Business Services Organisation

Chief Executive
2 Franklin Street
BELFAST
BT2 8DQ

Tel: 028 9536 3863
Email: FOI.BSO@hscni.net

12th August 2022

BY EMAIL
[redacted]

Our Ref: FOI 2246

Dear [redacted],

Your request for information was received on 5th July 2024 and was dealt with under the terms of the Freedom of Information Act 2000. Please be advised that the Office for Research Ethics Committees Northern Ireland (ORECNI) has now completed its search for the information you requested with regards to the study "Inpatient Safety in Mental Health".

Please accept my apologies for the delay in this matter.

Please find the information requested enclosed. Please note that some information within this document has been considered exempt from disclosure as set out by section 40(3A) (a) of the Freedom of Information Act 2000 ('Personal Information'). Section 40 is an absolute exemption, and no public interest test is required.

I hope that the information provided assists you. If you are dissatisfied in any way with the handling of your request, you have the right to request a review. You should do this as soon as possible or in any case within two months of the date of issue of this letter.

In the event that you require a review to be undertaken, you can do so by writing to

Information Governance Manager,
2 Franklin Street,
Belfast,
BT2 8DQ

If, following an internal review, carried out by an independent decision-making panel, you remain dissatisfied in any way with the handling of the request, you may make a complaint under Section 50 of the Freedom of Information Act, to the Information Commissioner's Office and ask that they investigate whether the BSO has complied with the terms of the Freedom of Information Act.

You can contact Information Commissioner at:

Website: www.ico.org.uk
Phone: 0303 123 1113
Email: casework@ico.org.uk
Post: Information Commissioner's Office
3rd Floor, 14 Cromac Place
Belfast
BT7 2JB

In most circumstances the Information Commissioner will not investigate a complaint unless an internal review procedure has been carried out. However, the Commissioner has the option to investigate the matter at his discretion.

Yours Sincerely,

Karen Bailey
Chief Executive

To,

Health Research Authority

Skipton House,

80 London Road,

London SE1 6LH

Oxehealth Ltd,

Magdalen Centre North

The Oxford Science Park,

Oxford OX4 4GA

06 September 2021

Dear HRA committee,

Please accept our research proposal for your approval.

Study Title: Inpatient Safety in Mental Health

IRAS project ID: 287453

Sponsor: London South Bank University

Funder: Oxehealth Limited, UK

The broad aim of our project is to improve inpatient safety in mental health. This is a collaborative project with London South Bank University and Oxehealth Limited along with three NHS Trusts.

We would like to use the data obtained in this dataset review project to enhance our understanding of untoward incidents and behaviours related to untoward incidents that occur in inpatient mental health settings. We aim to do this by reviewing and analysing anonymised incident data from NHS Trusts and creating a library of untoward incidents.

For this study only anonymised data on incidents will be reviewed and analysed without directly recruiting patients.

Please find the following documents for approval,

Document	Version	Date
Protocol	1.0	22 July 2021
Incident Data Requesting Form	1.0	22 July 2021

Please do not hesitate to contact me for further clarifications.

Sincerely,

[redacted]
Clinical Studies Coordinator
Oxehealth
www.oxehealth.com
Mobile [redacted]

On behalf of

[redacted]
London South Bank University

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Inpatient Safety in MH

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

(●) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Will you be processing identifiable data at any stage of the research (including in the identification of participants)? ( ) Yes (●) No

b) Please confirm that you will be processing only anonymised or pseudonymised data:

(●) Yes, only anonymised or pseudonmyised data ( ) No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

[x] England
[ ] Scotland

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

○ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out the research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre (BRC), NIHR Applied Research Collaboration (ARC), NIHR Patient Safety Translational Research Centre (PSTRC), or an NIHR Medtech and In Vitro Diagnostic Co-operative (MIC) in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

◉ Yes ○ No

The NIHR Clinical Research Network (CRN) provides researchers with the practical support they need to make clinical studies happen in the NHS in England e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR CRN. ***Submission of a Portfolio Application Form (PAF) is no longer required.***

6. Do you plan to include any participants who are children?

○ Yes ◉ No

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Study limited to working with data (specific project only)

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Inpatient Safety in MH

Please complete these details after you have booked the REC application for review.

REC Name:
PR Committee

REC Reference Number:
21/PR/1379

Submission date:
27/09/2021

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Inpatient Safety in Mental Health

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	[redacted]		[redacted]

Post	Professor of Mental Health
Qualifications	PhD
ORCID ID	0000 0001 9873 777X
Employer	London South Bank University
Work Address	103 Borough Road London London
Post Code	SE1 0AA
Work E-mail	[redacted]
* Personal E-mail	[redacted]
Work Telephone	[redacted]
* Personal Telephone/Mobile	[redacted]

Fax	00

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]

Address	Magdalen Centre North, The Oxford Science Park, Littlemore
Post Code	OX4 4GA
E-mail	[redacted]
Telephone	[redacted]
Fax	00

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	287453
Sponsor's/protocol number:	1.0
Protocol Version:	1.0
Protocol Date:	22/07/2021
Funder's reference number (enter the reference number or state not applicable):	not applicable
Project website:	na

Additional reference number(s):

Ref.Number Description	Reference Number
Clinicaltrials.gov	na

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

The overall aim of this research programme is to improve safety in inpatient mental health settings by identifying precursors to harm. In this study we will examine anonymised incident data from three Trusts. Retrospective data from up to 12 months prior to the start of the study will be reviewed, together with ongoing prospective data collection for up to a year.

Alongside incident data from Trust logs we will use anonymised data from a vision-based patient monitoring and management system, Oxevision (Oxehealth Limited, Oxford, UK) which is currently used in mental health wards across multiple NHS Trusts as part of routine care. The system supports staff caring for patients by providing contact free measurement of breathing rate and pulse rate, alerts and activity reports. This study is not designed to evaluate the Oxevision system itself, but to establish if insights may be obtained into precursors to harm by combining anonymised data from the system with anonymised data from Trust incident logs.

[redacted], the Chief Investigator, will lead the analysis to characterise the nature and frequency of UIs and establish a methodology for the use of anonymised data from Oxevision systems to explore the insights which may be obtained into UIs and their precursors.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Study Design
This will be an observational study. There will be no direct patient participation in this study; patient care and staff practices will be unaffected during the study. Only anonymised data on UIs will be reviewed with no harm expected to patients as a result of this study.

Recruitment and data collection
Patients will not be directly recruited into this study. Anonymised data on incidents will be gathered from the sites participating in this study. 12 months of retrospective incident data will be obtained through Trust incident logs. Monthly prospective data will be obtained from Trust incident logs. This routinely gathered UI data will be gathered from mental health adult inpatient wards (initially 3 Acute and 3 PICU across the Trusts) from Trusts where the Oxevision system is already installed and used in routine care. This data will be used to characterise the nature and frequency of UIs in bedroom settings in inpatient mental health.
For a selected sample of incidents, for rooms in these Trusts where Oxevision is installed and used as part of routine patient management, anonymised Oxevision system data will be reviewed in conjunction with the pseudonymised Trust incident reports. This will allow a methodology to be developed which identifies Oxevision data which may correlate with the subsequent occurrence of UI.

Consent
We will not seek individual patient consent since the study only involves reviewing and analysing anonymised data. Particular aspects we have considered include:

1. Oxevision is already used as part of routine patient care at the sites participating in this study.
2. Use of anonymised data for analysis. We will follow HRA guidelines as laid out under 'Research using anonymous health information', where a member of the care team enters information about patients into a database without any identifiers, where the primary purpose of the database is to support public health surveillance and wider clinical decision-making. That database would then hold information that would be anonymous to the researcher (where appropriate controls about linking that data to other data are put in place).
3. There will be no change to the medical care of patients as part of the study.
4. Level of risk to patients is minimal from participating in the study.
5. The nature of the UIs to be studied (including self-harm) means that it would be difficult to predict who is likely to be involved in an incident to obtain prior consent and it would also be inappropriate to discuss with the patients before the incidents have happened.

No identifiable video data will be collected, stored or used for this study. To ensure there are no privacy concerns the study procedures, data handling and storage have been scrutinized to ensure that any such issues are mitigated.

Effect on clinical care

There will be no change to patient medical management and care during this study. Only anonymised incident data will be reviewed by the research team. The aim of this study is to review behaviours and early warning signs to harmful events. In the process of incident data review it may be that specific current risks are recognised by the research team. In this event, although not the primary purpose of this study, the findings will be shared with Trusts if the Chief Investigator decides this is necessary to address an immediate risk to patient safety. This could result in changes to clinical care. The pathway of change in clinical care will not be proposed as part of this study and it is outside the scope of this study.

Safety

Oxevision is currently installed within several of our partner NHS Trusts and used in routine care. We do not intend to change routine care or evaluate the system in this study.

Patient risk

We do not anticipate any risks to patients from this study as there is no intervention as part of the study. Patients admitted to rooms with Oxevision installed are made aware of the system in their room upon admission through a standard information leaflet given to them by ward staff. Along with an explanation of how the ward staff will use Oxevision for their care they also have the option of requesting a demonstration of how the system is used.

Data Collection

Anonymised incident data will be used for this study. We will aim to obtain a heterogeneous sample of UI. These will be based on a mix of (not limited to), types of incidents, time of occurrence, involving males and females and younger and older age groups.

Data will be collected in two ways:

Data from Sites
12 months retrospective logs of reported incidents will be obtained from each site. Monthly prospective data on UI will also be requested from each site. Site PIs will be responsible for anonymisation of all UI data before being transferred for analysis by the study research team. The key to the pseudonymized data will be generated by and remain within the NHS facilities, managed by the site PI.

Data from Oxevision

Data collected will include numerical values of breathing and pulse rates and anonymised (heavily blurred) images of video data, obtained from the Oxevision system.

We will also review data involving patient behaviours that do not result in an incident, to distinguish patterns or combinations of behaviours that appear to lead to incidents. Timestamps will be used to avoid duplicate entries.

Participant comfort and dignity

The study does not require any changes to patient care or introduce any restrictions for patients or staff.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology

- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☑ Other (please specify)

This will be an observational study.

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

Can data from a non-contact vision-based patient monitoring and management system be used to reduce preventable UI events and support broader quality improvement programs within the sector?

The objective is to identify behaviours and biometric signs associated with UI in bedroom settings in inpatient mental health.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

1.Characterise the nature and frequency of UIs in bedroom settings in inpatient mental health

2.Develop a methodology to categorise Oxevision data which may correlate with the subsequent occurrence of UI

3.Identify any potential learnings from specific case studies which may support patient safety if shared with the professions

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

The care and safety needs of patients in inpatient mental health settings is complex, encompassing unpredictable actions and varying needs. The mental health services sector ranked second in terms of UI numbers after the acute care setting in England with approximately 300,000 reported incidents from April 2019 to Mar 2020. The top three most commonly reported types of incidents within the mental health setting were: self-harm behaviour (28%), disruptive-aggressive behaviour (including patient-to-patient) (16%) and patient accidents (13%) (NHS England » National patient safety incident reports up to June 2020. Available from: https://www.england.nhs.uk/publication/national-patient-safety-in cident-reports-up-to-june-2020/).

Recognizing and addressing setting-specific needs is key to development of effective programs and policies. The National Reporting and Learning System (NRLS), a voluntary scheme for reporting patient safety incidents in the NHS, allows all types of incidents to be documented, however, there exists no specific catalogue of early-warning signs to potentially predict these incidents in the mental health setting.

A vision-based patient monitoring and management system (Oxevision, Oxehealth Ltd) is already used for routine clinical measurement within ward processes at many UK Trusts, including those participating in this study. The system provides physiological and physical information to support staff caring for patients. It is an unobtrusive wall-mounted secure system that uses an infra-red optical sensor to obtain physiological and physical information as described below.

Physiological information

Computer vision and signal processing techniques are used to track breathing movements and changes in reflected light from several metres away. Breathing rate is measured by detecting small body movements due to breathing, just as a nurse conducting manual observations would count chest wall movements. Pulse rate is measured from small changes in reflected light from the skin, imperceptible to the human eye; this is the non-contact version of the photoplethysmography widely used in finger-worn pulse oximeters. The system allows the clinician to remotely obtain measurements of breathing rate and pulse rate without entering the patient's room. The British Standards Institute (BSI), acting as a Notified Body on behalf of the Medicines & Healthcare products Regulatory Agency (MHRA) has cleared the Vital Signs measurement software for use as a Class IIa medical device in Europe.

