

**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)

The TYPHOON Study

**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) Does the study involve the use of any ionising radiation? ☐ Yes ☒ No
- b) Will you be taking new human tissue samples (or other human biological samples)? ☐ Yes ☒ No
- c) Will you be using existing human tissue samples (or other human biological samples)? ☐ Yes ☒ No

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

☒ 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)  
☐ HM 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

**5c. You have indicated that your study has sites located in England. For the research sites located in England, do you wish for the study to be considered for NIHR Research Delivery Network (RDN) support and inclusion in the NIHR RDN Portfolio? Please see the information button for further details**

- ☒ Yes ☐ No

**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 Research administering questionnaires/interviews for quantitative analysis or mixed methodology study****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 familiar to lay reviewers of the application.

**Short title and version number:** (maximum 70 characters - this will be inserted as header on all forms)  
The TYPHOON Study

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

**REC Name:**

**REC Reference Number:**

**Submission date:**

**PART A: Core study information****1. ADMINISTRATIVE DETAILS****A1. Full title of the research:**

The TYPHOON Study: Tonsillectomy Postoperative Haemorrhage Outcomes and Observations National Cohort Study

**A3-1. Chief Investigator:**

	Title	Forename/Initials	Surname
	Professor	Catriona	Douglas
Post	Consultant Head and Neck Surgeon		
Qualifications	MBChB, BSc, MD, FRCS		
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Work Telephone	0141 211 3212		
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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 Adam Wade  
Address NHS GG&C Research and Innovation (R&I)  
Ward 11, Dykebar Hospital  
Grahamston Road, Paisley  
Post Code PA2 7DE  
E-mail adam.wade@nhs.scot  
Telephone 01413144347  
Fax

**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):

Sponsor's/protocol number: GN24EN290P

Protocol Version: 4

Protocol Date: 17/01/2025

Funder's reference number (enter the reference number or state not applicable): 000448

Project website: <https://entintegrate.co.uk/>

**Additional reference number(s):**

Ref.Number	Description	Reference Number
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*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.*

Tonsillectomy is one of the most commonly performed surgical procedures in Ear, Nose, Throat (ENT) surgery, with an estimated 28 000 procedures performed in the UK 2019/20. Historical data from the UK National Prospective Tonsillectomy Audit in 2005 suggested a post-tonsillectomy bleed (PTB) rate of 4.9% in adults, which has since been widely quoted to patients in the consent taking process. Specifically, the study found a three-times increased risk of PTB with "hot" surgical techniques for both dissection and haemostasis compared to cold steel tonsillectomy without the use of any "hot" techniques. National guidance released halfway through the audit changed practice and reduced rates of haemorrhage. However, data collection for this audit concluded over 20 years ago, and recent unpublished data from Hospital Episode Statistics indicates a significant increase in the PTB rate to 15.6% over the period 2022-2023, the reasons for which are currently unclear and need to be urgently addressed.

We plan to conduct a national, prospective, multicentre collaborative cohort study of all consecutive adult patients undergoing tonsillectomy over 28 days. The study will be run by INTEGRATE, the UK ENT Trainee Collaborative Network, on a voluntary basis. Patients will be expected to fill in a questionnaire on how their sore throat is impacting their quality of life (TOI 14 – Tonsillectomy Outcome Inventory). We will collect granular data on patient characteristics, previous episodes of sore throat, surgical and anaesthetic characteristics and post-operative management including analgesia. We will also telephone the patient at 28 days following surgery to determine if they have had any episodes of bleeding and how this was managed.

The aim of this study is to better understand the risk factors associated with an increased risk of PTB and how we can change our practice to reduce this risk for patients.

**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.*

Patient confidentiality and access to medical records: All submitted records will be pseudo-anonymised and no patient identifiable information will be shared between centres. Numerous steps will be taken to protect patient's data as detailed later in this application.

Patient consent: an informed consent form with a participant information sheet will be provided to participating prospective patients. Patients will be allowed to withdraw at any time and reason for withdrawal will be documented.

### 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)

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

To better understand the risk factors associated with an increased risk of post-tonsillectomy bleed (PTB) in the first 28 days following tonsillectomy.

