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)
Emergency Front of Neck Airway Registry

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Ionising Radiation for combined review of clinical trial of an investigational medicinal product

( ) Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device

( ) Clinical investigation or other study of a 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

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

[x] England
[x] Scotland
[x] Wales
[x] 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?

- [x] IRAS Form
- [x] Confidentiality Advisory Group (CAG)
- [ ] HM Prison and Probation Service (HMPPS)

4a. Will you be seeking data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?

( ) Yes (●) No

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

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (●) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

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)
Emergency Front of Neck Airway Registry

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

REC Name:
Yorkshire & The Humber - Leeds East Research Ethics Committee

REC Reference Number:
24/YH/0020

Submission date:
08/01/2024

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Emergency Front of Neck Airway Registry

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Prof	Iain	Moppett
Post	Professor of Anaesthesia and Perioperative Medicine /Honorary Consultant		
Qualifications	MB BChir MRCP FRCA DM		
ORCID ID	0000 0003 3750 6067		
Employer	University of Nottingham and Nottingham University Hospitals NHS trust		
Work Address	Anaesthesia and Critical Care Queen's Medical Centre Nottingham		
Post Code	NG7 2UH		
Work E-mail	iain.moppett@nottingham.ac.uk		
* Personal E-mail	iain.moppett@nottingham.ac.uk		
Work Telephone	01158230959		
* Personal Telephone/Mobile	07903337617		

Fax

** 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
	Mr	Ali	Alshukry
Address	Research and Innovation - University of Nottingham		
	E-floor, Yang Fujia Building Jubilee Campus Wollaton Road Nottingham		
Post Code	NG8 1BB		
E-mail	sponsor@nottingham.ac.uk		
Telephone	000		
Fax	000		

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):	000
Sponsor's/protocol number:	23047
Protocol Version:	1.0
Protocol Date:	19/06/2023
Funder's reference number (enter the reference number or state not applicable):	000
Project website:	N/A

Additional reference number(s):

Ref.Number Description	Reference Number
N/A	000

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.*

During an operation or a period in intensive care, patients may need help with their breathing to provide adequate oxygenation. Once a patient is anaesthetised, one key role of the anaesthetist is to 'manage their airway'. For most, this process is routine and straightforward. Very occasionally, successful airway management is much more challenging, and there is a risk of potential severe patient harm, including brain damage, cardiac arrest, and death. When anaesthetic teams encounter these 'difficult airways', they use guidelines to act decisively to deliver oxygen effectively in a timely manner. If these steps fail, the final option is to deliver oxygen directly into a patient's windpipe (trachea) through the front of the neck. This procedure is called an emergency front-of-neck airway ('eFONA') and can be lifesaving.

Emergency front-of-neck airways are very rarely required, however, collecting information about and learning from these events is difficult given their rarity.

In this project, the Royal College of Anaesthetists (who oversee UK airway training) and the Difficult Airway Society (a specialist society specifically interested in airway management) will collaborate with the University of Nottingham to create a UK Registry of eFONA events. We will collect anonymised data about eFONA events. A diverse panel (comprising clinicians working in intensive care, emergency medicine and anaesthetics) will review the cases to identify themes reviewing good and inadequate practice and make recommendations that will allow doctors working in anaesthesia, intensive care, and emergency medicine to improve patient care and save more lives in the future.

Data collected will be kept for seven years after the study to cover the eventuality before being destroyed as per the University of Nottingham Data Policy.

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.

1) Registry of rare events with a non-consent approach. Applying to Confidentiality Advisory Group (CAG) / NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP). Requirement to seek consent would seriously jeopardise the scientific validity of the study by introducing bias in types of cases submitted.

2) Potentially identifiable data. Although no directly identifiable data will be collected, the rarity of the event (c.100 / year in the UK) makes it possible that individuals may believe they are identifiable from information in the registry. Data presentations will be completely non-identifiable, and where quantitative data are presented small numbers will be suppressed when appropriate.

3. PURPOSE AND DESIGN OF THE RESEARCH

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

- [x] 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)

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

PURPOSE
i) To improve care and outcomes for patients who require an emergency front of neck airway to aid oxygenation.
ii) To reduce the risk of patients needing an emergency front of neck airway in the first instance by improving care and outcomes

PRIMARY OBJECTIVE
To provide a systems-based analysis of events, decision making and patient outcomes in the process of an emergency front of neck airway

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

Examine the qualitative relationships between eFONA and:
• Patient characteristics,
• The planned operation or procedure,
• Pre-anaesthetic assessment and investigation of the airway,
• Human factors,
• Equipment selection and techniques used,
• Guideline compliance and effectiveness.
• Patient outcomes.