Physical information

The system can also detect movement within the room and bathroom. The information detected includes patient location within the room, for example detecting that patient is on the bed. Clinicians can access an activity report that allows them to assess time spent in each location within the room. For example, if the patient spends a long time in the bathroom, the clinician may carry out checks to ensure that the patient is safe. In the event of a system alert, for example, if a patient is on the edge of the bed or has a fall, clinicians can access real-time video data by following a workflow. It provides them a glimpse into the room for a brief period of time to see if the patient is safe. This gives the clinicians an opportunity to intervene as necessary.

This study will not assess the Oxevision system itself but will use anonymous data from the system which can be accessed by our research team from the system under appropriate governance.

This will be the first exploration of the potential insights available by combining anonymised Trust incident logs with anonymised data from the Oxevision system. The particular focus of this research programme is the identification of precursors to harm, which can ultimately be used to improve patient safety in this setting.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Study Design

This will be an observational study. We will observe retrospective data up to 12 months prior to the start of the study and 12 months of prospective data.

Study Data

Anonymised UI data will be gathered from mental health adult inpatient wards (initially 3 Acute and 3 PICU across the Trusts) from Trusts where the Oxevision system is already installed and used in routine care. Involvement of these three Trusts will provide a geographical diversification across rural and urban settings, allowing a mixed cohort of incidents. This data will be used to characterise the nature and frequency of UI in bedroom settings in inpatient mental health (Analysis 1, broad characterisation of incidents).

For a selected sample of incidents, for rooms in these Trusts where Oxevision is installed and used as part of routine patient management, anonymised Oxevision system data will be reviewed in conjunction with the anonymised Trust incident reports. PIs from individual sites, along with the CI, will identify incidents for this sample so that a broad range of UIs is represented. This will allow a methodology to be developed which identifies Oxevision data which may correlate with the subsequent occurrence of UI (Analysis 2, detailed analysis of incidents).

Sample size

All retrospective (up to 12 months) anonymised incident data from the acute and PICU bedrooms from the 3 Trusts will be collected to characterize the UIs to create a catalogue of UIs (Analysis 1, broad characterisation of incidents). This will also include rooms without Oxevision installed in them.

In addition, prospective data on UIs from rooms with and without Oxevision will be collected on a monthly basis. This will also support Analysis 1, the broad characterisation of incidents.

In combination with the above incident data, a sample of data obtained from the Oxevision rooms (initially 20 incidents) will be used to explore how the Oxevision data may be used to describe behaviours and physiological information occurring in the time periods prior to UIs (Analysis 2, detailed analysis of incidents).

Data from two hours prior to an UI will be reviewed, initially for 20 incidents. In selecting the sample of incidents for Analysis 2, the CI and Trust PIs will identify incidents in line with the inclusion criteria stated below. These incidents will be based on purposive sampling. The time range of two hours is subject to literature review findings. Further incidents may then be reviewed to the point of data saturation.

Inclusion of UI

We will aim to obtain a heterogeneous sample of UI. These will be based on a mix of (not limited to), types of incidents,

time of occurrence,
males and females
age of patient

Informed consent

Informed consent will not be obtained for this study as this study involves review and analysis of anonymised datasets and no direct patient intervention. Data collected will include numerical values of breathing rates and pulse rates and heavily blurred images of the incidents from the Oxevision system. Incident data obtained from each site will be transferred to the research team members after all identifiers are removed. No identifiable data will be removed from local sites or published. There will be no change to the patient's medical management as part of this study and we do not anticipate any harm to come to the patient as a result of participation in this study.

Data Collection

Anonymised incident data will be used for this study.

Data from Site records:
12 months retrospective logs of reported incidents will be obtained from each site. Site PIs will be responsible for data anonymisation before being transferred for analysis.

Monthly prospective data on UI will be requested from each site using an Incident data request form. The key to the pseudonymized data will be generated by and remain within the NHS facilities, managed by the site PI. Data collected on the incident data request form will include:

Patient age and gender
Date of Incident
Type of Incident, according to NRLS categories of incidents
Description of incident, including whether the patient was alone at the time of the incident
Severity of Incident
Location of Incident
Immediate intervention used to manage the incident
Follow-up intervention if applicable

We wish to minimise the burden of this study on staff at participating Trusts. It may be that a Trust prefers to share data in a different format to the incident data request form, to avoid extensive time spent transcribing data. The study research team will try to accommodate each Trust's preferred format, provided that the anonymisation process is followed and as many of the data fields above as possible are available for the research team to analyse.

Data from Oxevision:
Data collected will include numerical values of breathing and pulse rates and heavily blurred images of video data, obtained from the Oxevision system.

Retrospective analysis of heavily blurred video data from sites will be carried out based on the stored cloud data from each site. Oxehealth has a rolling data deletion process as part of its data storage program. Upon gaining appropriate approvals for the study we will aim to retrieve data stored in the cloud for these specific sites for up to 12 months. Some rooms from these sites may not have data for the past 12 months depending on when Oxevision was installed. In addition, the site PI will provide information on which rooms have Oxevision installed and occupancy levels.
We will also review data involving patient behaviours that do not result in an incident, to distinguish patterns or combination of behaviours that lead to incidents. Timestamps will be used to avoid duplicate entries.

De-identification process
The OxeVision system generates numerical data and heavily pixelated images, making identifying individuals impossible. This "de-identification" by pixilation was initially tested manually by displaying pictures of famous people 1 metre from the camera and asking people to identify the pictures in the pixelated images from a list of options. Following this regular semi-automatic tests are carried out with each new release of the software to ensure that the pixelated images of the Medical Device (Oxevision) test runs don't change.

Data Access and Storage

Only anonymised data will be shared by local sites with authorised members of the research team. Data processing and sharing agreement will be in place as part of the Organisation Information Document (v1.6) between the participating sites and the Sponsor.

From the Oxevision system, anonymized data (numerical values of pulse and breathing rates, numerical movement and location data, and blurred video images) is regularly uploaded to a secure cloud server. This anonymised data will be used to perform data analysis for this study.

Only authorised NHS staff and site PIs will have access to identifiable patient data. The site PI will create and have access to the patient identifiable data key before the data is pseudonymised and made available to the study researchers.
Direct access to the anonymised data generated by Oxevision (pulse rates and breathing rates, movement and location data and heavily blurred images) will be granted to authorized representatives from the study research team (consisting of researchers and the Chief Investigator).

No identifiable data will be transmitted from local sites.

No identifiable video data will be collected or transferred from sites for this study.

For this study, anonymised data (breathing and pulse rates and heavily blurred images) accessed securely by the researchers' computers at Oxehealth will be held securely, protected by ISO 27001-certified processes, and encrypted where necessary.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- ☐ Design of the research
- ☐ Management of the research
- ☐ Undertaking the research
- ☐ Analysis of results
- ☐ Dissemination of findings
- ☑ None of the above

Give details of involvement, or if none please justify the absence of involvement.
The research protocol was developed in discussion with a group of senior management members within the NHS Mental Health setting. The data will be reviewed by the CI who is an expert with this setting. The periodic bulletin will be created with feedback from the CI and PIs of the study team who are also actively engaged in clinical care of patients.

A study program group will be formed of experts in the field from within the network of the CI and PIs to provide guidance based on the initial findings of the data reviewed. This group will serve as an expert reference group to provide direction to the study.

This initial study aims to establish the value of combining anonymised data from the Oxevision system with anonymised data from Trust logs, in seeking insights into precursors to harm. We anticipate that there will be opportunities to engage with service user groups in future phases of this research programme.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- ☐ Blood
- ☐ Cancer
- ☐ Cardiovascular
- ☐ Congenital Disorders

- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [x] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Data on UI incidents from adult patients admitted to Acute inpatient and Psychiatric Intensive Care Unit in mental health from the participating Trusts will be reviewed and analysed for this study.
We will aim to obtain a heterogeneous sample of UI. These will be based on a mix of (not limited to),
types of incidents,
time of occurrence,
involving males and females and
younger and older age groups

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Children will be excluded from this study.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

There will be no direct participation of patients in this study.

Routinely gathered, anonymised UI data will be gathered from mental health adult inpatient wards (Acute and PICU) from Trusts where the Oxevision system is already installed and used in routine care.

Trust PIs will be responsible for identification of incidents in line with the data inclusion criteria. Monthly logs of pseudonymised data will be collected from the PIs by the studies coordinator.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

A37. Please describe the physical security arrangements for storage of personal data during the study?

No personal identifiable data will be transferred from NHS sites. The storage of Trust incident reporting data will continue as guided by local policies. Only pseudonymised versions of this data will be shared with the research team. This data will be held securely on password-protected Oxehealth computers.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Data will be analysed by members of the study team using Oxehealth computers and laptops which are secure and protected by ISO 27001-certified processes. The data, which will all be anonymised data, will only be analysed in private offices or homes (given current COVID-19 restrictions), not in public environments.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]
Post	Vice President for Research		
Qualifications	D.Phil		
Work Address	Magdalen Centre North, The Oxford Science Park, Littlemore		
Post Code	OX4 4GA		
Work Email	[redacted]		
Work Telephone	[redacted]		
Fax			

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

The data for this study, which will all be anonymised, will be held securely by Oxehealth Limited. The company has

developed stringent procedures for data handling to meet a very high level of data protection and security. Oxehealth's office is within an alarmed building with on-site 24 hour security guards.

In addition to strong physical security, the Oxehealth systems have a high level of electronic security to address the risk of a network-based attack. This includes a perimeter firewall and active scanning and logging.

INCENTIVES AND PAYMENTS

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◉ Yes ○ No

If yes, please give details including the amount of any monetary payment or the basis on which this will be calculated:
This study will be funded by Oxehealth Limited.

As part of this funding, Oxehealth provide funding to London South Bank University (LSBU) to cover the costs of the time of the Chief Investigator in working on this study. These costs are calculated by LSBU at their standard daily rate.

The Chief Investigator does not have any other financial or other relationship with Oxehealth Limited.

NOTIFICATION OF OTHER PROFESSIONALS

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◉ Yes ○ No

Please give details, or justify if not registering the research.
Clinicaltrials.gov

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study?*Tick as appropriate:*

☑ Peer reviewed scientific journals
☑ Internal report
☑ Conference presentation
☑ Publication on website
☑ Other publication
☐ Submission to regulatory authorities
☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators

☐ No plans to report or disseminate the results

☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Only anonymised data will be published.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

☐ Independent external review

☑ Review within a company

☐ Review within a multi−centre research group

☑ Review within the Chief Investigator's institution or host organisation

☑ Review within the research team

☐ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The protocol has been reviewed by Oxehealth's research team: Dr Oliver Gibson (VP of Research) and Varsha Gandhi (Clinical Studies Co-ordinator).

The protocol will be reviewed by the London South Bank University's internal review board.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

☐ Review by independent statistician commissioned by funder or sponsor

☐ Other review by independent statistician

☑ Review by company statistician

☐ Review by a statistician within the Chief Investigator's institution

☑ Review by a statistician within the research team or multi−centre group

☐ Review by educational supervisor

☐ Other review by individual with relevant statistical expertise

☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]
Department	Research		

Institution	Oxehealth
Work Address	Magdalen Centre North, The Oxford Science Park, Oxford
Post Code	OX4 4GA
Telephone	[redacted]
Fax	
Mobile	
E-mail	[redacted]

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

Identify behaviours and biometric signs associated with UI in bedroom settings in inpatient mental health.

A58. What are the secondary outcome measures?*(if any)*

1.Characterise the nature and frequency of UIs in bedroom settings in inpatient mental health

2.Develop a methodology to categorise Oxevision data which may correlate with the subsequent occurrence of UI

3.Identify any potential learnings from specific case studies which may support patient safety if shared with the professions

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	20
Total international sample size (including UK):	0
Total in European Economic Area:	0

Further details:
We plan to study two samples of anonymised data:

1. All retrospective (up to 12 months) and prospective anonymised incident data from acute and PICU bedrooms from participating Trusts. This dataset will be used for broad analysis of the nature and frequency of incidents.