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

- Determine readmission and post-operative haemorrhage rate in the first 28 days following tonsillectomy and compare this to Hospital Episode Statistics data.
- Examine frequency and severity of tonsillitis episodes prior to being listed for surgery
- Evaluate differences in intra-operative and post-operative management of tonsillectomy patients
- Examine the management pathways for post-tonsillectomy haemorrhage

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

The recently published NATTINA study demonstrated that tonsillectomy was clinically effective at reducing the number of sore throat days compared to conservative management in adults with recurrent tonsillitis meeting the UK guidelines, providing a landmark contribution to the evidence base for the effectiveness of adult tonsillectomy for recurrent sore throats. Tonsillar haemorrhage following tonsillectomy is a significant post-operative complication with the potential to cause serious morbidity or death. Patients with PTB may require hospital re-admission including return to theatre for surgical arrest of haemorrhage. Due to the huge volume of procedures performed, even seemingly low rates of PTB at a population level can affect a large number of patients at a significant cost burden to the NHS.

Unpublished data from Hospital Episode Statistics suggests that the current bleed rate amongst adults has dramatically increased to 15.6% in 2022-3 from the 4.9% previously demonstrated in the National Prospective Tonsillectomy Audit in 2005. The reasons for this dramatic increase are unclear; whether there have been changes in the baseline morbidity of patients listed for a tonsillectomy or specific patient, surgical and anaesthetic, post-operative characteristics that may increase the risk of bleeding. Studies have also demonstrated a rise in the incidence of deep neck space infections following introduction of SIGN guidance for tonsillectomy, and it has been postulated that this may have also had an impact on PTB rates. Reducing the rate of PTB is a major national priority, particularly in the context of the trend towards day case procedures and lower readmission rates, as outlined in the recent Getting It Right First Time (GIRFT) specialty report

Our prospective, multi-centre, collaborative cohort study aims to provide an in-depth assessment of the risk factors associated with PTB, including but not limited to the following:

- Patient characteristics: Gender, age, indication for tonsillectomy, previous episodes of sore throat and quinsy, previous hospitalisations, anticoagulation and antiplatelets, alcohol consumption, smoking history, BMI and haemoglobin on admission
- Surgical characteristics: Dissection instrument and settings, haemostasis type and settings, haemostasis adjuncts, surgery duration
- Anaesthetic characteristics: Airway management, type of anaesthetic, intra-operative analgesia
- Post-operative management: Antibiotics, analgesia, duration of admission
- Complications: Date of readmission, reason for readmission, return to theatre, bleeding site, method of haemostasis, haemostasis adjunct, blood transfusion, antibiotics, date of discharge

We will also be collecting data on disease specific morbidity through TOI-14 in addition to questionnaire data on the pathways by which patients get listed for a tonsillectomy and the process by which patients with a post-operative complication present to hospital.

Our prospective, multi-centre, collaborative cohort study aims to provide an in-depth assessment of the risk factors associated with post tonsillectomy bleed. Our results have the potential to inform national quality improvement projects to produce evidence-based guidance around intra- and post-operative tonsillectomy care. The results may help guide clinicians on the safest surgical technique as well as identification of patients with a potential to bleed post-operatively. Reducing the number of patients that go back to theatre for surgical arrest of haemorrhage and readmission to hospital could also result in significant savings to the NHS. For example, a ~20% bleed rate among the 12,000 adult tonsillectomies performed each year, with a conservative 1/3 of patients being admitted for one night in hospital at a cost of £1000/night, would equate to a cost of approximately £800,000 pa. We also hope the results of

our study can be used to produce up to date and accessible information leaflets for medical professionals to provide to patients. We want to ultimately see the PTB rate reduce to below 10%.

We also have assurances from the Royal College of Surgeons England Research Surgical Specialty Lead and from The British Otorhinolaryngology & Allied Sciences Research Society (BOARS) that experienced academic clinicians will provide evening webinars and podcasts covering research skills and critical appraisal to support the study.

**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.*

TYPHOON is an exploratory, national prospective, multicentre, collaborative cohort study looking into the risk factors for post tonsillectomy bleeds. The study will be run by INTEGRATE, the UK ENT Trainee Collaborative Network.

Sites will be recruited through the INTEGRATE platform via a dedicated mailing list to ENT trainees. All centres performing tonsillectomy across the UK will be eligible to register for the study. Trainees will be asked to register interest in participating in the study 1 month prior to the study window on the 7th April. We hope to recruit 50 - 100 sites to participate in the study. Local management approval will need to be completed with each site. The site lead. A standardised letter to the research department will be provided. Each site will be asked to complete a survey on tonsillectomy practice in their unit.

