

## 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)

Endoscopic Submucosal Dissection in the UK: A Survey 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

**4b. Please confirm the reason(s) why the project does not require review by a REC within the UK Health Departments Research Ethics Service:**

- ☐ Projects limited to the use of samples/data samples provided by a Research Tissue Bank (RTB) with generic ethical approval from a REC, in accordance with the conditions of approval.  
☐ Projects limited to the use of data provided by a Research Database with generic ethical approval from a REC, in accordance with the conditions of approval.  
☐ Research limited to use of previously collected, non-identifiable information  
☐ Research limited to use of previously collected, non-identifiable tissue samples within terms of donor consent  
☐ Research limited to use of acellular material  
☐ Research limited to use of the premises or facilities of care organisations (no involvement of patients/service users as participants)  
☒ Research limited to involvement of staff as participants (no involvement of patients/service users as participants)

**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 an NIHR Biomedical Research Centre, NIHR Applied Research Collaboration, NIHR Patient Safety Research Collaboration, or an NIHR HealthTech Research Centre 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 Research Delivery Network (RDN) Support and inclusion in the NIHR RDN Portfolio?**

**Please see information button for further details.**

☐ Yes ☒ No

*The NIHR Research Delivery Network (RDN) enables the health and care system to attract, optimise and deliver research across England e.g. by supporting the successful delivery of high-quality research, as an active partner in the research system.*

*If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR RDN.*

**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

Please describe briefly the involvement of the student(s):

I will be the only student involved in this project. My role involves survey design and dissemination, data collection and analysis, report writing.

This project is being undertaken as part of my PhD.

**9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?**

☒ 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**

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)  
Endoscopic Submucosal Dissection in the UK: A Survey Study

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

Endoscopic Submucosal Dissection (ESD) in the UK: A Survey of Training Pathways and Practice Trends

**A2-1. Educational projects**

Name and contact details of student(s):

**Student 1**

Title Forename/Initials Surname

[TITLE] [FORENAME] [SURNAME]

Address

Queen Elizabeth the Queen Mother Wing (QEQM)

St Mary's Campus

10 S Wharf Rd, London

Post Code

W2 1PE

E-mail

[EMAIL]

Telephone

[TELEPHONE]

Fax

[FAX]

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:

Doctor of Philosophy (PhD) in Surgery and Cancer

Name of educational establishment:

Imperial College London

Name and contact details of academic supervisor(s):

**Academic supervisor 1**

Title Forename/Initials Surname

[TITLE] [FORENAME] [SURNAME]

Address	Academic Department of Surgery Hammersmith Hospital, 72 Du Cane Road London, United Kingdom
Post Code	W12 0HS
E-mail	[EMAIL]
Telephone	[TELEPHONE]
Fax	[FAX]

Please state which academic supervisor(s) has responsibility for which student(s):

*Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.*

Student(s)	Academic supervisor(s)
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Student 1 [NAME]	<input checked="" type="checkbox"/> [NAME]
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*A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.*

#### A2-2. Who will act as Chief Investigator for this study?

- ☐ Student  
☒ Academic supervisor  
☐ Other

#### A3-1. Chief Investigator:

Title Forename/Initials Surname

[TITLE] [FORENAME] [SURNAME]

Post Qualifications	Clinical Senior Lecturer and Consultant Upper GI Surgeon,
ORCID ID	Imperial College London
Employer Work Address	MBChB, BSc (Hons), PhD, FRCS (Gen Surg) Imperial College London Academic Department of Surgery Hammersmith Hospital, 72 Du Cane Road London, United Kingdom
Post Code	W12 0HS
Work E-mail	[EMAIL]
* Personal E-mail	
Work Telephone	[TELEPHONE]
* Personal Telephone/Mobile	
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

[TITLE] [FORENAME] [SURNAME]

Address Level 5 Sherfield Building, Imperial College Union  
 Prince Consort Rd, South Kensington  
 London

Post Code SW7 2BB

E-mail [EMAIL]

Telephone [TELEPHONE]

Fax [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: N/A

Protocol Version: N/A

Protocol Date: N/A

Funder's reference number (enter the reference number or state not applicable): N/A

Project

website:

**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.*

Endoscopic Submucosal Dissection (ESD) is a minimally invasive procedure used to remove early-stage gastrointestinal (GI) cancers and complex polyps without the need for major surgery. Compared to conventional techniques such as Endoscopic Mucosal Resection (EMR), ESD allows for more precise removal of abnormal tissue in one piece, reducing the risk of recurrence. However, ESD is technically challenging, requiring extensive training and advanced endoscopic skills.