2. A detailed analysis will be performed for a subset of these incidents (initially 20 incidents). Data from a time period (initially two hours) prior to an UI will be reviewed for this subset of incidents. Trust PIs will identify incidents in line with the inclusion criteria. These incidents will be based on purposive sampling. The time range of two hours is subject to literature review findings. Further incidents may then be reviewed subject to data saturation. Time ranges with no incident may also be reviewed for comparison.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The sample size for the broad analysis depends on the number of incidents that occur at the participating Trusts. For the detailed analysis, an initial sample of 20 incidents was chosen to give a reasonable balance between assessing a range of different incidents and the time required of the researchers to review each incident.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

An initial review of the literature will be performed to identify documentation of early warning signs/behaviours leading to UI. We will use the outcomes of this review to guide our methodology including analysis of the time period prior to an UI.
Data gathered through the Trust incident logs will be used to understand and characterise the UI. It will also be used to assess the preceding events (where documented) leading to UI. A catalogue of UI and behaviours will be documented.
Descriptive analysis may include but not be restricted to, types of behaviours observed, frequency and severity of behaviours, location of behaviour and incidents and environmental factors such as objects used and involvement of other individuals.
Data from Oxevision will provide an insight into the time leading to UI. The time period prior to a UI will be analysed to identify potential early warning signs. Analysis of physiological data gathered from Oxevision on breathing rates and pulse rates may provide insights into changing vitals prior to an UI. This may help develop a hypothesis on potential correlation of physiological parameters for future investigation.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title Forename/Initials Surname
	[redacted]
Post	Vice President for Research
Qualifications	MEng Msc DPhil CEng
Employer	Oxehealth Limited
Work Address	Oxehealth The Oxford Science Park Littlemore Oxford
Post Code	OX4 4GA
Telephone	[redacted]
Fax	
Mobile	
Work Email	[redacted]

	Title Forename/Initials Surname
	[redacted]
Post	Clinical Studies Coordinator
Qualifications	MSc
Employer	Oxehealth Limited
Work Address	Magdalen Centre North, The Oxford Science Park, Oxford
Post Code	OX4 4GA
Telephone	[redacted]
Fax	
Mobile	
Work Email	[redacted]

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]

Post	Clinical Research Analyst
Qualifications	MSc
Employer	Oxehealth Limited
Work Address	Magdalen Centre North, The Oxford Science Park, Littlemore
Post Code	OX4 4GA
Telephone	[redacted]
Fax	
Mobile	
Work Email	[redacted]

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	London South Bank University
Given name	[redacted]
Family name	[redacted]
Address	103 Borough Road,
Town/city	London
Post code	SE1 0AA
Country	United Kingdom
Telephone	[redacted]
Fax	00
E-mail	[redacted]

Legal representative for clinical investigation of medical device (studies involving Northern Ireland only)
Clinical Investigations of Medical Devices that take place in Northern Ireland must have a legal representative of the sponsor that is based in Northern Ireland or the EU

Contact person

Name of organisation
Given name
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [ ] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [x] No application for external funding will be made

What type of research project is this?

- (•) Standalone project
- ( ) Project that is part of a programme grant
- ( ) Project that is part of a Centre grant
- ( ) Project that is part of a fellowship/ personal award/ research training award
- ( ) Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (•) No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (•) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]

Organisation	RDaSH NHS Foundation Trust
Address	Woodfield House, Tickhill Road Site, Balby, Doncaster
Post Code	DN4 8QN
Work Email	[redacted]
Telephone	[redacted]
Fax	
Mobile	

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

Yorkshire and Humber

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/10/2021
Planned end date: 31/03/2023
Total duration:
Years: 1 Months: 5 Days: 31

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 3

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- ☑ NHS organisations in England 3

- [ ] NHS organisations in Wales
- [ ] NHS organisations in Scotland
- [ ] HSC organisations in Northern Ireland
- [ ] GP practices in England
- [ ] GP practices in Wales
- [ ] GP practices in Scotland
- [ ] GP practices in Northern Ireland
- [ ] Joint health and social care agencies (eg community mental health teams)
- [ ] Local authorities
- [ ] Phase 1 trial units
- [ ] Prison establishments
- [ ] Probation areas
- [ ] Independent (private or voluntary sector) organisations
- [ ] Educational establishments
- [ ] Independent research units
- [ ] Other (give details)

Total UK sites in study: 3

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The study may be monitored or audited by responsible individuals from the study sponsor and the NHS Trusts involved.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

◉ Yes ○ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN1	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	[redacted] [redacted] [redacted]
	Organisation name	ROTHERHAM DONCASTER AND SOUTH HUMBER NHS FOUNDATION TRUST	Qualification (MD...)	
	Address	WOODFIELD HOUSE TICKHILL ROAD DONCASTER	Country	United Kingdom
	Post Code	DN4 8QN		
	Country	ENGLAND		
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	[redacted] [redacted] [redacted]
	Organisation name	TEES, ESK AND WEAR VALLEYS NHS FOUNDATION TRUST	Qualification (MD...)	
	Address	TRUST HEADQUARTERS WEST PARK HOSPITAL EDWARD PEASE WAY DARLINGTON	Country	United Kingdom
	Post Code	DL2 2TS		
	Country	ENGLAND		
IN3	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	
	Organisation name	ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST	Qualification (MD...)	
	Address	THE LODGE LODGE APPROACH RUNWELL WICKFORD	Country	United Kingdom
	Post Code	SS11 7XX		

Country	ENGLAND

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.

10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.

12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- ○ Chief Investigator
- ○ Sponsor
- ◉ Study co-ordinator
- ○ Student
- ○ Other – please give details
- ○ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by [redacted] on 06/09/2021 13:11.

Job Title/Post:	Professor of Mental Health
Organisation:	London South Bank Unversity
Email:	[redacted]

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by [redacted] on 06/09/2021 16:50.

Job Title/Post:	Professor
Organisation:	LSBU
Email:	[redacted]

Inpatient Safety in Mental Health

Protocol

22.07 2021 Version 1.0

IRAS ID – 287453

Ethics Ref: TBC

Chief Investigator	[redacted]
Co applicants	[redacted]
Study sponsor	London South Bank University
Study Funder	Oxehealth Limited

Contents

SYNOPSIS

Study Title	Inpatient Safety in Mental Health
Study Design	Observational Study
Study Participants	Adult patients admitted to acute in-patient mental health facilities.
Planned Sample Size	3 sites
Planned Study Period	12 months
Aim	To improve inpatient safety by identifying precursors to harm and clinical lessons learned, including: - To review the literature related to untoward incidents (UIs) in bedroom settings in mental health services, and precursor behaviours associated with mental health UIs - Characterising the frequency and nature of UIs in this setting - Establishing a systematic methodology by which observational data, available from Oxevision system, may be examined to identify correlations with the subsequent occurrence of UI
Research Question	Can data from a non-contact vision-based patient monitoring and management system be used to reduce preventable UIs events and support broader quality improvement programs within the sector?
Objectives	
Primary Objective	Identify behaviours and biometric signs associated with UIs in bedroom settings in inpatient mental health.
Secondary Objectives	1. Characterise the nature and frequency of UIs in bedroom settings in inpatient mental health 2. Develop a methodology to categorise Oxevision data which may correlate with the subsequent occurrence of UIs 3. Identify any potential learnings from specific case studies which may support patient safety if shared with the professions

ABBREVIATIONS

UI	Untoward Incident
NHS	National Health Service
PI	Principal Investigator
PMG	Program Management Group
PICU	Psychiatric Intensive Care Unit
BR	Breathing rate
PR	Pulse rate

SUMMARY

Learning from incidents and near misses is an important aspect of improving inpatient safety. The overall aim of this program of work is to improve inpatient safety in mental health facilities by identifying precursors to UI and clinical lessons learned. This work would examine detailed data about precursors and warning signs, using previously unavailable data, providing insights into the nature of risks leading to UIs that have not been investigated before. For the purpose of this study we will adopt the NHS definition of 'UI' which is defined as any event, incident, occurrence or accident, which could have or did lead to unintended harm, loss or damage to a patient, visitor or member of staff or hospital Trust property(1).

This stepwise program will include observation of UIs to create a catalogue of behaviours and their characteristics, such as frequency and nature of behaviours leading to UI in inpatient mental health settings.

It will establish a systematic methodology by which observational data available from Oxevision systems in patient bedrooms may be examined to draw correlations as precursors to UIs.

Oxehealth has developed a vision-based patient monitoring and management system, that is currently being routinely used in mental health wards across 18 NHS Trusts. The system allows clinicians to measure their patients' breathing and pulse rates remotely. It also allows clinicians to respond to alerts, for example related to a patient's location within their room, and to view activity reports. The system is designed to provide monitoring in patient bedrooms, and does not provide full coverage of communal areas or en suite bathrooms. The primary aim of this project is not to evaluate the Oxevision system itself.

Patients admitted to rooms with Oxevision at the organisations in this study are given a standard information leaflet regarding the system, informing them of what Oxevision is and how it may be used by the nurse as part of their routine care. Patients can also request a demonstration and be shown how the system is used while in the room.

By reviewing anonymised data from currently used Trust incident reporting systems alongside anonymised data from the Oxevision system, we ultimately aim to identify precursors leading to UIs.

Therefore, to address the research question and objectives listed above, two analyses will be conducted by the study researchers:

Analysis 1 (broad characterisation of incidents): reviewing anonymised incident logs from participating Trusts, to analyse the frequency and characteristics of incidents

Analysis 2 (detailed analysis of incidents): reviewing a smaller number of incidents in more detail, using anonymised data from the Oxevision system alongside the anonymised incident logs, to

establish how this combination of data may be used to seek additional insights into the incidents and their precursors. In assessing the value of potential precursors, anonymised data from time periods where no incident occurred may also be reviewed.

BACKGROUND AND RATIONALE

The care and safety needs of patients in inpatient mental health settings are complex, encompassing unpredictable actions and varying needs. The mental health services sector ranked second in terms of UI numbers after the acute care setting in England with approximately 300, 000 reported incidents from April 2019 to Mar 2020. The top three most commonly reported types of incidents within the mental health setting were: self-harm behaviour (28%), disruptive-aggressive behaviour (including patient-to-patient) (16%) and patient accidents (13%)(2).

Suicide and attempted suicide events remain of particular concern in inpatient mental health wards, with the majority of attempts occurring in bedrooms and bathrooms by strangulation using low-lying ligature points (3).

Recognizing and addressing setting-specific needs is key to development of effective programs and policies. The National Reporting and Learning System (NRLS), a voluntary scheme for reporting patient safety incidents in the NHS, allows all types of incidents to be documented, however, there exists no specific catalogue of early-warning signs to potentially predict these incidents in the mental health setting.

The Vision Based Patient Monitoring and Management System (Oxevision)

Oxevision is already used for routine clinical measurement within ward processes at the participating Trusts. The system provides physiological and physical information to support staff caring for patients. It is an unobtrusive wall mounted secure system that uses an infra-red optical sensor (4). It is currently used in a range of settings, including care homes, acute care wards, and mental health inpatient settings (5). Within the mental health wards, it is most widely used in Adult Acute care and Psychiatric intensive care units (PICU).

Physiological information

Computer vision and signal processing techniques are used to track breathing movements and changes in reflected light from several metres away. Breathing rate is measured by detecting small body movements due to breathing, just as a nurse conducting manual observations would count chest wall movements. Pulse rate is measured from small changes in reflected light from the skin, imperceptible to the human eye; this is the non-contact version of the photoplethysmography widely used in finger-worn pulse oximeters. The system allows the clinician to remotely obtain measurements of breathing rate and pulse rate without entering the patient's room. **Figure 1.**

The British Standards Institute (BSI), acting as a Notified Body on behalf of the Medicines & Healthcare products Regulatory Agency (MHRA) has cleared the Vital Signs measurement software for use as a Class IIa medical device in Europe.

Physical information

The system can also detect movement within the room. The information detected includes patient location within the room, for example detecting that patient is on the bed. Clinicians can access an activity report that allows them to assess time spent in each location within the room. For example,

if the patient spends a long time in the bathroom, the clinician may carry out checks to ensure that the patient is safe.

In the event of a system alert, for example, if a patient is on the edge of the bed or has a fall, clinicians can access real-time video data by following a workflow. It provides them a glimpse into the room for a brief period of time to see if the patient is safe. This gives the clinicians an opportunity to intervene as necessary.

This study will not assess the Oxevision system itself but will use anonymous data which can be accessed by our research team from the system under appropriate governance.