All consecutive adult patients undergoing tonsillectomy between 7th April and 30th May will be included in the study. Local centres will prospectively identify for inclusion into the study through either the informatics department or theatre schedule. The clinic notes and investigation results for these patients will be reviewed by the local team and full eligibility criteria applied.

#### Methodology

We will obtain full written consent and provide a participant information sheet to all patients. We will ask all adult patients to complete a Tonsillectomy Outcome Inventory 14 (TOI-14) to measure disease specific QOL on the day of their surgery. We will collect granular data on patient characteristics, previous episodes of sore throat, surgical and anaesthetic characteristics and post-operative management including analgesia. We will telephone the patient at 28 +/- 3 days following surgery to determine if they have had any episodes of bleeding and how this was managed. Pseudo-anonymised data will be submitted via a dedicated case report form in Microsoft Excel and entered into a pooled analysis. We will perform multivariate analysis to determine the risk factors for primary and secondary PTB.

**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 study protocol and patient facing documents were reviewed by the patient and public involvement group (PPI) from NHS Research Scotland at the University of Glasgow on the 15th of August 2024. Specifically, there were concerns about the amount of time patients had to consent for the study, therefore the protocol was amended to ensure that the Participant Information Sheet was sent out with the appointment letter for surgery to give patients an appropriate amount of time to consider their participation

## 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
- ☐ 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: 100 Years

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

All consecutive adult patients undergoing bilateral tonsillectomy in a two-month period between the 7th of April and the 8th of September 2025. Adult patients will be defined as >18 years of age at the time of their surgery. All patients will need to be English speaking.

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

- Known bleeding disorder
- Tonsillar biopsy
- Tonsillectomy for known or suspected cancer
- Tonsillectomy performed with palatal surgery
- Any second or revision tonsil operation (revision or remnant tonsillectomy)

**RESEARCH PROCEDURES, RISKS AND BENEFITS**

**A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.**

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Consent to participate in research study	1	N/A	10 minutes	Member of the surgical team in the surgical admission unit
Completion of the Tonsillectomy Outcome Inventory-14 (TOI-14)	1	N/A	10 minutes	Member of the surgical team in the surgical admission unit
Telephone call to patient at 28 days following surgery	1	N/A	10 mins	Member of the surgical team via telephone

**A21. How long do you expect each participant to be in the study in total?**

Patients will be followed up at 28 +/- 3 days following the date of their surgery.

**A22. What are the potential risks and burdens for research participants and how will you minimise them?**

*For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.*

No additional risk is anticipated for patients that could occur as a result of participation in the research.

**A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?**

☐ Yes ☒ No

**A24. What is the potential for benefit to research participants?**

Research participants will receive a follow up phone call at 28 +/- 3 days following their surgery to determine if they have experienced any post surgical complications which would not routinely take place.

**A26. What are the potential risks for the researchers themselves? (if any)**

No anticipated risks

**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).**

Local investigators will be advised to acquire a prospective list of all patients undergoing either tonsillectomy via the

Informatics departments and / or through the theatre schedule.

**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:*

Patient information in their electronic records will be screened by medical professionals affiliated with the study. Whilst patient identifiable information will be viewed in the electronic patient record, this information will not be recorded as part of the study.

**A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants. Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.**

Data handling and record keeping

An pseudonymised Excel spreadsheet will be submitted by each centre and received by the Project Management Team. They will then be stored on the Trust shared drive with security to protect against unauthorised access, in line with local data governance protocols. Data from each centre's individual Excel spreadsheet will be amalgamated onto a master spreadsheet, with each update saved as a separate version and old versions retained. Study IDs will be applied on data submission.

Access to data

Direct access will be granted to authorised representation from regulatory authorities to permit study related monitoring, audits and inspections, in line with participant consent.

Anonymisation of patients.