Provide quantitative descriptions of the populations, techniques, processes and outcomes reported

Provide evidence-based recommendations for practice at national, hospital and individual level

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

During an operation or a period in intensive care, patients may need help with their breathing to provide adequate oxygenation. Once a patient is anaesthetised, one key role of the anaesthetist is to ‘manage their airway’. For most, this process is routine and straightforward. Very occasionally, successful airway management is much more challenging, and there is a risk of potential severe patient harm, including brain damage, cardiac arrest, and death. When anaesthetic teams encounter these ‘difficult airways’, they use guidelines to act decisively to deliver oxygen effectively in a timely manner. If these steps fail, the final option is to deliver oxygen directly into a patient’s windpipe (trachea) through the front of the neck. This procedure is called an emergency front-of-neck airway (‘eFONA’) and can be lifesaving.

Emergency front-of-neck airways are very rarely required, however, collecting information about and learning from these events is difficult given their rarity.

The 4th National Audit Project (NAP4) of the Royal College of Anaesthetists and the Difficult Airway Society was a pan-UK service evaluation of adverse events in airway management.
It included 58 cases of eFONA out of approximately 3 million surgical episodes. However the authors concluded “Further research focused at identifying the success rates and optimal techniques of cannula cricothyroidotomy is required.” A randomized controlled trial in this area will never be possible due to ethical implications, therefore a national registry may offer an opportunity to safely gather this information.

Why is this registry needed?
An anaesthetic is not a treatment but rather it facilitates surgery to an affected organ or limb; mechanical ventilation of a critically ill patient; or the emergency management of a sick or injured patient in the emergency department. Whilst the need for the creation of an emergency front of neck airway is rare the potential for an adverse outcome (brain

damage or death) is significant should this occur.

The creation of an emergency front-of-neck airway is recognised as the final step in attempting to provide enough oxygen to a patient under general anaesthetic. Fortunately, it is needed rarely, but this means that experience is gathered on individual case reports of success and failure. There are multiple factors that are thought to impact on the need for and success of eFONA. These include patient characteristics (e.g. age, body habitus); the context (e.g. emergency situations); the operator (e.g. seniority, training); the preceding events (e.g. airway assessment and management); techniques used (type of eFONA equipment), team-work and human factors. A registry will allow these cases to be examined fully and systematically to identify significant themes common to some or all cases, areas of good and inadequate practice and make recommendations that will allow doctors working in anaesthesia, intensive care and emergency medicine to save more lives in the future.

Collecting data from a cohort of cases will allow practice in this field to be improved and save lives, resulting in decreasing the risk of harm to patients and allowing more patients access to surgery safely for its primary purpose.

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.*

The registry will collect details of voluntary, anonymously reported, de-identified cases of emergency front of neck airway, a rare, life-threatening event occurring only during the reporting period. Data will be reported by clinicians from hospitals within the UK.

These reports will then be analysed using a formal systems-based approach (SEIPS 2.0) by an expert and diverse panel who will receive specific training on this methodology. A systems-based approach means looking for how things interact - such as the equipment people use, their training, the other people present etc. It goes beyond simply describing the events as they occurred. The data and themes gathered from this analysis will be used to inform a generation of evidence-based recommendations for practice at national, hospital and individual levels.

Data will be voluntarily uploaded by a participating clinician to a secure research database hosted by the University of Nottingham. The project will not directly contact clinicians to submit cases/ participate. The Registry will instead be advertised through the Royal College of Anaesthetists Airway Leads Network, through journal articles of the Royal College of Anaesthetists and the Difficult Airway Society Newsletter and presentations/ reminders at national meetings where clinicians involved in airway management will be present.

A reporter will use their recollections, alongside access to patient records, to complete the case report. The reporter will either be the clinician directly involved, or in conjunction with a local clinical colleague (the department 'airway lead') who will also be part of the clinical care team, and involved in the local review of the case.

Reporters will enter data directly into a secure research database, REDCap. The database portal will be accessed using a password issued to a clinician who may or may not be the reporting clinician by emailing or telephoning the administrative team at the Royal College of Anaesthetists. There is no mechanism to allow the central team to identify whether a request for a password translates to the submission of case details.