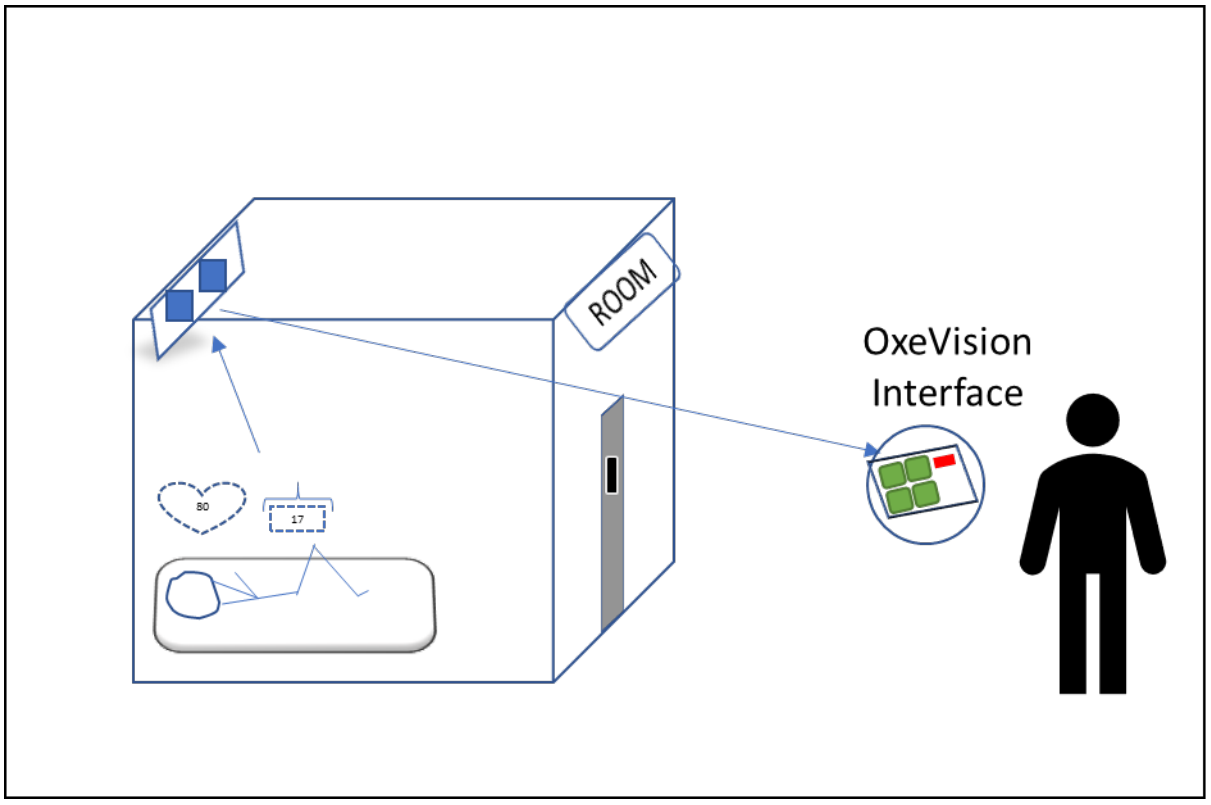

Figure 1. Diagram to show non-contact use of Oxevision. Diagram is not to scale and does not represent the Oxevision user interface.

METHODS

Study Design

This will be an observational study. We will observe retrospective data up to 12 months prior to start of the study and 12 months of prospective data.

Study Data

Anonymised UI data will be gathered from mental health adult inpatient wards (initially 3 Acute and 3 PICU across the Trusts) from Trusts where the Oxevision system is already installed and used

in routine care. Involvement of these three Trusts will provide a geographical diversification across rural and urban settings, allowing a mixed cohort of incidents. This data will be used to characterise the nature and frequency of UI in bedroom settings in inpatient mental health (Analysis 1, broad characterisation of incidents).
For a selected sample of incidents, for rooms in these Trusts where Oxevision is installed and used as part of routine patient management, anonymised Oxevision system data will be reviewed in conjunction with the anonymised Trust incident reports. PIs from individual sites, along with the CI, will identify incidents for this sample so that a broad range of UIs is represented. This will allow a methodology to be developed which identifies Oxevision data which may correlate with the subsequent occurrence of UI (Analysis 2, detailed analysis of incidents).

Sample size

All retrospective (up to 12 months) anonymised incident data from the acute and PICU bedrooms from the 3 Trusts will be collected to characterize the UIs to create a catalogue of UIs (Analysis 1, broad characterisation of incidents). This will also include rooms without Oxevision installed in them.

In addition, prospective data on UIs from rooms with and without Oxevision will be collected on a monthly basis. This will also support Analysis 1, the broad characterisation of incidents.

In combination with the above incident data, a sample of data obtained from the Oxevision rooms (initially 20 incidents) will be used to explore how the Oxevision data may be used to describe behaviours and physiological information occurring in the time periods prior to UIs (Analysis 2, detailed analysis of incidents).

Data from two hours prior to an UI will be reviewed, initially for 20 incidents. In selecting the sample of incidents for Analysis 2, the CI and Trust PIs will identify incidents in line with the inclusion criteria stated below. These incidents will be based on purposive sampling. The time range of two hours is subject to literature review findings. Further incidents may then be reviewed to the point of data saturation.

Inclusion of UIs

We will aim to obtain a heterogeneous sample of UI. These will be based on a mix of (not limited to),

types of incidents,
time of occurrence,
males and females
age of patient

DATA COLLECTION

Anonymised incident data will be used for this study.

Data from Site records

12 months retrospective logs of reported incidents will be obtained from each site. Site PIs will be responsible for data anonymisation before being transferred for analysis.

Monthly prospective data on UIs will be requested from each site using an Incident data request form. The key to the pseudonymized data will be generated by and remain within the NHS facilities, managed by the site PI.

Data requested on the incident data request form will include:

Patient age and gender

Date of Incident

Type of Incident, according to NRLS categories of incidents (6)

Description of incident, including whether the patient was alone at the time of the incident

Severity of Incident

Location of Incident

Immediate intervention used to manage the incident

Follow-up intervention if applicable

We wish to minimise the burden of this study on staff at participating Trusts. The incident data request form is created to align with the NHS Learn from patient safety events service (LFPSE)(7) allowing transfer of anonymised UIs onto the incident data request form. It may be that a Trust prefers to share data in a different format to the incident reporting form, to avoid extensive time spent transcribing data. The study research team will try to accommodate each Trust's preferred format, provided that the anonymisation process is followed and as many of the data fields above as possible are available for the research team to analyse.

Data from Oxevision

Data collected will include numerical values of breathing and pulse rates and heavily blurred images of video data, obtained from the Oxevision system. **Figure 4.**

Retrospective analysis of heavily blurred video data from sites will be -carried out based on the stored cloud data from each site. Oxehealth has a rolling data deletion process as part of its data storage program. Upon gaining appropriate approvals for the study we will aim to retrieve data stored in the cloud for these specific sites for up to 12 months. Some rooms from these sites may not have data for the past 12 months depending on when Oxevision was installed.

In addition, the site PI will provide information on which rooms have Oxevision installed and occupancy levels.

We will also review data involving patient behaviours that do not result in an incident, to distinguish patterns or combination of behaviours that lead to incidents. Timestamps will be used to avoid duplicate entries.

DATA MANAGEMENT

Access to data

Only anonymised versions of incident data will be shared with the research team.

From the Oxevision system, anonymized data (numerical values of pulse and breathing rates, numerical movement and location data, and blurred video images) is regularly uploaded to a secure cloud server. This anonymised data will be used to perform data analysis for this study. The flow diagram below shows the access points and flow of data. **Figure 3**

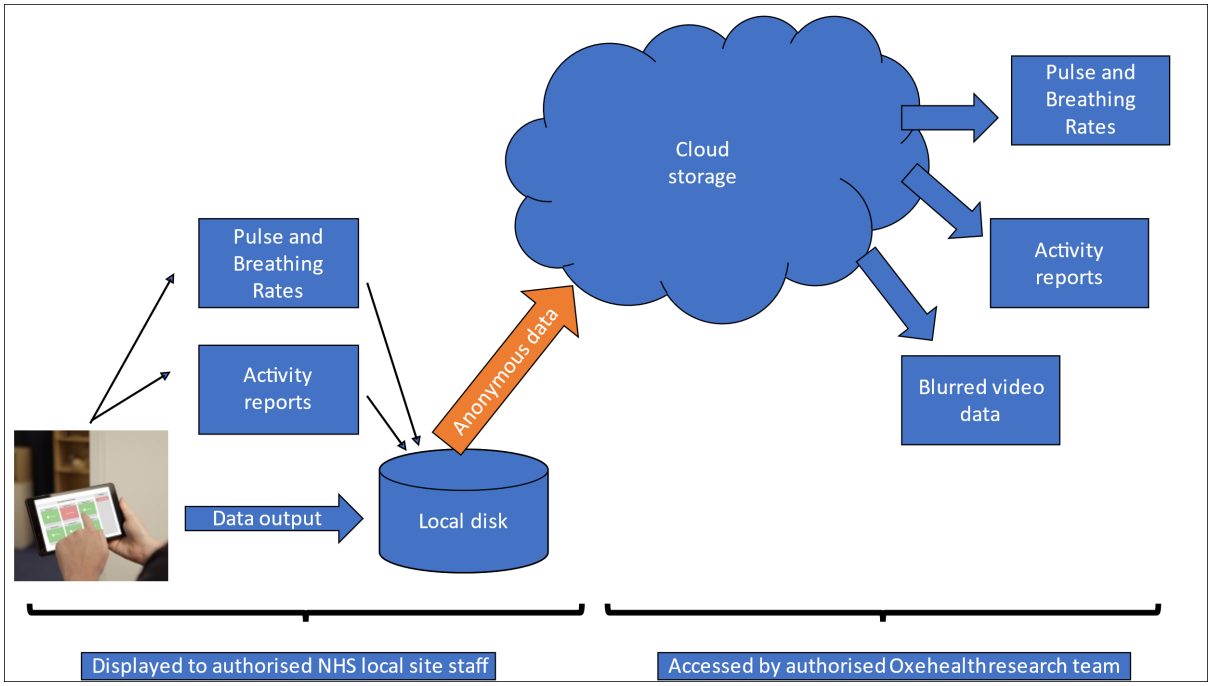

Figure 3. Flow diagram showing data collection and access.

Only authorised NHS staff and site PIs will have access to identifiable patient data. The site PI will create and have access to the patient identifiable data key before the data is pseudonymised and made available to the study researchers.

Direct access to the anonymised data generated by Oxevision (pulse rates and breathing rates, movement and location data and heavily blurred images) will be granted to authorized representatives from the study research team (consisting of researchers and the Chief Investigator).

Data recording and handling

No identifiable data will be transmitted from local sites.

No identifiable video data will be collected or transferred from sites for this study.

Data will be analysed by members of the study team using Oxehealth computers and laptops which are secure and protected by ISO 27001-certified processes. The data, which will all be anonymised data, will only be analysed in private offices or homes (given current COVID-19 restrictions), not in public environments.

Data Storage

Anonymised study data will be stored in Oxehealth secure servers for a period of 5 years. Oxehealth's office is within an alarmed building with on-site 24 hour security guards. In addition to strong physical security, the Oxehealth systems have a high level of electronic security to address

the risk of a network-based attack. This includes a perimeter firewall and active scanning and logging.

DATA ANALYSIS

An initial review of the literature will be performed to identify any literature reporting early warning signs/behaviours that occur prior to UI (or behaviour that would be classified as a UI if they occurred within mental health services). Should literature provide relevant evidence, we will use the outcomes of this review to guide our methodology, for example in terms of the time period prior to a UI that should be examined for specific behaviours or bio signs.

Data gathered through the incident data request forms will be used to understand and characterise the UIs. It will also be used to assess the preceding events (where documented) leading to UI. A catalogue of UIs and behaviours will be documented.

Descriptive analysis may include but is not restricted to, types of behaviours observed, frequency and severity of behaviours, location of behaviour and incidents and environmental factors such as objects used and involvement of other individuals.

Data from Oxevision will provide additional insight into the time leading to UIs. The time periods prior to UIs will be analysed to identify potential early warning signs. Analysis of physiological data gathered from Oxevision on breathing rates and pulse rates will provide insights into changing vitals prior to an UI. This may help develop a hypothesis on potential correlation of physiological parameters for future investigation. For example, previous research of identification of biological indicators of suicide risk suggests that people who attempt suicide have a reduced capacity to regulate their response to stress, resulting in decreased heart rate variability (8).