The Project Management Team will not request the names, addresses, medical record numbers (MRN) or identifiable data for any patients. Dates of birth, surgery, discharge and readmission (where applicable) will be used locally to generate durations. Durations (not dates) will then be submitted to the PMT. Reporting and analysis will not identify individual cases in any subsequent reports, presentations or publications. Data flow will be one way, from the Data Discloser to the Data Receiver (i.e. Project Management Team). There will be no traceability from the Project Management Team's database to local records. If any identifiable data is received, the files will be deleted and the site will be informed and asked to report the breach as per local protocols. Study level IDs will be added on submission, and thus the data will be considered pseudonymised.

**A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?**

☐ Yes ☒ No

**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?**

Local site leads will arrange for information about the study and a Participant Information Sheet with a QR code linking to the study website to potential participants prior to their admission date for surgery.

Patients will be consented before surgery either at the preassessment clinic or at the time of surgery. All contact regarding informed consent will be undertaken in person. Patients will be given an adequate period of time to ask questions and consider their involvement in the study before providing consent. Patients will be allowed to withdraw at any time, without reason, and the reason for withdrawal will be documented.

**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.*

All potential participants will be sent information about the study and the participant information sheet prior to admission to hospital. A member of the clinical team participating in the study will then obtain written informed consent on the day of surgery. All contact regarding informed consent will be undertaken in person and the patient will not be contacted via telephone.

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

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

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

Patients will be consented before surgery (either at the pre-admission clinic or around the time of surgery) and will given an adequate period of time to consider their involvement in the study and to answer any questions they may have. Patients will have already been sent information about the study prior to coming into hospital. As the study does not involve any additional risks for patients, and the only deviation from normal practice is a telephone follow up phone call at 28 +/- 3 days post-surgery, we do not anticipate any significant implications associated with participating in the study.

**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)**

Due to funding restrictions for this project, we do not have the capability to translate the required documents and videos into multiple languages

**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?**

Arrangements can be made for translation of the study patient information leaflet and informed consent form as required.

**A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.**

- ☐ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ☒ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ☐ The participant would continue to be included in the study.

- ☐ Not applicable – informed consent will not be sought from any participants in this research.
- ☐ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

*Further details:*

*If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.*

## 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:*

Patient data will be accessed by local investigators as part of the INTEGRATE network. Participating medical staff will be members of the patient's usual head and neck team.

Patient identifiable information will not be accessed or shared between centres. All data will be stored in an online password protected database.

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

Source data from patient paper or electronic patient records, the latter of which is accessible only via a secure username and password as per local trust policy.

**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.*

- Information related to study participants will remain confidential and be managed in accordance with the General Data Protection Regulation (2018), NHS Caldicott Principles, UK Policy Framework for Health and Social Care, and the conditions of Research Ethics Committee Approval.
- Immediately identifiable patient data including names, addresses or NHS/ medical record numbers (MRN) will not be collected as part of the study.
- Each submitted patient case will be provided with a study ID number generated by the INTEGRATE committee and shared with local collaborators. This will help the project management team clarify any unclear data points with local collaborators whilst maintaining patient anonymisation. As the study ID may be traced to a local hospital number, the data stored should be considered pseudonymised.
- Each site will record their participant data on a secured, password-protected Excel spreadsheet on an NHS computer. The spreadsheet will not contain any personal identifiable information, only the study ID for each patient. Each update of the data will be recorded and saved as a separate version in the folder so there will be no deletion of the entered data. Each site will send their completed spreadsheet to the INTEGRATE Project Management Team. Each spreadsheet will be reviewed and checked for error and inconsistencies in accordance with the Monitoring Plan. Data from each participating centre will then be amalgamated into a master spreadsheet that only the INTEGRATE trial management team will have access to.
- Data on Excel are regularly backed-up which can be retrieved easily. Data monitoring will be done by the INTEGRATE committee. Any data inconsistencies identified during data monitoring will be raised by the INTEGRATE committee to participating sites to address.
- NHS Greater Glasgow and Clyde will be the data controller. The INTEGRATE committee will be the data processor.

**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.*

Patient clinical records will only be accessed by appropriately trained co-investigators who are members of the patient's local direct care team. Personal identifiable data will not be shared between research sites. Data shared between sites will be pseudonymised with a unique research ID number generated by the INTEGRATE project management team.

#### 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?**

Statistical analysis will be performed by the INTEGRATE head and neck subcommittee with assistance from Dr David Young, a statistician at the University of Strathclyde.