The data collected are detailed in uploaded documents. The broad domains of the data are:

Screening: Ensuring cases meet inclusion criteria
Patient: Details about the patient
Settings and Timing: Times of day, where (eg. Operating theatres, emergency department)
Preparation: Planning, assessment and preparation
Personnel: Who was present
Checklist: Checklists and guidelines used
Plan: Primary and backup plans for airway management
Preoxygenation: Process of delivering oxygen / removing nitrogen from the lungs
Process: What happened, in what order etc.
Airway Problems: How were the initial airway problems managed?
eFONA: How was the eFONA managed?
Outcome: What were the outcomes?

Periodically (depending on the frequency of reporting, but 3 monthly is indicative) during the three-year case reporting period, the expert review panel will meet and review the data. The panels will use the SEIPS 2.0 framework to integrate these aspects, using the concepts of the work system, processes and outcomes. This is a formal, structured process used widely within healthcare and by investigatory bodies such as the Health and Social Care Safety Investigation Branch (HSSIB).

The panel consists of a group of clinicians and lay members with varied experience and expertise in planned and emergency airway management. This will include difficult airway experts and anaesthetists of varying grades (experienced and less experienced individuals) to ensure diversity and to encourage a variety of perspectives and backgrounds, with the aim of reducing the risk of groupthink.

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?

- [x] Design of the research
- [ ] Management of the research
- [x] Undertaking the research
- [x] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Patient and Public Involvement/Engagement (PPI/E) has been and will continue to be embedded within the project. The Difficult Airway Society Lay representative has been involved in several years of discussions around the proposal for the eFONA Registry.

This project proposal was discussed at Patient, Carer & Public Involvement and Engagement (PCPIE) - Centre for Research and Innovation PCPIE group. Feedback from the group highlighted the strengths and need of this project as the formation of an emergency front-of-neck airway (eFONA) is a major complication of anaesthesia with significant implications for both the patient and the healthcare team. Because of the rarity of eFONA, learning at the individual or local level is likely to be very limited. A registry would address the difficulties of gaining meaningful information through other research methods. Most of the group members felt that the severity of eFONA and the recognised need for learning justifies the proposal to collect data without explicit consent from the patient (or consultation with a close friend or family member). Overall the group are happy to provide ongoing support to this project.

A lay representative will be specifically recruited to the expert review panel. In addition, they will be integral to the publication of the results and to make the results accessible and interpretable to the general public. The Centre for Research & Innovation (CR&I) of the Royal College of Anaesthetists (RCoA) also includes formal lay representation on its Board, where all projects (including eFONA) are reviewed on a regular basis.

Topic selection
The broad study question was identified as necessary following the publication of the NAP4 report by both the Royal College of Anaesthetists and the Difficult Airway Society where there is significant lay input.

A lay representative will be an integral part of the expert analysis group ensuring that the themes identified are relevant to patients directly.

Undertaking the research
We do not anticipate asking lay representatives to be involved in numerical data analysis, but once the data is collated their opinions will be actively sought. Lay representatives will not have access to any patient-identifiable information, nor will they directly access the REDCap database.

Dissemination of the research
Lay members of the expert panel will be involved in the dissemination and presentation of results as they wish. In addition, they will be involved in ensuring that the results are expressed in a digestible format for the general public.

A14-2. Have you tested the acceptability of using patient identifiable data in this study without consent?

Please give details.
Yes. A nearly identical process was used in the NAP4 service evaluation which had PPI representatives on the panel and provided some of the data on eFONA that supports this protocol. Since then three more National Audit Projects (service evaluations, but using essentially the same methods as this research project) have taken place with no concerns expressed to the Royal College of Anaesthetists before, during or after the projects or their publication.

The data as reported will not be directly identifiable and are anonymous. No clinician-identifiable factors or site location data will be collected. Therefore it will not be possible to reverse identify using site or clinician factors.

However, due to the rarity of these events, it may not be possible to fully anonymise the data but rather it is possible to de-identify it and we have processes in place to ensure this.

When this point was discussed at the PCPIE group, the group members recognised that there is a risk of de-anonymisation of reported cases because of the rarity and severity of the event – meaning that people reading an anonymised report might recognise other details of the case and be able to work out who the patient is. Most members of the group felt that this risk was small and justifiable.

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
- [x] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] 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: 0	Years
Upper age limit:	No upper age limit

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

All cases where an eFONA procedure has been attempted or performed, whether successfully of unsuccessfully, will be eligible for inclusion.