In the UK, ESD is increasingly being adopted by specialist endoscopists. Yet, there remains limited data on how clinicians are trained, the techniques and tools they employ, and the challenges they encounter in practice. This study

aims to explore the current landscape of ESD training and practice across the UK.

We will conduct an online nationwide survey targeting endoscopists who perform ESD to explore their training backgrounds, the techniques and tools they use, and the barriers they face in adopting or expanding this procedure.

The findings will help identify gaps in ESD training, highlight challenges faced by endoscopists, and provide insights into how ESD practice can be improved in the UK. The results will be shared with medical societies, policymakers, and training bodies to inform future training programmes and standardisation efforts.

This study does not involve patients or patient data, and all responses will be collected anonymously.

**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, R&D office 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.*

This study presents minimal ethical, legal, or management risks as it involves a survey of healthcare professionals and does not include patients, patient data, or direct patient care. However, the following considerations have been addressed to ensure compliance with ethical and governance standards:

**1. Confidentiality and Anonymity**

The survey will be conducted anonymously using Qualtrics Platform, which complies with the UK General Data Protection Regulations (GDPR). No personally identifiable information will be collected.

**2. Informed Consent**

Participants will be asked to provide an electronic consent (tick box) before they begin the survey. Participants may exit the survey at any time before submission; however, due to anonymisation, withdrawal after submission will not be possible.

**3. Data Security and Retention**

All survey data will be stored securely and retained for 10 years following study completion, in line with institutional policies, before being securely deleted.

**4. Survey Distribution and Professional Engagement**

The survey will be disseminated via professional medical societies in the UK and professional networks known to the research team. NHS emails will be used for survey invitations, but participation remains entirely voluntary.

Given these safeguards, the study poses minimal risk and adheres to ethical and regulatory requirements.

### 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.**

This study aims to answer the following key questions:

What are the current training pathways and available opportunities for UK endoscopists to learn ESD?

What are the common techniques and methods ESD endoscopists use in practice?

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

This study will also explore the following areas:

1. The current landscape of ESD practice in the UK – Who is performing ESD, where it is being done, and how it fits within existing endoscopy services.
2. Barriers to wider adoption of ESD – What challenges prevent more endoscopists from performing ESD.
3. Endoscopists' perspectives on robotic devices for ESD – How UK endoscopists view the potential role of robotic technologies in assisting with ESD procedures.

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

ESD is a specialised technique that allows doctors to remove early-stage cancers and complex polyps from the digestive tract without major surgery. Compared to traditional endoscopic methods, ESD provides more precise removal of abnormal tissue in one piece, reducing the risk of cancer recurrence. However, ESD is technically demanding and requires specialised training, which has limited its widespread use in the UK.

As ESD becomes more commonly performed, it is important to understand how endoscopists are trained, what techniques they use, and what challenges they face in practice. Currently, there is little information on the availability of ESD training in the UK and the factors that may be limiting its wider adoption.

This study aims to fill this gap by surveying UK endoscopists who perform ESD to identify existing training pathways, common techniques, and barriers to practice. Additionally, the study will explore clinicians' perspectives on the use of robotic devices to assist ESD, which may help shape the future of training and technological innovation in this field.

By gathering this information, the study will provide valuable insights that can help improve training opportunities, support standardisation of ES practice, and ultimately enhance patient care by making this advanced technique more accessible.

**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.**

What will happen in the study?

1. A single online survey will be distributed to UK-based endoscopists who perform ESD.

2. Distribution via the following methods:

We will request professional organisations, including (but not limited to) the UK and Ireland Oesophagogastric Society (UKIOG), the British Society of Gastroenterology (BSG), the Association of Upper Gastrointestinal Surgeons (AUGIS), and the Association of Coloproctology of Great Britain and Ireland (ACPGBI), to distribute the survey through their mailing lists to reach relevant endoscopists.