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

	Title Forename/Initials Surname
	Mr Andrew Williamson
Post	Head and Neck Clinical Research Fellow
Qualifications	Bsc, MBChB, MSc
Work Address	The Royal Marsden NHS Foundation Trust
	203 Fulham Road
	London
Post Code	SW3 6JJ
Work Email	Andrew.williamson2@rmh.nhs.uk
Work Telephone	
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: 5

Months:

**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.**

All study documents will be archived via e-files by NHS Greater Glasgow and Clyde following submission of the end of study report. Archiving will be conducted in line with local guidelines. These documents will be stored in a location determined by the Sponsor in line with their standard operating procedures. Any destruction of essential documents will require authorisation from the NHS Greater Glasgow and Clyde. Documents will be retained for 5 years.

**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****A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?**

☐ Yes ☒ No

*If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.*

## 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.*

The study protocol will be published on a public registry (ClinicalTrials.gov) after HRA approval.

*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?**

No patient identifiable data will be used or stored as part of this project

**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.*

As data will be pseudonymised and there will be no formal process for informing patients of study results, however results will be available on journal, conference, and the INTEGRATE and ENTUK websites.

## 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 the INTEGRATE head and neck subcommittee, and representative members from ENT UK and The British Otorhinolaryngology & Allied Sciences Research Society (BOARS) - Mr James O'Hara and Professor Catriona Douglas.

The protocol has also undergone independent, expert and proportionate peer review by Mr Matt Smith and Mr David Hamilton.

*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 David Young
Department	Department of Mathematics and Statistics
Institution	University of Strathclyde
Work Address	16 Richmond Street Glasgow
Post Code	G1 1XQ
Telephone	+44 (0)141 552 4400
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?**

Risk factors associated with post tonsillectomy bleed on multivariate analysis

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

- Determine rate of post-operative haemorrhage and readmission in the first 28 days following tonsillectomy

- Evaluate management of post-tonsillectomy haemorrhage
- Assess reasons for readmission following tonsillectomy procedures
- Examine frequency and severity of tonsillitis episodes prior to being listed for surgery
- Understand pathways patients are listed for tonsillectomy

**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: 1000

Total international sample size (including UK):

Total in European Economic Area:

*Further details:*

All INTEGRATE sites in the UK undertaking tonsillectomy procedures will be invited to participate in the study one month prior to the start of the study.

**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.*

This is an exploratory pilot study therefore no power calculation has been performed. We anticipate our study will be able to demonstrate feasibility of the methodology and provide data for the purposes of larger studies in the future.

Based on Hospital Episode Statistics data, we assume between 1000 – 1200 adult tonsillectomies will be performed a month. We expect to capture approximately one quarter of the total, equating to approximately 500 – 600 patients over a two-month period. Based on an expected bleed rate of 20%, we would expect 100 - 120 patients to be readmitted for bleeding.

**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.**

Patient demographic data will be presented with mean and SD for continuous variables and counts and proportions for categorical variables. Categorical data will be analysed with the Chi-square or Fisher's Exact test as appropriate. Quantitative continuous variables will be analysed using descriptive statistics such as mean, standard deviation, median, quartiles, minimum/maximum and range.

Complication rates will be expressed as percentages and relative risks calculated as a ratio of the complication rate. Multilevel multiple logistic regression will be used to adjust for potential confounding factors (such as age, sex and grade of operating surgeon). P-values of <0.05 will be considered significant.

## 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
	Mr Andrew Williamson
Post	Clinical Research Fellow / INTEGRATE Chair
Qualifications	MBChB
Employer	Royal Marsden Hospital Trust

Work Address Royal Marsden Hospital  
203 Fulham Road  
London  
Post Code SW3 6JJ  
Telephone 07595944828  
Fax  
Mobile  
Work Email andrew.williamson2@rmh.nhs.uk

Title Forename/Initials Surname  
Miss Lucy Li  
Post ENT Specialty Registrar  
Qualifications MBChB  
BMedSci  
Employer NHS Greater Glasgow and Clyde  
Work Address 1355 Govan Road  
Glasgow  
Post Code G51 4TF  
Telephone 01412011100  
Fax  
Mobile 07722052123  
Work Email lucy.li@nhs.scot