ORGANISATION

Program Management Group

A PMG will be formed and consists of the Chief Investigator, Oxehealth research team members and experts in the area of mental health safety who can provide independent advice and scrutiny. The group will meet after the initial stage of review of literature and analysis of UIs to guide the study based on the outcomes of the initial findings. The research team will seek advice and guidance from this group on an ongoing basis.

Study Timeline

Please refer to Appendix 1.

ETHICAL CONSIDERATIONS

This study will only include anonymised UIs data from adult participants, hence individual participant consent will not be obtained.

This study follows a similar approach to analysis of an anonymised dataset of Oxevision-obtained physiological measurements and heavily blurred images, to a study that was recently granted

approval by the London Surrey Research Ethics Committee (REC reference: 20/PR/1001, IRAS ID 287454, approval date 19 March 2021).

Particular aspects considered include:

1. Oxevision is already used as part of routine patient care at the sites participating in this study.
2. Use of anonymised data for analysis. We will follow HRA guidelines as laid out under 'Research using anonymous health information', where a member of the care team enters information about patients into a database without any identifiers, where the primary purpose of the database is to support public health surveillance and wider clinical decision-making. That database would then hold information that would be anonymous to the researcher (where appropriate controls about linking that data to other data are put in place) (9).
3. There will be no change to the medical care of patients as part of the study.
4. Level of risk to patients is minimal from participating in the study.
5. The nature of the UIs to be studied (including self-harm) means that it would be difficult to predict who is likely to be involved in an incident to obtain prior consent and it would also be inappropriate to discuss with the patients before the incidents have happened.

No identifiable video data will be collected, stored or used for this study. To ensure there are no privacy concerns the study procedures, data handling and storage have been scrutinized to ensure that any such issues are mitigated.

De-identification process

The OxeVision system generates numerical data and heavily pixelated images, making identifying individuals impossible. This "de-identification" by pixilation was initially tested manually by displaying pictures of famous people 1 metre from the camera and asking people to identify the pictures in the pixelated images from a list of options. Following this regular semi-automatic test are carried out with each new release of the software to ensure that the pixelated images of the Medical Device (Oxevision) test runs don't change. These data and images are retrieved by Oxehealth proprietary software on occasion to enable reviews of performance. Examples of clear and blurred images are attached at the end of the protocol.

All data will be kept as strictly confidential. All video data (which will only be anonymised, blurred data) will be stored securely using industry standard methods. The location of storage devices will be monitored at all times.

Access to the data will be restricted to authorised individuals from the research team.

There is a remote possibility that data indicative of illegal activities such as patient abuse or suboptimal practice which may involve potential or possible harm occurring to the participant may be recorded. The Chief Investigator has received NHS child and adult safeguarding training, is a registered healthcare professional (RN mental health) and has extensive knowledge of current practice and standards in NHS mental health inpatient settings. If a researcher is concerned by data they have seen, this will be reported to the Chief Investigator who will take appropriate actions.

FUNDING

This project will be funded by Oxehealth Ltd.

STUDY SPONSORSHIP AND INSURANCE

The study will be sponsored by London South Bank University. LSBU insurance and indemnity cover will be provided in the event of participant suffering harm as a result of their involvement in this study.

PUBLICATION POLICY

The final results of the study will be documented in technical reports and journal or conference publications. No identifiable data from individual participants will be published without their specific written permissions.

INFORMATION DISSEMINATION

Newsletters will be circulated regarding the progress of the study. Academic publications and presentations will be undertaken by the lead collaborators as appropriate to inform the community of the benefits and resources available through outcomes of the ongoing data analysis.

Benefits of the proposed project,

This project will combine anonymised data on UI, with expert interpretation and analysis.

Will provide a review of literature related to precursors of UI in mental health settings

Develop a methodology for analysing data from the Oxevision system that is widely used within NHS mental health services.

Provide an analysis of the type and frequency of UI occurring in bedrooms, providing useful information to NHS trusts and a baseline for further research on incident reduction.

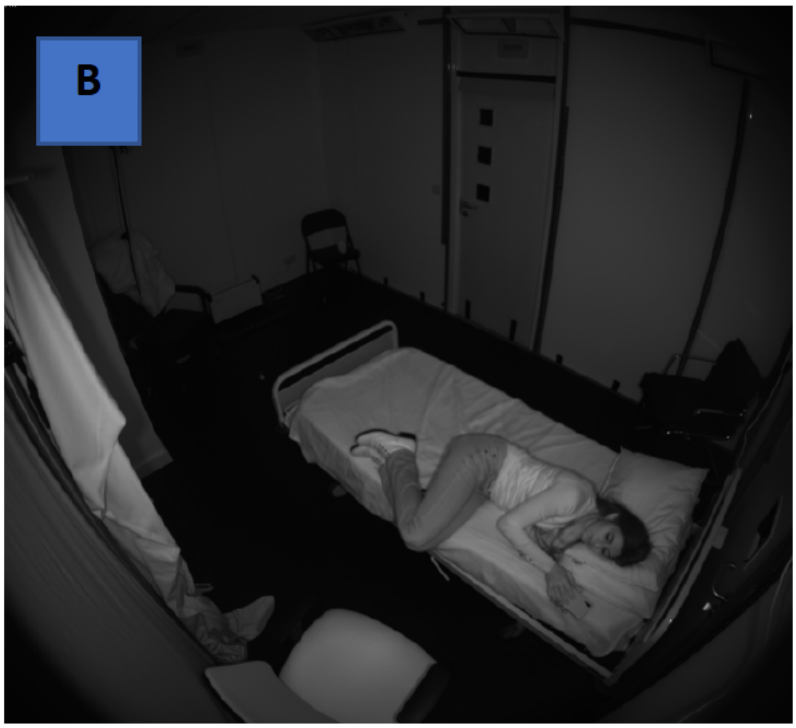

Figure 4 This example shows the blurring process developed in order to prevent identification of the person being viewed. **Picture B** shows the original image, in which the person could be identified. **Picture A** shows the same image after the de-identification process (involving heavy blurring) has been applied.

Only de-identified images such as **Picture A** will be used in this study.

The de-identification process is automatically run by the Oxevision system on all images of the type used in this study before the images would be accessible to the study research team.

(In these example images, the person shown is a member of the research team, not a patient.)

REFERENCES

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Appendix 1. Study Timeline

	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Review of Literature	x	x	x	x													
Trust UI collection (retrospective data)		x	x	x													
Trust UI collection (prospective data)		x	x	x	x	x	x	x	x	x	x	x	x	x			
Analysis of UI		x	x	x	x	x	x	x	x	x	x	x	x	x			
PMG meeting					x				x				x			x	
Publication of findings (review of literature, safety bulletins/reports and peer reviewed articles)					x	x										x	x

CURRICULUM VITAE

Name:

[redacted]

Present appointment:

[redacted], Department of Health and Social Care, London South Bank University

Address:

[redacted]

Telephone number:	**Email address:**
[redacted]	[redacted]

Qualifications:

PhD, MSc, BSc, RN

Professional registration:

Nursing and Midwifery Council 83A2223E. Registered from 1986 to current

Previous and other appointments:

- Non-Executive Director (p/t) - Barnet, Enfield and Haringey NHS Mental Health Trust, 2018- current.
- Consultant Editor (p/t) - 'Mental Health Practice', RCNi, 2020- current
- Clinical Lead – Mental Health (p/t), London Urgent and Emergency Care Collaborative, 2018-2020
- Executive Director of Nursing – South London and Maudsley NHS Foundation Trust, 2013-2017

Research experience:

Experience in leading and contributing to a range of studies related to changing roles and skills of workers in mental health services and aspects of acute inpatient mental health care delivery. Investigated attitudes towards the introduction of a technological innovation in mental health inpatient settings (Brimblecombe et al 2019b). Led studies on changing professional roles in mental health care, with particular reference to mental health nursing, including national surveys of non-medical prescribing (Dobel Ober and Brimblecombe 2016) and nurse consultants in mental health (Brimblecombe et al 2019a) and attitudes towards advanced practice roles in mental health services (Brimblecombe and Nolan in print). Led study of factors associated with admission to acute mental health services, with particular reference to perceived suicide risk (Brimblecombe et al 2003). Contributed to studies of staff experience of using workload measurement tools in mental health inpatient settings (Fanneran et al 2013) and experience of mental health inpatient service users (Nolan et al 2011)

Research training: *(*

Good Clinical Practice (GCP) Refresher eLearning Modules Completed - July 2021

Relevant publications:

Brimblecombe N. and Nolan F. (2021) Qualitative study of perceptions of senior health service staff as to factors influencing the development of Advanced Clinical Practice roles in mental health services. *Journal of Psychiatric and Mental health Services*

Drennan V, Collins, L, Allen H, Brimblecombe N, Halter M, Taylor F. (2021) Advanced clinical practice roles in the National Health Service, England: a remedy for workforce problems? A qualitative study of senior staff perspectives. *Journal of Health Services Research & Policy*
DOI: 10.1177/13558196211036727/

Simpson A., Brimblecombe N., Hannigan B. and Turner, J. (2021) Mental Health Nurse Academics can help attain Goals for Mental Health Research and influence Policy. *Journal of Mental Health* 10.1080/09638237.2021.1898568. Available at https://doi.org/10.1080/09638237.2021.1898568 .

Brimblecombe, N. (2020) Editorial - Mental health nurses should influence what data are gathered for service users. *Mental Health Practice.* 23 (5), pp. 5-5. https://doi.org/10.7748/mhp.23.5.5.s1

Brimblecombe N., Nolan F., Khoo M.E., Culloty L., O'Connor K., McGregor-Johnson L. (2019a) The nurse consultant in mental health services: A national, mixed methods study of an advanced practice role. *Journal of Psychiatric and Mental Health Nursing* 26, 117-130. doi: 10.1111/jpm.12533

Brimblecombe, N, Quist, H and Nolan, F (2019b). A mixed methods survey to explore views of staff and service users in mental health inpatient wards prior to introduction of a digital early warning system for physical deterioration. *Journal of Psychiatric and Mental Health Nursing.* 26 (3-4), pp. 65-76. https://doi.org/10.1111/jpm.12511

Dobel-Ober D., & Brimblecombe N. (2016) National survey of nurse prescribing in mental health services; a follow-up 6 years on. *Journal of Psychiatric and Mental Health Nursing*, 23(6-7), 378-386.

Fanneran T., Brimblecombe N., Bradley E., Gregory S. (2015). Using workload measurement tools in diverse care contexts: the experience of staff in mental health and learning disability inpatient settings. *Journal of Psychiatric and Mental Health Nursing* 22, 764-772.

Nolan P. Bradley E., Brimblecombe N. (2011) Disengaging from Acute In-Patient Psychiatric Care: a description of service-users' experiences and views. *Journal of Psychiatric and Mental Health Nursing* 18, 4, 359-367.

Brimblecombe N., O'Sullivan G. and Parkinson B. (2003) Home treatment as an alternative to in-patient admission: characteristics of those treated and factors predicting hospitalization. *Journal of Psychiatric and Mental Health Nursing.* 10, 683-687.

Signature:	**Date:**
[redacted]	21/07/2021

STUDY

Inpatient Safety in Mental Health

INCIDENT DATA REQUEST FORM

Version 1.0 22 July 2021

Chief Investigator: [redacted]

DO NOT INCLUDE PATIENT IDENTIFIABLE INFORMATION OR THAT OF INDIVIDUALS OTHER THAN THOSE OF THE REPORTER FOR COMMUNICATION PURPOSES

Date this form was filled	
Reporting Site	
Ward name	
Room number (if known)	

A. Patient Information

Age	
Gender	
Ethnicity	
Diagnoses (All)	

B. Incident Information

Date of Incident	
Type of Incident (based on NHS Incident Category)	
Time of Incident during patient's stay	At admission Initial week of admission At transfer At discharge Other
Was the patient alone?	Yes No
If patient was not alone who was with them?	
Direction of Incident	Self Staff Carer Visitor
Reason for Incident if known	Change in medication Refused to take medication Aggravation from/towards other individuals Environmental factors (e.g. change of room, change of staff, new routine)

	Family reasons (e.g. unexpected family event, new visitor) Other -
Was anyone injured? If yes - who was injured?	
Did the injuries require medical attention from external service providers? If so – who?	
Time of Incident	
Location of Incident	
Was the incident witnessed? If YES – who witnessed the incident?	
Reporter's job title	

C. Incident Description

Before the Incident	**Incident**	**After the Incident**
Any change in patient behaviour noted before the incident? *Example change noted in patient's* *Behaviour* *Actions* *Interactions* *Medications*	What happened? How was the incident identified?	Immediate action taken after the incident

D Follow up Action Plan

Who was notified?	**CQC** (Care Quality Commission), **NRLS** (The National Reporting and Learning System), **CCG** (Clinical Commissioning Groups), **MHRA** (The Medicines and Healthcare products Regulatory Agency), **HSE** (The Health and Safety Executive), **IG Toolkit** (The Data Security and Protection Toolkit)
Temporary change to manage safety?	
Permanent change to manage safety	
Any factors identified that you were not able to change to improve safety?	