All patients can be included regardless of age (although we expect the number of cases involving children to be exceedingly small).

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

Non-emergency front of neck airway (this is sometimes performed as a planned procedure).

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).*

The project will be based on voluntary reporting of events/cases by clinicians from secondary care hospitals. The project will not directly contact clinicians to submit cases/ participate. The Registry will instead be advertised through the Royal College of Anaesthetists Airway Leads Network, through journal articles of the Royal College of Anaesthetists and the Difficult Airway Society Newsletter and presentations/ reminders at national meetings where clinicians involved in airway management will be present.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:
Reporters will be reporting cases which they have been directly involved with, so no screening will be required.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

The project will not directly contact clinicians to submit cases/ participate. The Registry will instead be advertised through the Royal College of Anaesthetists Airway Leads Network, through journal articles of the Royal College of Anaesthetists and the Difficult Airway Society Newsletter, through social media and presentations/ reminders at national meetings where clinicians involved in airway management will be present.

A30-1. Will you obtain informed consent from or on behalf of research participants?

○ Yes ◉ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

If you are not obtaining consent, please explain why not.

Due to the eFONA reporting methodology, no explicit patient consent is sought. The study team and expert review panel will not receive any directly identifiable patient data from reporting clinicians. Although direct identifiers are not being collected, the rarity of events, and the collection of some case characteristics (e.g. sex, ethnicity) means that we are seeking approval from relevant panels (e.g. Confidentiality Advisory Group (CAG) / NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP)).

Seeking consent from individuals involved risks creating bias in the registry, as well as allowing identification of the reporter. Similar issues have been recognised in other rare case registries. The bias risks the scientific integrity of the study as it is unknown whether 'good' or 'bad' outcomes are more or less likely to be reported.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

○ Yes ◉ No

If No, how will it be recorded?

A30-3. Why is it not practicable for either the researcher's organisation, or the current holder of the information required by the researcher, to seek or obtain patient consent for proposed use of patient identifiable information?

Due to eFONA reporting methodology, no explicit patient consent is sought. eFONA follows the methodology of previous National Audit Projects of the Royal College of Anaesthetists (service evaluations). NAP studies are undertaken without seeking individual consent and use limited identifiable data to protect the confidentiality of the patient and the reporter. (Details of the methods and results of NAPs are provided in the supporting information).

Consent can not be obtained prospectively due to the rare and emergency nature of the event. After the event, some patients may be unable to give consent (death or incapacity) or disinclined to do so (due to the nature of the event or other conditions). Documenting consent identifies both the patient and the reporter. Anonymous reporting is known to improve the quality and candour of reporting of safety events/incidents. Breaking this anonymity for the reporter is likely to lead to biased and/or incomplete reporting.

Given that a key aim of the registry is to learn from when things work well and when they don't a registry that is biased (to an unknown extent) towards good outcomes will fundamentally undermine the purpose of the study.

None of the above factors will preclude appropriate clinical governance at a local level following an eFONA event, including the legal duty of candour if necessary.

A31. How long will you allow potential participants to decide whether or not to take part?

Not applicable for the patients. Reporters have as long or as short a time to submit a case as they wish, provided they can still recall key details.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Not applicable. All reporters will be UK-employed doctors.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

All reporters will be UK-employed doctors and we do not foresee a need to translate the registry into Welsh. This is consistent with other UK-wide registries.

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.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☐ Manual files (includes paper or film)
  - ☐ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:
Direct entry of case details into an electronic data registry.

Data is stored in the UoN data centre on the locally hosted REDCap instance at the University of Nottingham Kings meadow campus data centre where access is restricted. Access to the REDCap data is via username and password on a secure web pages (SSL 256 encryptions), access is granted on a per user basis, where users are assigned to roles that defines their system privileges. Users are then granted access to specific sites (REDCap terminology DAGs – data access groups).

Electronic storage of cases will be held on secure University of Nottingham databases with access limited to specific research team members.

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

The REDCap instruments will only collect the minimum required information for the purposes of the study. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

No direct identifiers will be collected (age, place, date of event). All study data will be stored securely on University of Nottingham servers.
All members of the research team will comply with the Data Protection Act principles.

Reported data from clinicians will not be linked to any clinical data. Patient names, initials or contact details will not be collected. Age will be collected in age brackets.

