origin, and the lack of information about hand dermatitis or ability to self-report its presence across the six Fitzpatrick skin phototypes, we will also stratify our results by Fitzpatrick phototypes, with a potential to identify skin phototypes in which accuracy of the screening questionnaire is lower.

- *RQ3 Is the self-assessment screening questionnaire and photographic method acceptable and feasible to use in healthcare staff in a busy NHS setting?*

We will assess this by asking a series of questions relating to the ease with which participants are able to a) complete the self-assessment screening questionnaire and b) follow the instructions for taking and submitting hand photographs. We will set out the response options in Likert scale format to aid analyses of results. We will further ask their willingness to involve their line-managers in the skin surveillance and whether they would accept referral to occupational health if the assessment showed signs of dermatitis. The questionnaire will also include the option for participants to provide further qualitative (free text) feedback on a) reservations about completing the questionnaires and/or uploading photos, b) on barriers and facilitators to implementation of the proposed methods, and c) anything not covered by the questions above. In addition, we will administer a brief case report form to capture feedback from the clinical leads and service managers from the participating departments on the acceptability and feasibility of delivering the skin surveillance method in the clinical setting. We will also enquire about barriers/facilitators of implementing the proposed surveillance method and future practical strategies to optimise its use if this skin health surveillance activity was delegated to them. We will also enquire about existing skin surveillance approaches (if any) at each participating site.

12.1 Statistical power

Considering as the primary study outcome the sensitivity of the single-item questionnaire (with secondary outcomes being its specificity, positive and negative predictive value) we enquired six occupational physicians with experience in NHS work what they would consider as the minimum acceptable sensitivity for such a self-assessment screening tool (single-item questionnaire) to be administered by managers to detect hand dermatitis in at risk healthcare workers. The majority (3 out of 4 who responded to our enquiry) reported a sensitivity of 80%. Assuming a prevalence of hand dermatitis among healthcare workers of 15%, and a high sensitivity of 0.90% with a width of confidence interval 0.10 (targeting a lower bound for sensitivity of 0.80), the estimated required sample size is 231. We hypothesised the same prevalence for clinical and non-clinical staff, and also for staff of light, medium and dark skin. This totals 1386 participants (i.e. 231 participants for each of the 6 groups clinical/non-clinical staff and type of skin), which would give sufficient power for any analysis stratification. We aim to recruit approximately equal numbers (~460 participants) from each of the 3 sites in the study.

13 PEER REVIEW

The research plan was developed with input from clinical academic researchers. The research plan (grant application) was independently assessed by experts in the field as part of the grant application process and satisfactory responses to peer reviewer feedback were collated and approved by the funding body (The Colt Foundation) prior to Health Research Authority submission.

14 FINANCING

The Colt Foundation awarded funding of £70,450 to support conduct of this study. The funding period is two years and cover pay (salary) and non-pay costs (expenses).

15 INSURANCE AND INDEMNITY

This study is sponsored by Guy's and St Thomas' NHS Foundation Trust (GSTFT) and indemnity is provided through NHS Resolution's Clinical Negligence Scheme for Trusts (CNST) which provides indemnity for clinical negligence. In the case of negligent harm, health care professionals undertaking clinical trials or studies on volunteers, whether healthy or patients, in the course of their NHS employment are covered by NHS Resolution. In the case of non-negligent harm, legal liability does not arise where a person is harmed but no one has acted negligently. In exceptional circumstances NHS bodies may consider whether an ex-gratia payment could be offered.

16 DATA CONTROLLER

Guy's and St Thomas' NHS Foundation Trust is the Data Controller as defined by UK general data protection legislation (UK GDPR) for this study and as such agrees to comply with the obligations placed on a Data Controller by the UK GDPR. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to Processing of Personal Data (Article 5 UK GDPR).

17 REPORTING AND DISSEMINATION

17.1.1 Potential relevance to policy and practice

If the findings from this study indicate that the single-item questionnaire with follow-up of those reporting possible hand dermatitis using teledermatology (selfie hand photographs taken with a mobile phone camera) is feasible, acceptable, and effective as a self-assessment screening tool in a workplace surveillance programme then we envisage the findings will have important relevance to policy and clinical practice of skin health surveillance programmes in the health service.

Most notably, the potential to implement this self-assessment screening tool more widely across the NHS workforce and to other high-risk worker groups will lead to improvements in the early detection and management of workers hand dermatitis, and such favourable outcomes will have wider benefits to the NHS. We are evaluating the health surveillance tool in the health service setting for pragmatic reasons, but since we are testing the tool in non-clinical staff, there is no reason why the results should not be generalisable to other industries such as care homes, hairdressing, and floristry where workers also have a high risk of developing hand dermatitis.

17.1.2 Dissemination

At the end of the study, we will convene a one-off stakeholder forum involving representatives from infection, prevention, and control (IPC), occupational health, NHS Employers, and the regulatory body (Health and Safety Executive) to consider the findings of the study and recommendations for the wider adoption of the self-assessment screening tool across the NHS if the results are favourable.

The findings from the research will be written up into a final study report (for the funder) and journal articles. Additionally, we will present the findings of this research at professional forums (Faculty and Society of Occupational Medicine Annual Scientific Meeting) and will disseminate findings via our research website. Additionally, we will provide a summary report to participating sites and participants who request this information.