E Impact or potential impact did the event have on the patient (physical and psychological)?

Apparent Outcome of Incident: Please describe: Please categorise **PHYSICAL** significance/potential significance (tick A for actual harm and P for potential harm)				
None	**Low Harm**	**Moderate Harm**	**Severe Harm**	**Death**

P A	P A	P A	P A	P A

None	Low Harm	Moderate Harm	Severe Harm	Death
Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving care. This may be locally termed a 'near miss'.	Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons.	Any unexpected or unintended incident that resulted in further treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused short-term harm to one or more persons.	Any unexpected or unintended incident that caused permanent or long-term harm to one or more persons.	Any unexpected or unintended event that caused the death of one or more persons.

Apparent Outcome of Incident:

Please describe:

Please categorise **PSYCHOLOGICAL** significance/potential significance
(Circle one of the options, None, Low Harm, Moderate Harm or Severe Harm)

None	Low Harm	Moderate Harm	Severe Harm
Distress is inherent in being involved in any patient safety incident, but please select this option if there is no specific psychological harm over and above this	Low psychological harm is when at least one of the following apply: - distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit - distress that did not or is unlikely to affect the patient's normal activities for more than a few days - distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition	Moderate psychological harm is when at least one of the following apply: - distress that did or is likely to need a course of treatment or therapy sessions that extends for less than six months - distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than six months - distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, but where recovery is expected within six months	Severe psychological harm is when at least one of the following apply: - distress that did or is likely to need a course of treatment or therapy sessions that continues for more than six months - distress that did or is likely to affect the patient's normal activities or ability to live independently for more than six months - distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within six months

Likelihood of Reoccurrence: *Please attempt to assess the likelihood of a similar event happening again.*				
Almost certain	**Likely**	**Don't know**	**Unlikely**	**Rare**

F Impact or potential impact did the event have on the staff?

Staff involved needed medical attention?	**Yes**	**No**
Staff requested post-incident support?	**Yes**	**No**
If YES - type of support provided if known		

Oxehealth Limited
Magdalen Centre North,
Oxford Science Park, Oxford
OX4 4GA
www.oxehealth.com

Tuesday, 20 July 2021

To whom it may concern,

Inpatient Safety in Mental Health

IRAS Project ID: 287453

Inpatient Safety in Mental Health is a collaborative research project led by [redacted] at London South Bank University and the Oxehealth Clinical Research Forum at Oxehealth Limited, Oxford, UK.

I confirm that Oxehealth Limited will contribute equipment, provision staff time and provide funding for external researchers as well as make available any other appropriate resource, as is specifically required, to support this project.

Best regards,

[redacted]

[redacted]

Vice-President of Research, Oxehealth Ltd.

Organisation Information Document – Non-Commercially Sponsored Studies

(Template version: 1.6)

Guidance on Using This Document

Please use this document to create the outline Organisation Information Document/s that you will submit with your IRAS Form. In most instances the Organisation Information Document should be localised before sharing with participating NHS / HSC organisations.

Questions/items marked with an asterisk * (Questions 1-3, 5, 8 and 12-15 and 18, as well as items throughout the appendices as applicable) must be completed prior to submission of the IRAS Form in all cases. Only if the localised Organisation Information Document is to be used as the Agreement between the parties should the Sponsor or authorised delegate check the relevant check boxes at the top of each subsequent appendix and complete the authorisation section.

Items marked with a caret ^ are completed by the participating NHS / HSC organisation, after the Local Information Pack is shared and where relevant.

Remaining questions may be answered on the localised Organisation Information Document either by the Sponsor or authorised delegate prior to sharing the Local Information Pack, or by the participating NHS / HSC organisation (or collaboratively between the two) after the Local Information Pack is shared, as appropriate.

To provide an answer in the document, click in a box with the grey text (click here to enter text), or choose the relevant option if presented with a drop-down list.

A separate guidance document is provided and should be consulted prior to completion of this document. Please also read the question specific guidance where present.

We welcome your feedback on the use of the UK Local Information Pack using our online feedback form.

Study Information

1.* IRAS Project ID	287453
2.* Full Title of the Study	Inpatient Safety in Mental Health
3.* Legal Name(s) of Sponsor/Co-Sponsors/Joint-Sponsors	London South Bank University
4. Contact details of person acting on behalf of Sponsor for questions relating to study set up. Please enter details of the person who is the Sponsor's main point of contact for all correspondence on setting up the study at this NHS / HSC organisation. This contact may be the Sponsor, a Study Manager, Clinical Research Scientist or Study Coordinator. Where a Contract Research Organisation (CRO) or Clinical Trials Unit (CTU) has been delegated to handle set up on behalf of the Sponsor, the contact at the CRO or CTU should be named here.	
Name	[redacted]
Telephone Number	[redacted]
Email Address	[redacted]
5.* Are all participating NHS / HSC organisations undertaking the same protocol activities?	
Yes	
If 'No' give details of the activities taking place at NHS / HSC organisations that you will use this outline Organisation Information Document with. Additional outline Organisation Information Documents may be required for NHS / HSC organisations undertaking different activities.	
If no, give details	

Participating NHS / HSC Organisation Information

6. Name of Participating NHS / HSC Organisation. If this Organisation Information Document is being used as an Agreement the name must be entered prior to agreement.
Enter name of participating NHS / HSC Organisation
7. Location/s*:* Please provide detail below where it is planned to undertake the research only at specified locations with the participating NHS / HSC organisation (i.e. hospital(s), GP Practice(s) and/or Research Unit(s))**.** It is not intended that the level of detail provided here captures individual departments within the participating NHS / HSC organisation.

Location (enter text below)	**Activity** (enter text below)
Acute and Psychiatric Intensive Care units (PICU) inpatient wards	Anonymised incident data from these wards will be reviewed in this study.

8*. What is the role of the person responsible for research activities at the participating NHS / HSC organisation?

- Principal Investigators are expected to be in place at participating NHS / HSC organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single centre studies where the Chief Investigator will also be the Principal Investigator.
- Where this is not the case, local collaborators are expected to be in place where central study staff will be present at the participating organisation to undertake research procedures (the role of the Local Collaborator is to facilitate the presence of Sponsor / CRO research staff).
- Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at the participating NHS / HSC organisation, select Chief Investigator.

Principal Investigator

9. Contact details of person responsible for research activities at this participating NHS / HSC organisation as indicated in question 8 (if known). If known, please enter the details of the person you have spoken to about their role in this study at this participating NHS / HSC organisation. If unknown, please leave blank and that person can be identified and listed here during the setup of the study.

Name	Enter name
Post / Job Title	Enter post
Name of Employing Organisation	
Email Address	Enter email address
Telephone number	Enter telephone number

Timescales

10. Predicted Start and End Dates of the Study at this Participating NHS / HSC Organisation The Sponsor or authorised delegate should propose a date on which it intends to start and complete research activity at this participating NHS / HSC organisation. Alternatively, this may be left blank when the Local Information Pack is shared, for agreement during study set up at the Participating NHS / HSC Organisation.	
Predicted Start Date (activities at this organisation)	01/10/2021
Predicted End Date (activities at this organisation)	31/03/2023
For many types of study the following dates are not applicable and this may be stated in answer. Where they are applicable, they should be provided by the Sponsor or authorised delegate before sharing the Local Information Pack, as indicative targets for agreement, or they may be negotiated between Sponsor or authorised delegate and participating NHS / HSC organisation after sharing the pack.	
Predicted Site Initiation Visit Date	Not applicable
Predicted Start Date for participant recruitment	Not applicable
Predicted End Date for participants recruitment (i.e. when the study moves into "follow up" activities.)	Not applicable
Predicted End Date for all study activities (i.e. "last patient visit" completed and study is ready to be archived.)	Not applicable

Participant Numbers

11. How many research participants are expected at this participating NHS / HSC organisation? For studies not directly involving human participants, please indicate the number of samples or data-sets to be obtained. Please state if number of participants is per month, per year, overall, etc.
This is a dataset analysis study. The exact sample size will vary based on the occurrence and documentation of incidents at each Trust.

12 months of retrospective data will be requested from sites. This will include anonymised data on all the incidents that occur in the acute and PICU wards. This will be obtained from incidents logged by the Trusts. Prospective data collection will include monthly data collection on all incidents **from all acute and PICU wards.**

Study set up and delivery arrangements at Participating NHS / HSC Organisations

12*. The following are needed at the participating NHS / HSC organisation to deliver the study: e.g. specific equipment, patient/participant groups, service support, nursing time, etc**.** Please detail any specific requirements for participating NHS / HSC organisations to deliver this study, including by clarifying any requirements on participating NHS / HSC organisations relating to monitoring / self-monitoring, e.g. requirements for staff signature and delegation logs to be returned to the Sponsor and/or any particular access requirements that the Sponsor may have that it wishes to bring to the attention of the participating NHS / HSC organisation, likelihood of staff not employed at the participating NHS / HSC organisation coming on site, etc.
There are no additional setup requirements for the participating sites. The participating sites already uses Oxevision as part of their routine patient management. They also follow local and national guidelines on reporting incidents. A staff member/research nurse delegated by the PI or the PI themselves will assist with anonymisation of the incidents before they are transferred to the research team for data review and analysis. This will occur on a monthly basis.
13*. The following training will be provided by the Sponsor or authorised delegate for local research team members. Where only specific team members (e.g. the Principal Investigator) will receive this training, this should be specified.
No specific training is required for this study.

14*. The Sponsor expects that local research team members will have the following skills and where they do not have those skills that they will undertake the relevant training before undertaking the relevant study activities. It would not be usual for the Sponsor to expect study specific training additional to that which it will provide. This section does however allow Sponsors to state, for example, that when they expect **training in Good Clinical Practice** for appropriate team members where the study is a Clinical Trial of an Investigational Medicinal Product, they will accept UK nationally recognised GCP training, training recognised on the **Transcelerate mutual recognition scheme**, etc.
No specific training is expected. GCP and GDPR training is recommended to all members involved in the data anonymisation process.
15*. The following funding/resources/equipment, etc. is to be provided to this participating NHS / HSC organisation. The Sponsor should answer this question whether this Organisation Information Document is to be used as the Agreement with the participating NHS / HSC organisation or not. Where the document is intended as the Agreement, further detail should be provided in Appendix 2.
The participating site will not receive additional funding for this study.

16^ The Participating NHS / HSC Organisation confirms (by use of the drop-down box) that the Principal Investigator, where one is required, is aware of and has agreed to discharge their responsibilities in line with the UK Policy Framework for Research and Social Care..	Confirmed
17^ The Participating NHS / HSC Organisation has considered and mitigated any conflict/s of interest declared by the principal investigator.	Yes
If yes, please detail conflict of interest	

Sponsor Authorisation

18* Authorised on behalf of Sponsor by:	
Name	[redacted]
Job Title	Professor of Kidney Care
Organisation Name	London South Bank University
Date	16 August 2021

Appendices

(Contents)

The sponsor or authorised delegate should answer the question at the top of Appendix 1 and, if it intends that this Organisation Information Document will be incorporated into an exchange of correspondence to form the Agreement ("Agreement") between itself and the participating NHS / HSC organisation, the questions that appear at the top of each subsequent appendix.

Appendix 1: General Provisions

***Does the Sponsor intend that this Organisation Information Document forms the Agreement between itself and the participating NHS / HSC Organisation, or has a separate site agreement been provided?**	Organisation Information Document

It is recommended that the Organisation Information Document is used as the Agreement between Sponsor and participating NHS / HSC organisation for studies that are not clinical trials or investigations. The model Non-Commercial Agreement (mNCA) should be used for clinical trials or investigations.

Where the Organisation Information Document is to be used as the Agreement between the Sponsor and participating NHS organisation (hereafter singly "Party" or collectively the "Parties"), this document forms a formal legal contract between the Parties. In all cases where this document is the Agreement between the Parties, this Appendix 1 applies in full.