A39. Please specify whether identifiers will be held in the same database as the clinical data, or in a separate database and linked through a unique study or case number. *If held separately, please specify how and at what point the separation will occur. If held in the same database, will the identifiers be encrypted? If so, specify what will be encrypted and who will continue to have access.*

Direct identifiers (name / initials, age, date of birth, postcode etc.) are NOT being collected. The two items of direct information that are being collected (sex, ethnicity) will be kept with the individual case record as these are integral to the data review process.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Direct identifiers (name / initials, age, date of birth, postcode etc.) are NOT being collected. The two items of direct information that are being collected (sex, ethnicity) will be kept with the individual case record as these are integral to the data review process. These data will be accessible to the study team. Members of the research team are not part of each individual's usual care team and consent will not be sought for each individual. As discussed, this is being carried out to avoid under-reporting and potential bias in the results.

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 generated by the study will be analysed by the study researchers based at the University of Nottingham under supervision of the Chief Investigator - Iain Moppett

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

	Title	Forename/Initials	Surname
	Prof	Iain	Moppett
Post	Professor of Anaesthesia and Perioperative Medicine /Honorary Consultant		
Qualifications	MB BChir MA MRCP FRCA		
Work Address	Anaesthesia and Critical Care		
	Queen's Medical Centre		
	Nottingham		
Post Code	NG7 2UH		
Work Email	iain.moppett@nottingham.ac.uk		
Work Telephone	01158230959		
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- (●) Less than 3 months
- ( ) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years
- ( ) Over 3 years

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

Years: 7
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.*

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.
The study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include study databases and associated meta-data encryption codes.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

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

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.
Information about the registry will be publicly available through the RCoA and Difficult Airway websites, with a dedicated page. A protocol / methods paper will be published.

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:*

- [x] Peer reviewed scientific journals
- [x] Internal report
- [x] Conference presentation
- [x] 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)

An interim summary will be produced annually and published in an appropriate format such as peer reviewed scientific publications, conference presentations, on the Royal College of Anaesthetists Centre for Research & Innovation and Difficult Airway Society webpages.

A final summary report will be produced and similarly disseminated. Alongside this, recommendations will be made for institutions, training bodes, and departments and disseminated through appropriate channels.

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

All data will be reviewed before dissemination to ensure that no individual can be identified as being one of fewer than five people in each of several categories.

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
Individual patients will be unaware that they are (or are not) entered in the registry. We will not know who the individual submitting clinicians are either. We will provide regular updates to the anaesthetic community through reports, bulletins, conferences and webinars etc.

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
- [x] Review within the Chief Investigator's institution or host organisation
- [x] 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:
See protocol for further information

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
	Dr	Chris	Partlett
Department	Nottingham Clinical Trials Unit		
Institution	University of Nottingham		
Work Address	Building 42		
	Applied Health Research		
	University of Nottingham		
Post Code	NG7 2RD		
Telephone			
Fax			
Mobile			
E-mail			

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

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

PURPOSE

To improve care and outcomes for patients at risk of needing an emergency front of neck airway.

PRIMARY OBJECTIVE
To provide a systems-based analysis of events, decision-making and patient outcomes in the process of eFONA

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

To examine the qualitative relationships between eFONA and:
• Patient characteristics,
• The planned operation or procedure,
• Pre-anaesthetic assessment and investigation of the airway,
• Human factors,
• Equipment selection and techniques used,
• Guideline compliance and effectiveness.
To provide quantitative descriptions of the populations, techniques and processes reported
To provide evidence-based recommendations for practice at national, hospital and individual levels

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: 300
Total international sample size (including UK):
Total in European Economic Area:

Further details:

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.*

We estimate that there will be around 100 eligible cases per / year across the UK, but the precise number is unknown. We have therefore taken a pragmatic approach to our registry duration, balancing the need to collect data with the possibility of participant fatigue. A three year period in the first instance allows one year after the registry shuts for analysis and publication and keeps us within a 5 year window.

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.

Quantitative
Simple descriptive statistics will be used to summarise the characteristics of submitted cases numerically (e.g. means, median, modes, counts) and visually (e.g. box-plots) with due regard for suppression of small case numbers.

Qualitative

Periodically (depending on the frequency of reporting, but 3 monthly is indicative) during the three-year case reporting period,, an expert review group will meet and review the uploaded cases to identify themes around patient factors, equipment factors, technique used and human factors in the performance of eFONA.