In parallel, two ESD practitioners collaborating with the research team are assisting in compiling a database of UK-based ESD endoscopists, containing their names and NHS email addresses. Where contact details are missing,

these are being sourced through the NHS contact directory (NHS.net). Identified endoscopists will be contacted directly via their NHS email addresses

3. Participants will be invited to complete the survey once, which will take approximately 15-20 minutes.
4. The survey will collect anonymous responses, meaning no personal details will be linked to the answers.

What does the survey include?

The first section of the survey will contain a participant information sheet (PIS) eligibility question, and consent statement.

Then, the survey will have the following five main sections:

1. Demographics and professional background.
2. ESD training – Where and how they learned ESD.
3. Current practice – how they currently do it.
4. ESD techniques and methods – The tools, strategies, and variations in how ESD is performed. Endoscopists' perspectives on the use of robotic devices in ESD.
5. Barriers and challenges – Factors limiting ESD adoption.

What happens after participation?

1. No further involvement is required after completing the survey.
2. The responses will be analysed to identify trends and challenges in ESD training and practice.
3. Findings will be presented at relevant conferences or published in peer-reviewed journals.

This study does not involve patients, direct patient care, or the collection of personal data, and participation is entirely voluntary.

**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.*

This study does not involve patients, service users, carers, or members of the public in the research process because it is focused on surveying healthcare professionals (endoscopists) about their training, techniques, and challenges in ESD.

As the study does not involve patient care, patient data, or interventions affecting patients directly, there is no requirement for direct public or patient involvement in the design, management, or conduct of the research.

However, the findings may have indirect relevance to patient care by identifying gaps in ESD training and potential improvements in practice. Where appropriate, we will share key results with relevant patient advocacy groups and professional societies to ensure that the insights gained contribute to future training and policy development, ultimately benefiting patient outcomes.

#### 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: 30 Years Years

Upper age limit: 67

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

1. UK-based endoscopists – Participants must be actively working in the UK.
2. Practising ESD – Participants must currently perform ESD as part of their clinical practice for the treatment of early gastrointestinal cancers or complex polyps.

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

1. Non-UK-based endoscopists – The study focuses on the UK healthcare system, so endoscopists practising outside the UK will be excluded.
2. Endoscopists who do not perform ESD – Clinicians who do not actively perform ESD as part of their practice will not be eligible.

**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
Online Survey	1	0	15-20 minutes	Participants will complete the survey online, remotely, and during their own convenient time. Consent will be obtained electronically via a tick box before starting the survey.

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

Each participant is expected to be in the study for a total of approximately 15-25 minutes.

**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.*

This study presents minimal risk to participants, as it involves a one-time, anonymous online survey.

Potential Risks and Burdens:

1. Time Commitment:

Completing the survey will take approximately 15-20 minutes, which may be a minor inconvenience for busy healthcare professionals. Participants will have the option to pause the survey and resume it later. Alternatively, they can withdraw from the study at any time before submission.

2. Professional Reflection and Disclosure:

Some participants may find questions about their training experiences or barriers to ESD practice thought-provoking or reflective of challenges they have faced.

3. Data Security and Confidentiality Concerns:

Some participants may have concerns about their responses being linked to their identity. To minimise this risk, all responses will be collected anonymously. No personally identifiable information—or any details that could be used to link responses to individuals (such as names, email addresses, or hospital affiliations)—will be recorded.

**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?**

This study is unlikely to provide direct personal benefits to participants. However, there are several indirect benefits:

1. Contribution to ESD Training and Standardisation:

By sharing their experiences, participants will help identify gaps in ESD training and barriers to wider adoption, which could lead to improvements in training opportunities and resources in the UK.

2. Professional and Policy Impact:

The findings may inform training programmes, professional societies, and policymakers, potentially influencing future standardisation efforts and support for ESD training.

**3. Increased Awareness and Networking Opportunities:**

The study may highlight common challenges faced by UK endoscopists, encouraging professional discussions and engagement with relevant medical societies.