Additionally, the Sponsor or authorised delegate should use the questions at the top of each subsequent appendix to indicate whether or not that appendix also forms part of the Agreement.

Text highlighted in yellow is optional, including where alternative versions of the same clause may be used. The applicable option/s should be selected and text not to be used should be deleted prior to IRAS submission. No changes should be made to any text that does not appear in yellow highlight.

1. OBLIGATIONS OF THE PARTIES

1.1. The Parties agree to comply with all relevant laws, regulations and codes of practice applicable to this Agreement including to the performance of the study. The Parties agree to comply with the World Medical Association Declaration of Helsinki, titled "Ethical Principles for Medical Research Involving Human Subjects" (where applicable) and the UK Policy Framework for Health and Social Care Research. The Parties shall conduct the study in accordance with:

1.1.1. the Protocol, including appropriately made amendments thereto (which is/are hereby incorporated into this Agreement by reference);

1.1.2. the terms of all relevant permissions and approvals. These may include, but are not limited to the terms and conditions of the favourable opinion given by the relevant NHS Research Ethics Committee, where applicable.

1.2. The Parties shall carry out their respective responsibilities in accordance with this Agreement.

1.3. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participants and study personnel.

1.4. The Sponsor shall, on the giving of reasonable prior written notice to the Participating NHS / HSC Organisation, have the right to audit the Participating NHS / HSC Organisation's compliance with this Agreement. The Sponsor may appoint an auditor to carry out such an audit. Such right to audit shall include access, during normal working hours to the Participating NHS / HSC Organisation's premises and to all relevant documents and other information relating to the study.

1.5. The Participating NHS / HSC Organisation shall;

1.5.1. promptly notify the Sponsor should any responsible body conduct or give notice of intent to conduct any inspection at the Participating NHS / HSC Organisation in relation to the study;

1.5.2. allow the Sponsor to support the preparations for such inspection; and

1.5.3. following the inspection, provide the Sponsor with the results of the inspection relevant to the study. The Sponsor will be responsible for sharing such results with the funder if required.

1.6. In accordance with participant consent, the Participating NHS / HSC Organisation shall permit the Sponsor's appointed representatives and any appropriately appointed monitor access to all relevant data for monitoring and source data verification. The Parties agree that such access will be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the study, reasonable access to relevant members of staff at the Participating NHS / HSC Organisation and the right to examine any procedures or records relating to the study, subject at all times to clause 6 of this appendix. The Sponsor will alert the Participating NHS / HSC Organisation promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the study.

2. LIABILITIES AND INDEMNITY

2.1. Nothing in this clause 2 shall operate so as to restrict or exclude the liability of a Party in relation to statutory or regulatory liability (including but not limited to breach of the data protection legislation), death or personal injury caused by the negligence or wilful misconduct of that Party or its agent(s), fraud or fraudulent

misrepresentation or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.

2.2. Where a Party is a non-NHS/HSC organisation, or an NHS/HSC organisation that is not a member of an NHS indemnity scheme, then that Party shall maintain all proper insurance or equivalent indemnity arrangements to cover liabilities arising from its participation in the study, in respect of any claims brought by or on behalf of a participant. Where the Party is an NHS/HSC organisation and is a member of an NHS indemnity scheme, it shall maintain its membership therein or otherwise ensure it has appropriate cover against claims arising as a result of clinical negligence by the Party and/or its agents brought by or on behalf of the participants. Each Party shall provide to the other such evidence of their insurance or equivalent indemnity cover maintained pursuant to clause 2.2 as the other Party shall from time to time reasonably request, such evidence might comprise confirmation that an NHS/HSC organisation is a member of one of the NHS indemnity schemes.

2.3. **[SINGLE SPONSOR]** Subject to clauses 2.4, 2.5, 2.6, 2.7 and 2.8, the Sponsor shall indemnify the Participating NHS / HSC Organisation and its agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands ("Claims") to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Sponsor, and/or contracted third party, in its performance of this Agreement or in connection with the study.

2.4. Subject to clauses 2.3, 2.5, 2.6 and 2.8, the Participating NHS / HSC Organisation shall indemnify the Sponsor and its agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Participating NHS / HSC Organisation, or its agents, in its performance of this Agreement or in connection with the study.

2.5. An indemnity under clauses 2.3 or 2.4 shall only apply if the indemnified Party:

2.5.1. informs the Party providing the indemnity in writing as soon as reasonably practicable following receipt of notice of the claim or proceedings;

2.5.2. upon the indemnifying Party's request and at the indemnifying Party's cost gives the indemnifying Party full control of the claim or proceedings and provides all reasonable assistance; and

2.5.3. makes no admission in respect of such claim or proceedings other than with the prior written consent of the indemnifying Party.

2.6. Any indemnity under clauses 2.3 or 2.4 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from the negligent acts or omissions or wilful misconduct or breach of statutory duty of the indemnified Party.

2.7. The indemnity under clause 2.3 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from:

2.7.1. Participating NHS / HSC Organisation carrying out a treatment or procedure that would be routinely undertaken at or for that Participating NHS / HSC Organisation as part of National Health Service treatment; or

2.7.2. Participating NHS / HSC Organisation preparing, manufacturing or assembling any equipment which is not done in accordance

2.7.2.1. with the protocol; or

2.7.2.2. with written instructions of the manufacturer; or

2.7.2.3. (where such instructions differ from the instructions of the manufacturer) other written instructions of the Sponsor.

2.8. No Party shall be liable to another in contract, tort/delict, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts, or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement.

2.9. If a Party incurs any loss or damage (including costs and expenses) ("Loss") arising or resulting from this Agreement and:

2.9.1. All Parties are NHS bodies as defined in Section 9(4) of the National Health Service Act 2006 or Section 17 of the National Health Service (Scotland) Act 1978 or Section 7 (4) of the NHS (Wales) Act 2006 or Articles 16 and 26 of the Health and Personal Social Services (Northern Ireland) Order 1972, which established the Boards and Central Services Agency respectively and Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991: which established Trusts in Northern Ireland as appropriate; or

2.9.2. One or more Party is a NHS body and the other Party (ies) is a NHS Foundation Trust; or

2.9.3. All Parties are NHS Foundation Trusts;

Then clauses 2.10, 2.11 and 2.12 shall apply.

2.10. If all Parties are NHS bodies / NHS Foundation Trusts in England, Wales or Northern Ireland and are indemnified by the same indemnity scheme (being one of the NHS Resolution's clinical negligence schemes or the Welsh Risk Pool or the Clinical Negligence Fund in Northern Ireland) and the Party incurring any loss can recover such loss under one of the indemnity schemes, then such Party shall rely on the cover provided by the indemnity scheme and not seek to recover the Loss from the other Party (ies). Where the other Party (ies) caused or contributed to the Loss, it undertakes to notify the relevant indemnity scheme(s) to take this into account in determining the future levies of all Parties in respect of the indemnity schemes.

2.11. If:

2.11.1. The Parties are members of the same indemnity scheme in England, Wales or Northern Ireland and the Party incurring the Loss is not indemnified for that Loss by its indemnity schemes; or

2.11.2. All Parties are NHS bodies in Scotland; or

2.11.3. The Parties are NHS bodies/Foundation Trusts established in different jurisdictions within the United Kingdom;

Then the Parties shall apportion such Loss between themselves according to their respective responsibility for such Loss.

2.12. If one or more Parties are NHS Foundation Trusts and the Party incurring the Loss is not responsible for all or part of the Loss and is not indemnified in respect of the Loss by one of the indemnity schemes then the Party incurring the Loss shall be entitled to recover the Loss from the other Party (ies) pursuant to the provisions of this Agreement.

2.13. **[SINGLE SPONSOR]** Subject to clause 2.1 and 2.7 the liability of the Participating NHS / HSC Organisation to the Sponsor and the liability of the Sponsor to the Participating NHS / HSC Organisation arising out of or in connection with any breach of this Agreement or any act or omission of either Party in connection with the performance of the study should be the greater of the amount of fees payable by the Sponsor to the Participating NHS / HSC Organisation under this Agreement or one hundred thousand (£100,000 GBP) pounds. For the avoidance of doubt, this cap applies also but not exclusively to the indemnities offered under clauses 2.3 and 2.4.

2.14. Notwithstanding clause 2.13, in the case of equipment loaned by or on behalf of the Sponsor to the Participating NHS / HSC Organisation for the purposes of the study, the Participating NHS / HSC Organisation's liability for damage to or loss of that equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the replacement value of the equipment.

2.15. **[OPTION FOR NON-NHS SPONSORS ONLY]** The Sponsor agrees that in respect of any personal injury or death of any participant as a result of participation in the study, it will provide no-fault compensation and will be insured to pay out on any such claims.

3. PUBLICITY

3.1. [None of the Parties] shall use the name, logo or registered image of the other [Party] / [Parties] or the employees of such other Party in any publicity, advertising or press release without the prior written approval of an authorised representative of that Party.

3.2. The content and timing of any publicity, advertising or press release shall be agreed by [all] Parties, such agreement not to be unreasonably withheld.

4. PUBLICATION

4.1. In accordance with all relevant laws, regulations and codes of practice, it is agreed that the Sponsor has an obligation to and shall publish the results of the full study

and that the Participating NHS / HSC Organisation shall not publish any study data, including through presentation or submission of an abstract, without the prior permission in writing from the Sponsor (which shall not be unreasonably withheld or delayed).

5. FREEDOM OF INFORMATION

5.1. Parties to this Agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another Party shall notify and consult that Party, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.

5.2. The Parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the Party responding to the request.

5.3. Where the Party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other Party in writing, giving at least four (4) working days' notice of its intended disclosure.

6. CONFIDENTIALITY

6.1. Subject to clause 5 above, the Participating NHS / HSC Organisation agrees to treat the results, excluding any clinical data of the study, as confidential information of the Sponsor and the Sponsor agrees to treat personal data and confidential patient information as confidential information.

6.2. The receiving Party agrees:

6.2.1. To take all reasonable steps to protect the confidentiality of the confidential information and to prevent it from being disclosed otherwise than in accordance with this Agreement

6.2.2. To ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the Study are made aware of, and abide by, the requirement of this clause 6.2.

6.2.3. To use confidential information solely in connection with the operation of the Agreement and not otherwise, except in the case where the confidential information is personal data and/or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the data protection legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.

6.2.4. Not to disclose confidential information in whole or in part to any person without the disclosing Party's prior written consent or, where the confidential

information is personal data and/or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the data protection legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.

6.3. The provision of clause 6.2 shall not apply to the whole or any part of the confidential information that is:

6.3.1. lawfully obtained by the receiving Party free of any duty of confidentiality;

6.3.2. already in the possession of the receiving Party and which the receiving Party can show from written records was already in its possession (other than as a result of a breach of clause 6.2.1 or 6.2.2);

6.3.3. in the public domain (other than as a result of a breach of clause 6.2.1 or 6.2.2);

6.3.4. independently discovered by employees of the receiving Party without access to or use of confidential information;

6.3.5. necessarily disclosed by the receiving Party pursuant to a statutory obligation;

6.3.6. disclosed with prior written consent of the disclosing Party;

6.3.7. necessarily disclosed by the receiving Party by virtue of its status as a public authority in terms of the FOIA or the FOI(S)A;

6.3.8. published in accordance with the provisions of clause 4.

6.4. The restrictions contained in clause 6.2 shall remain in force without limit in time in respect of personal data and any other information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

Appendix 2: Finance Provisions

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
*Are there funds / resources / equipment, etc. being provided to this participating NHS / HSC organisation by the Sponsor? If no, this appendix should be left blank. If yes, this finance appendix forms part of the Agreement between the participating NHS / HSC organisation and the Sponsor.	No

A. Financial Arrangements

The overall, study-wide recruitment for this study is competitive with a maximum figure of [X] Participants. Once this target has been reached, the Sponsor will notify the Participating NHS / HSC Organisation. No additional per participant payments will be made by the Sponsor to the Participating NHS / HSC Organisation for participants consented after such notification becomes effective.

	*Area of Cost	*Payment (£ Sterling)
1*	Click here to enter text	Click here to enter text
2*	Click here to enter text	Click here to enter text
3*	Click here to enter text	Click here to enter text
4*	Click here to enter text	Click here to enter text
5*	Click here to enter text	Click here to enter text

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment of the agreed costs on presentation of a VAT invoice in which the VAT is stated as a separate item. Such invoices should quote the Participating NHS / HSC Organisation's VAT registration number. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

Schedule of payments and details of payment arrangements

*Invoices to be submitted [Insert FREQUENCY OR INTERVAL e.g. quarterly] to:

[Insert JOB TITLE, NAME OF BODY & ADDRESS]

^Payment to be made by cheque payable to:

[Insert NAME OF PARTICIPATING NHS / HSC ORGANISATION]

^and remitted to:

[Insert JOB TITLE/POSITION]

[Insert ADDRESS]

^Or arrange BACS Transfer to: [Insert BANK NAME].