The panels will use the SEIPS 2.0 framework to integrate these aspects, using the concepts of the work system, processes and outcomes

The panels will review each case as a small group (3-4 members). The whole panel will then review all of the cases together to compare and contrast across cases, and to seek consensus on key themes within and between the systems and subsystems for individual / groups of cases. As an iterative process, the factors and themes are likely to develop during the time of the registry. Indicative domains, based on the experience of NAP4, subsequent NAPs, and expert opinion, include:

Patient and context information: (Age category, Gender, operative speciality (includes critical care), presence of absence of airway assessment, previously recorded airway difficulties)
To help identify and understand the at-risk population.

Cycle of events information
To determine the effectiveness of the rescue strategies employed and to see whether or not they followed nationally recognised guidelines

eFONA technique employed
In the absence of a clinical trial (which is infeasible due to the rarity of events), it is impossible to dictate one technique over another, although the adoption of one technique has been recommended within the UK to simplify training.

Other influencing factors
o Training of the team
o Time of day
o Availability of senior personnel
o Effective functioning of available emergency equipment

Patient outcome:
To explore if any inferences can be drawn between those with successful and unsuccessful outcomes including death or disability (as far as known at time of reporting).

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
	Dr	Alastair	McNarry
Post	Consultant Anaesthetist		
Qualifications	MB BChir MA FRCA		
Employer	NHS Lothian		
Work Address	Anaesthesia Western General Edinburgh		
Post Code	EH4 2XU		
Telephone			
Fax			
Mobile			
Work Email	althegasman@btinternet.com		

	Title	Forename/Initials	Surname
	Dr	Parineeta	Ghosh
Post	eFONA Research Fellow and ST7 Anaesthetics		
Qualifications	MbChB FRCA MSc		
Employer	UCLH		
Work Address	250 Euston Road London		
Post Code	NW1 2BU		
Telephone	+447854288293		
Fax			
Mobile			
Work Email	parineeta@doctors.org.uk		

	Title	Forename/Initials	Surname
	Dr	Fiona	Kelly
Post	Consultant Anaesthetist		
Qualifications			
Employer	Royal United Hospitals Bath NHS Foundation Trust		
Work Address	Royal United Hospitals Bath NHS Foundation Trust		
Post Code			
Telephone			
Fax			
Mobile			

Work Email	fiona.kelly@doctors.org.uk

Title	Forename/Initials	Surname
Dr	Anil	Patel

Post	Consultant Anaesthetist
Qualifications	
Employer	University College London Hospitals NHS Foundation Trust
Work Address	University College London Hospitals NHS Foundation Trust 250 Euston Road
Post Code	NW1 2BU
Telephone	
Fax	
Mobile	
Work Email	dranilpatelent@gmail.com

Title	Forename/Initials	Surname
Dr	Fauzia	Mir

Post	Consultant Anaesthetist
Qualifications	
Employer	St George’s University Hospitals NHS Foundation Trust
Work Address	
Post Code	
Telephone	
Fax	
Mobile	
Work Email	fauziaahmadmir@yahoo.com

Title	Forename/Initials	Surname
Dr	Ravi	Bhagrath

Post	Consultant Anaesthetist
Qualifications	
Employer	Barts Health NHS Trust
Work Address	
Post Code	
Telephone	
Fax	
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Work Email	ravi.bhagrath@nhs.net

Title	Forename/Initials	Surname
Dr	Imran	Ahmed

Post	Consultant Anaesthetist
Qualifications	
Employer	Guys and St Thomas’ NHS Foundation Trust

Work Address	
Post Code	
Telephone	
Fax	
Mobile	
Work Email	drimranahmad1@gmail.com

Title	Forename/Initials	Surname
Dr	Andy	Higgs

Post	Consultant Anaesthetist
Qualifications	
Employer	Warrington and Halton Hospitals NHS Trust
Work Address	
Post Code	
Telephone	
Fax	
Mobile	
Work Email	andyhiggs@doctors.org.uk

Title	Forename/Initials	Surname
Dr	Kariem	El-Boghdadly

Post	Consultant Anaesthetist
Qualifications	
Employer	Guys and St Thomas' NHS Foundation Trust
Work Address	
Post Code	
Telephone	
Fax	
Mobile	
Work Email	Kariem.ElBoghdadly@gstt.nhs.uk