**4. Potential for Future Technological Advancements**

Participants will also have an opportunity to express their views on robotic assistance in ESD, contributing to discussions on future innovations in endoscopic surgery.

While there are no direct personal incentives (such as payment or certification), the study offers participants a chance to shape the future of ESD training, practice, and potential technological advancements in the UK.

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

This study poses no significant physical, psychological, or legal risks to the researchers. The primary consideration relates to data security and the responsible management of sensitive information. These risks will be minimised by using the GDPR-compliant Qualtrics platform for data collection and adhering strictly to institutional data protection and management protocols. All survey responses will be anonymised, and no identifiable information will be collected. Data will be stored on secure, password-protected servers with access restricted to authorised members of the research team.

**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 social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).****How Will Potential Participants Be Identified?**

Potential participants will be identified using the following methods:

**1. Distribution via Professional Medical Societies:**

[NAME] will request relevant professional medical organisations to distribute the survey via their mailing lists to reach ESD endoscopists.

**2. Distribution via Professional Networks:**

Two experienced ESD practitioners, [NAME] and [NAME], are collaborating with the research team to compile a list of UK-based ESD endoscopists. Identified endoscopists will be contacted via their NHS email addresses (Invites will be sent directly using Qualtrics).

**Who Will Carry This Out?**

[NAME] will be responsible for distributing the survey through the above-mentioned channels.

**Resources Used:**

1. Qualtrics (online survey platform) – To send invitations and collect survey responses.

2. Professional society mailing lists and communication platforms – To facilitate survey distribution.

**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:*

1. This study does not involve reviewing or screening identifiable personal information of patients, service users, or any other individuals.
2. No patient records, medical databases, or confidential NHS systems will be accessed to identify participants.

**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?**

Potential participants will be approached through the following targeted recruitment strategies:

1. Professional Medical Societies and Organisations:

The survey link will be shared with relevant professional medical organisations, such as UKIOG, BSG, ACPGBI and AUGIS. These organisations will distribute the survey through their mailing lists and internal communication platforms.

2. Distribution via Professional Networks:

Two ESD practitioners, [NAME] and [NAME], are collaborating with the research team to compile a list of UK-based ESD endoscopists, including their names and NHS email addresses. Identified ESD endoscopists will be contacted via their NHS email addresses (Invites will be sent directly using Qualtrics).

Who Will Make the First Approach?

[NAME] will oversee survey distribution through professional societies and networks.

**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.*

The first section of the survey will contain a participant information page, an eligibility question and consent statement.

The information page will outline the purpose of the study, what participation involves, data confidentiality, the voluntary nature of participation, and contact details for further information or queries.

Participants will then be required to answer an eligibility question and indicate their consent by ticking a mandatory consent box before proceeding to the survey questions.

This study does not involve vulnerable groups, adults lacking capacity, or children. Therefore, no additional consent arrangements are required.

*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?**

1. Participants can choose to complete the survey at their convenience.
2. There is no fixed deadline for participation, but a general recruitment period of approximately 2 months is planned.
3. Participants will receive the survey link and can review the study information as long as needed before deciding whether to proceed.
4. As participation is entirely voluntary and anonymous, there is no pressure or obligation to respond immediately.

**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)**

Since the study targets trained medical professionals who routinely use English in clinical practice, additional language or communication support is not expected to be necessary.

**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?**

In accordance with the Welsh Language Act 1993 and the Welsh Language (Wales) Measure 2011, participants based in Wales may request study materials in Welsh. If such a request is received, the research team will consider translating the participant information and survey.

As the study involves healthcare professionals and not public-facing services, Welsh-language materials are not anticipated to be essential. Recruitment will occur through professional networks and societies that typically operate in English.

**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:*

Since the survey is self-administered online, it is not possible to assess changes in participants' capacity after they have

given consent and completed the survey. As a result, continued capacity will be assumed for all participants who provide electronic consent and proceed with the survey.

## 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:*

Data will be transferred for analysis and stored on the Imperial College One drive account of [NAME]. Access will only be provided to other members of the research team as required.

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

This study does not involve collecting, storing, or processing personal data, as all survey responses will be anonymous.