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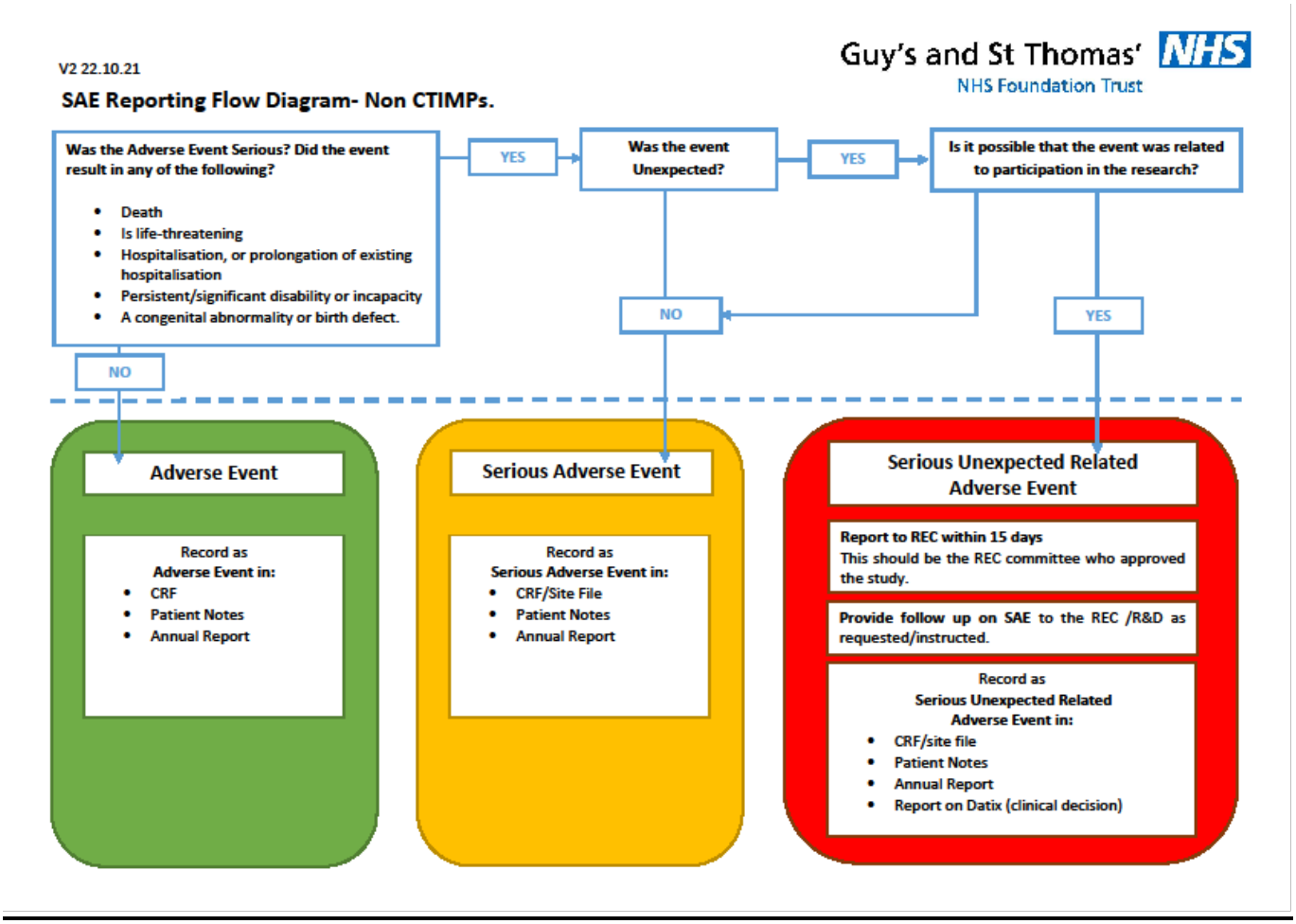
APPENDIX 1

SAE Reporting Flow Diagram-Non CTIMPs



APPENDIX 2

Information with regards to Safety Reporting in Non-CTIMP Research

	Who	When	How	To Whom
SAE (related and unexpected)	Chief Investigator	-Report to Sponsor within 24 hours of learning of the event -Report to the MREC within 15 days of learning of the event	SAE Report form for Non-CTIMPs, available from NRES website.	Sponsor and MREC
Urgent Safety Measures	Chief Investigator	Contact the Sponsor and MREC Immediately Within 3 days	By phone Substantial amendment form giving notice in writing setting out the reasons for the urgent safety measures and the plan for future action.	Main REC and Sponsor Main REC with a copy also sent to the sponsor. The MREC will acknowledge this within 30 days of receipt.
Progress Reports	Chief Investigator	Annually (starting 12 months after the date of favourable opinion)	Annual Progress Report Form (non-CTIMPs) available from the NRES website	Main REC with a copy to be sent to the Sponsor
Declaration of the conclusion *or* early termination of the study	Chief Investigator	Within 90 days (conclusion) Within 15 days (early termination) *The end of study should be defined in the protocol*	End of Study Declaration form available from the NRES website	Main REC with a copy to be sent to the sponsor
Summary of final Report	Chief Investigator	Within one year of conclusion of the Research	No Standard Format However, the following Information should be included:- Where the study has met its objectives, the main findings and arrangements for publication or dissemination including feedback to participants	Main REC with a copy to be sent to the sponsor