^Sort code: [Insert SORT CODE]

^Account: [Insert ACCOUNT NUMBER]

^And send the relevant paper work to [Insert ADDRESSEE FOR PAPERWORK] at the above address

Invoices must be paid promptly [within xx days of receipt]. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding has been irrecoverably reclaimed by the funder as a result of such delay or inadequacy.

B. Supplies Arrangements

Any equipment, materials, consumables, software or other items being provided by the Sponsor or procured by the participating organisation for use in the study shall be specified below.

Note 1: Parties should complete the table below. If the Participating NHS / HSC Organisation is to procure any items and is to be reimbursed by the Sponsor this should be specified in this appendix. Similarly if the Participating NHS / HSC Organisation is to pay the Sponsor for any items provided to the Participating NHS / HSC Organisation by or on behalf of the Sponsor this should be specified in this appendix.

Note 2: Parties should specify in this appendix, as appropriate, arrangements for:

- Ownership of items
- Insurance

- Storage instructions
- Instructions for use, return and/or destruction
- Any training to be provided
- Maintenance of equipment

Item	Quantity	Frequency of supply	Responsibility to supply/procure (either Sponsor or Participating NHS / HSC Organisation only)
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text

Appendix 3: Material Transfer Provisions

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
* Does this study involve the transfer of human biological material from this participating NHS / HSC organisation to the Sponsor or its agents? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	No

Material, as used in this appendix, means any clinical biological sample or portion thereof, derived from participants, including any information related to such Material, supplied by the Participating NHS / HSC Organisation to the Sponsor/Joint Sponsors/either of the Co-Sponsors or [its] / [their] nominee.

1. In accordance with the protocol, the Participating NHS / HSC Organisation shall send Material to the Sponsor/joint Sponsors/a co-Sponsor or, in accordance with provision 7 below, to a third party nominated by the Sponsor/joint Sponsor s/either of the co-Sponsors.
2. The Participating NHS / HSC Organisation warrants that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)) and as required by the protocol.
3. Subject to provision 2 above, the Materials are supplied without any warranty, expressed or implied, including as to their properties, merchantable quality, fitness for any particular purpose, or that the Materials are free of extraneous or biologically active contaminants which may be present in the Materials.
4. The Sponsor/joint Sponsors/one of the co-Sponsors shall ensure, or procure through an agreement with the Sponsor's/joint Sponsors'/co-Sponsor's nominee as stated in provision 1 above that:
   - 4.1. the Material is used in accordance with the protocol, the consent of the participant, and the ethics approval for the study;
   - 4.2. the Material is handled and stored in accordance with applicable law;
   - 4.3. the Material shall not be redistributed or released to any person other than in accordance with the protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the participant's consent.
5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.

6. The Participating NHS / HSC Organisation and the Sponsor/joint Sponsors/a co-Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this appendix.
7. To the extent permitted by law the Participating NHS / HSC Organisation and its staff shall not be liable for any consequences of the supply to or the use by the Sponsor/joint Sponsors/co-Sponsor of the Material or of the supply to or the use by any third party to whom the Sponsor/joint Sponsors/co-Sponsor subsequently provides the Material or the Sponsor's/joint Sponsors'/co-Sponsor's nominee as stated in provision 1 above, save to the extent that any liability which arises is a result of the negligence of the Participating NHS / HSC Organisation.
8. The Sponsor/joint Sponsors/co-Sponsor undertake(s) that, in the event that Material is provided to a third party in accordance with provision 2 above, [it] / [they] shall require that such third party shall undertake to handle any Material related to the study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in this appendix.
9. Any surplus Material that is not returned to the Participating NHS / HSC Organisation or retained for future research (in line with participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)).

**These provisions do not remove the need for the Sponsor to clearly lay out in their protocol (and to potential participants in the participant information) at a minimum the following information for all Material taken: 1) The nature of the Materials, 2) The reason that the Material is being taken, 3) where the Material is to be sent and, 4) what will happen to any remaining Material once it has been processed/analysed, etc. for the purposes of this study (e.g. return, retention or destruction). Detailed guidance on what information should be included in a protocol may be found on the HRA website: www.hra.nhs.uk*

Appendix 4: Data Processing Agreement

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
* Does this study involve any processing of personal data by this participating NHS / HSC organisation on behalf of the Sponsor. If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation. For the avoidance of doubt, when used, these provisions are intended to form a legally binding contractual obligation for the purposes of compliance with the GDPR, specifically GDPR Article 28 (3).	Yes

1. For the purposes of the data protection legislation, the Sponsor is the controller and the Participating NHS / HSC Organisation is the Sponsor's processor in relation to all processing of personal data that is processed for the purpose of this study and for any future research use under the controllership of the Sponsor, that would not have taken place but for this Agreement regardless where that processing takes place.
2. The Parties acknowledge that whereas the Sponsor is the controller in accordance with Clause 1 of this appendix, the Participating NHS / HSC Organisation is the controller of the personal data collected for the purpose of providing clinical care to the participants. This personal data may be the same personal data, collected transparently and processed for research and for care purposes under the separate controllerships of the Sponsor and Participating NHS / HSC Organisation.
3. Where the Participating NHS / HSC Organisation is the Sponsor's processor and thus where the processing is undertaken by the Participating NHS / HSC Organisation for the purposes of the study, Clauses 5.a. to 5.j below will apply. For the avoidance of doubt, such Clauses do not apply where the Participating NHS / HSC Organisation is processing the participant personal data as a controller.
4. The Participating NHS / HSC Organisation agrees only to process personal data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the study and to ensure the Sponsor’s compliance with the data protection legislation;
5. The Participating NHS / HSC Organisation agrees to comply with the obligations applicable to processors described by Article 28 GDPR including, but not limited to, the following:
    a. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the controller by Article 28(1);

b. to not engage another processor without the prior written authorisation of the Sponsor (Article 28(2)) [DELETE IF THE STUDY DOES NOT INVOLVE PICS, such authorisation for engaging Participant Identification Centres (PICs) being hereby given. The Participating NHS / HSC Organisation will notify the Sponsor of any new PIC engaged in advance of that PIC's commencement of PIC activities and the Sponsor will notify the Participating NHS / HSC Organisation of any objections in a timely manner];

c. to process the personal data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Participating NHS / HSC Organisation shall notify the Sponsor before processing, or as soon as possible after processing if legislation requires that the processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a)).;

d. to ensure that personnel authorised to process personal data are under confidentiality obligations (Article 28(3b));

e. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c));

f. to respect the conditions described in Article 28(2) and (4) for engaging another processor (Article 28(3d));

g. to, taking into account the nature of the processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising data subjects' rights (Article 28(3e));

h. to assist the controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the processing and the information available to the Participating NHS / HSC Organisation (Article 28(3f));

i. to, at the choice of the Sponsor, destroy or return all personal data to the Sponsor at the expiry or early termination of the Agreement, unless storage is legally required (Article 28(3g)) or where that personal data is held by the Participating NHS / HSC Organisation as controller for the purpose of clinical care or other legal purposes; and

j. to maintain a record of processing activities as required by Article 30(2) GDPR.

6. The Participating NHS / HSC Organisation shall ensure that:

a. its agents do not process personal data except in accordance with this Agreement (and in particular the protocol);

b. it takes all reasonable steps to ensure the reliability and integrity of any of its agents who have access to the personal data and ensure they:

i. are aware and comply with the Participating NHS / HSC Organisation 's duties under this clause;

ii. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and

iii. are informed of the confidential nature of the personal data and understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.

7. The Participating NHS / HSC Organisation agrees to:

   a. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Participating NHS / HSC Organisation's compliance with the obligations described by this Appendix, data protection legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the participating site and/or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and

   b. obtain prior agreement of the Sponsor to store or process personal data outside the European Economic Area.

8. Where the Participating NHS / HSC Organisation stores or otherwise processes personal data outside of the European Economic Area as the Sponsor's processor, it warrants that it does so in compliance with the Data Protection Legislation.

Appendix 5: Data Sharing Agreement

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS/HSC organisation, please select an option below.	
* Does this study involve the transfer of personal data from this participating NHS / HSC organisation to the Sponsor or its agents, or transfer of confidential information between the Parties? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	No

1. Personal data shall not be disclosed to the Sponsor by the participating NHS / HSC organisation, save where this is required directly or indirectly to satisfy the requirements of the protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a participant in connection with the study.
2. The Sponsor agrees to use personal data solely in connection with the operation of the Agreement, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular,
   2.1. Not to disclose personal data to any person except in accordance with applicable legal requirements and codes of practice.
3. The Sponsor agrees to comply with the obligations placed on a controller by the data protection legislation. 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 GDPR)
4. The Sponsor agrees to ensure persons processing personal data under this Agreement are equipped to do so respectfully and safely. In particular:
   4.1. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the participating NHS / HSC organisation) processing personal data understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.
   4.2. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating NHS / HSC Organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
5. The Sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular,
   5.1. To ensure that personal data are only accessible to persons who need it for the purposes of the study and to remove access as soon as reasonably possible once it is no longer needed.
   5.2. To ensure all access to personal data on IT systems processed for study purposes can be attributed to individuals.

5.3. To identify, review and improve processes which have caused breaches or near misses, or which force persons processing personal data to use workarounds which compromise data security.
5.4. To adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice.
5.5. To take action immediately following a data breach or near miss.

6. The Sponsor agrees to ensure personal data are processed using secure and up to date technology. In particular,
6.1. To ensure no unsupported operating systems, software or internet browsers are used to support the processing of personal data for the purposes of the study.
6.2. To put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as Cyber Essentials.
6.3. To ensure IT suppliers are held accountable via contracts for protecting personal data they Process and for meetings all relevant information governance requirements.

Appendix 6: Intellectual Property Rights

Where this Organisation Information Document is to be used as the Agreement between Participating NHS / HSC organisation, please select an option below.	
*Does this study require the protection of background intellectual property rights, or is there potential for the generation of new intellectual property? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	Yes

1. All background intellectual property rights (including licences) and know how and their improvements used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not knowingly infringe any third party's rights.
2. All intellectual property rights and know how in the Protocol, and in the study data, excluding clinical procedures developed or used by the Participating NHS / HSC Organisation independently of the Study, shall belong to the Sponsor. The Participating NHS / HSC Organisation hereby assigns all such intellectual property rights, and undertakes to disclose all such know how, to the Sponsor.
3. Subject to clauses 1 and 2, all intellectual property rights deriving or arising from the Material or any derivations of the Material provided to the Sponsor by the Participating NHS / HSC Organisation shall belong to the Sponsor.
4. At any time within the duration of the Study, the Participating NHS / HSC Organisation shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest the intellectual property rights in the Sponsor. To give effect to this clause 4, the Participating NHS / HSC Organisation shall ensure that its agents involved in the Study assign such intellectual property rights falling within clauses 2 and 3 and disclose such know how to the Participating NHS / HSC Organisation.
5. Subject to this Clause 5 and Clause 6, nothing in this Appendix shall be construed so as to prevent or hinder the Participating NHS / HSC Organisation from using its own know how or clinical data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor, or their funder. This clause 5 does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results. Any study data not so published remains the confidential information of the Sponsor, or their funder.
6. The Participating NHS / HSC Organisation may, with the prior written permission of the Sponsor (such permission not to be unreasonably withheld), use study data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor or their funder. This clause

6 does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the Study.

Authorisation When Using This Organisation Information Document as An Agreement

(when used as an Agreement, the Participating NHS Organisation is a "Party" to the Agreement and the Sponsor is a "Party" to the Agreement – collectively the "Parties").

Authorisation on behalf of Participating NHS / HSC Organisation It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the Sponsor and participating NHS / HSC organisation. Instead, Sponsors are expected to accept confirmation by email from an individual empowered by the Participating NHS / HSC Organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).	
^ Authorised on behalf of Participating NHS / HSC Organisation by:	
Name	Enter name
Job Title	Enter job title
Organisation Name	Enter organisation name
Date	Select date of authorisation

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