Title Forename/Initials Surname  
Miss Ying Ki Lee  
Post ENT Specialty Registrar  
Qualifications MBChB  
Employer NHS Greater Glasgow and Clyde  
Work Address 1355 Govan Road  
Glasgow  
Post Code G51 4TF  
Telephone  
Fax  
Mobile 07706656397  
Work Email yingki.lee@nhs.scot

Title Forename/Initials Surname  
Miss Alison Lim  
Post ENT Specialty Registrar  
Qualifications MBChB, BMSc  
Employer NHS Greater Glasgow and Clyde  
Work Address 1355 Govan Road  
Glasgow  
Post Code G51 4TF  
Telephone  
Fax  
Mobile 07724761798

Work Email	alison.lim3@nhs.scot
	Title Forename/Initials Surname
	Mr James O'Hara
Post	Consultant Head and Neck Surgeon
Qualifications	MBChB, BSc, MD, FRCS
Employer	The Newcastle upon Tyne Hospitals NHS Foundation Trust
Work Address	The Freeman Hospital
	High Heaton
	Newcastle-upon-Tyne
Post Code	NE7 7DN
Telephone	
Fax	
Mobile	
Work Email	james.o'hara@newcastle.ac.uk

**A64. Details of research sponsor(s)****A64-1. Sponsor****Lead Sponsor**Status: ☒ NHS or HSC care organisation

Commercial status: Non-Commercial

☐ Academic☐ Pharmaceutical industry☐ Medical device industry☐ Local Authority☐ Other social care provider (including voluntary sector or private organisation)☐ Other*If Other, please specify:***Contact person**

Name of organisation NHS Greater Glasgow and Clyde

Given name Adam

Family name Wade

Address NHS GG&amp;C Research &amp; Innovation (R&amp;I), Ward 11 Dykebar Hospital, Grahamston Road

Town/city Paisley

Post code PA2 7DE

Country United Kingdom

Telephone 01412116389

Fax

E-mail adam.wade@nhs.scot

**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
- ☐ 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	ENT UK
Address	38-43 Lincoln's Inn Fields
	London
Post Code	WC2A 3PE
Telephone	020 740 48 373
Fax	
Mobile	
Email	entuk@entuk.org

Funding Application Status: ☒ Secured ☐ In progress

Amount: £1500

Duration

Years: 1

Months:

*If applicable, please specify the programme/ funding stream:*

What is the funding stream/ programme for this research project?

ENT UK Foundation Grant

**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
	Ms Shanice White
Organisation	NHS GG&C Research and Innovation (R&I)
Address	Dykebar Hospital (Ward 11)
	Grahamston Road
	Paisley
Post Code	PA2 7DE
Work Email	shanice.white@nhs.scot
Telephone	01412116389
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: 07/04/2025

Planned end date: 27/06/2025

Total duration:

Years: 0 Months: 2 Days: 21

**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
- ☒ 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:

0

**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?**

A Project Management Group (PMG) will be set up and membership will include Chief Investigator, Principle investigator, and the INTEGRATE HN subcommittee. Other key study personnel will be invited to join the PMG as appropriate. The PMG has operational responsibility for the conduct of the trial. The PMG is responsible for monitoring recruitment, safety and governance of the study as well as collaborating with subsequent translational sub-studies.

Internal study team auditing will be performed to ensure appropriate conduct of research. Monitoring and auditing will be in line with the study sponsor standard operating systems. The sponsor has implemented an audit programme, based on risk, for its non-CTIMP studies. The study falls under the remit of this programme and therefore may be subject to audit.

#### 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)

*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)

*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.*

- ☒ 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

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**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	<input checked="" type="radio"/> NHS/HSC Site <input type="radio"/> Non-NHS/HSC Site	
	Organisation name	GREATER GLASGOW AND CLYDE
	Address	GARTNAVEL ROYAL HOSPITAL 1055 GREAT WESTERN ROAD GLASGOW
	Post Code	G12 0XH
	Country	SCOTLAND
		Forename Catriona
		Middle name
		Family name Douglas
		Email Catriona.douglas@ggc.scot.nhs.uk
		Qualification (MD...) MBChB, BSc, MD, FRCS
		Country 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 Dr Catriona Douglas on 19/02/2025 12:38.

Job Title/Post:

Organisation:

Email:

**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 Dr Adam Wade on 27/02/2025 10:17.

Job Title/Post: Research Facilitator  
Organisation: NHS GGC  
Email: adam.wade@nhs.scot