Title	Forename/Initials	Surname
Prof	Tim	Cook

Post	Consultant Anaesthetist
Qualifications	MB BChir MA FRCA
Employer	Royal United Hospitals Bath
Work Address	Anaesthesia Royal United Hospitals Bath NHS Foundation Trust Bath
Post Code	BA1 3NG
Telephone	
Fax	
Mobile	
Work Email	timcook007@gmail.com

	Title	Forename/Initials	Surname
	Dr	Barry	McGuire
Post	Consultant Anaesthetist		
Qualifications			
Employer	NHS Tayside		
Work Address			
Post Code			
Telephone			
Fax			
Mobile			
Work Email	barry.mcguire@nhs.scot		

	Title	Forename/Initials	Surname
	Ms	Laura	Cortes
Post	Research Co-ordinator		
Qualifications			
Employer	Royal College of Anaesthetists		
Work Address	Churchill House		
	Red Lion Square		
	London		
Post Code	WC1R 4SG		
Telephone			
Fax			
Mobile			
Work Email	lcortes@rcoa.ac.uk		

	Title	Forename/Initials	Surname
	Ms	Christine	Taylor
Post	Research Manager		
Qualifications			
Employer	Royal College of Anaesthetists		
Work Address	Churchill House		
	Red Lion Square		
	London		
Post Code	WC1R 4SG		
Telephone			
Fax			
Mobile			
Work Email	ctaylor@rcoa.ac.uk		

	Title	Forename/Initials	Surname
	Mr	Jose	Lourtie
Post	Head of Research		
Qualifications			
Employer	Royal College of Anaesthetists		
Work Address			

Post Code	
Telephone	
Fax	
Mobile	
Work Email	jlourtie@rcoa.ac.uk

Title	Forename/Initials	Surname
Ms	Sharon	Drake

Post	Director of Clinical Quality and Research
Qualifications	
Employer	Royal College of Anaesthetists
Work Address	
Post Code	
Telephone	
Fax	
Mobile	
Work Email	sdrake@rcoa.ac.uk

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	University of Nottingham
Given name	Ali
Family name	Alshukry
Address	E-floor office, Yang Fujia Building
Town/city	Jubilee Conference Centre, Wollaton Road
Post code	NG8 1BB
Country	

Telephone	0115 8467906
Fax	
E-mail	sponsor@nottingham.ac.uk

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.

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] 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:

Please give details of funding applications.

Organisation	Royal College of Anaesthetists
Address	Churchill House Red Lion Square
Post Code	WC1R 4SG

Telephone
Fax
Mobile
Email

Funding Application Status: (•) Secured ( ) In progress

Amount: £10000

Duration
Years: 3
Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
Centre for Research Improvement / Difficult Airway Society Collaboration

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
		Jennifer	Boston
Organisation	Nottingham University Hospitals NHS Trust		
Address	Research & Innovation		
	Queen's Medical Centre Campus		
	Nottingham		
Post Code	NG7 2UH		
Work Email	ResearchSponsor@nuh.nhs.uk		
Telephone	01159249924		
Fax			
Mobile			

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

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

Planned start date: 02/01/2024
Planned end date: 02/01/2029

Total duration:

Years: 5 Months: 0 Days: 1

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

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	200
☑ NHS organisations in Wales	8
☑ NHS organisations in Scotland	14
☑ HSC organisations in Northern Ireland	5
☐ 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:	227

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 REDCap database includes a full audit trail.

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria); accountability of study materials.

The Study Coordinator or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made.

Monitoring of study data shall include data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

Where corrections to the REDCap data have been made these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

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*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- [x] NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- [ ] Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

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

○ Yes ◉ No ○ Not sure

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

Some eFONA events will occur in children (we estimate around 10%). It is important to understand the factors around these events just as much as those in adults. Learning from adults may or may not be applicable to children. The registry is collecting data after the event has occurred, so there is no meaningful risk to the child, and potential future benefit to other children.

There are no age restrictions for the registry.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

Not applicable.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

Consent is not being sought for any of the cases.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

Consent is not being sought for any of the cases.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

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	Iain Moppett Iain.Moppett@nottingham.ac.uk
	Institution name Department name Street address Town/city Post Code Country	University of Nottingham Nottingham NG7 2RD United Kingdom	Qualification (MD...) Country	MB BChair MRCP FRCA DM United Kingdom

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 Iain Moppett on 08/01/2024 12:14.

Job Title/Post:

Organisation:

Email: iain.moppett@nottingham.ac.uk

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 Mr Ali Alshukry on 21/12/2023 14:42.

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