**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.**

#### Anonymisation of Data:

The survey is fully anonymous, meaning participants will not be asked to provide any personal or identifiable information within the survey (e.g., names, email addresses, or hospital affiliations).

#### Secure Data Collection and Storage:

The survey will be hosted on Qualtrics, a GDPR-compliant platform that ensures secure, encrypted data collection. The data will then be transferred and stored on the Imperial College One drive account of [NAME] for



analysis. Access will only be provided to other members of the research team as required. Collection and storage of data will be done in line with Imperial College policies and the Data Protection Act 2018

**No Sharing of Personal Data:**

The survey is not designed to collect any personal data.

**Data Retention and Disposal:**

Responses will be retained for 10 years in line with institutional guidelines. After this period, all data will be securely deleted following best practices for data protection.

**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.*

Not applicable – No personal data will be collected, stored, or accessed during this study.

**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?**

1. The anonymised survey data will be analysed by [NAME], as a PhD student, at Imperial College London.
2. If needed, [NAME], may seek help from expert analysts for assistance with specific aspects of the data analysis.
3. The analysis will follow institutional data security policies and UK GDPR compliance.

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

Title Forename/Initials Surname

[TITLE] [FORENAME] [SURNAME]

Post

Qualifications MD MSc (Oxon) MRCS (Eng)

Work Address Queen Elizabeth the Queen Mother Wing (QEQM)

St Mary's Campus

10 S Wharf Rd, London

Post Code W2 1PE

Work Email [EMAIL]

Work Telephone [TELEPHONE]

Fax [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

*If longer than 12 months, please justify:*

The anonymised data will be retained for up to 10 years for research purposes, in compliance with institutional guidelines. After this period, the data will be securely deleted. This retention period is necessary to ensure adequate time for data analysis, publication, and potential future research related to the study.

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

Years: 10

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.**

Where will the data be stored?

The anonymised responses will be stored on Qualtrics' Platform, a GDPR-compliant software. Data will then be transferred to the Imperial One Drive Account of [NAME] for data analysis.

Who will have access to the data?

[NAME], as the PhD student, and approved members of the research team (if needed) will have access to the anonymised data.

Data retention and deletion:

The anonymised data will be retained for 10 years, following the study's completion, in accordance with institutional guidelines. After this period, the data will be securely deleted.

**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****A50-1. Will the research be registered on a public database?**

☐ Yes ☒ No

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

As study does not involve clinical trials or interventions, and it is primarily an observational, descriptive study, there is no requirement to register the research on a public database. However, the findings may be published in peer-reviewed journals and presented at relevant professional conferences.

*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)

The findings of the study will be disseminated through:

1. Peer-reviewed scientific journals to ensure broad and credible dissemination of the research outcomes.
2. Presentations at relevant conferences (e.g., those organised by UKIOG, BSG, AUGIS, ACPGBI) to engage with the academic and clinical communities.
3. Reports and publications shared with professional societies to inform training and policy development.

These avenues will ensure that the study's findings are widely accessible to the academic, clinical, and professional communities involved in gastrointestinal endoscopy.

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

Not applicable – This study will not collect identifiable personal data.

**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.*

After the study is completed and the findings have been analysed and published (anticipated within 6 to 12 months of data collection), a summary of the study outcomes will be shared with relevant professional medical societies. These organisations will be encouraged to disseminate the findings to their wider communities, including those who participated in the survey.

**5. Scientific and Statistical Review**

**A54-1. 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:*

1. The scientific quality of the research and the research plan, including the study design and methodology, has been reviewed by my educational supervisor, two ESD endoscopists collaborating with our team, and the Research Governance and Integrity Team (RGIT) at Imperial College London.

2. Feedback from this process has helped to refine the study's objectives, ensure methodological rigor, and align the research with ethical guidelines and institutional standards.

The outcome of the review confirmed the feasibility and scientific integrity of the proposed study, ensuring it is well-positioned to contribute valuable insights to the field of ESD practice in the UK.

*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

[TITLE] [FORENAME] [SURNAME]

Department

Institution Imperial College London

Work Address [DEPARTMENT]

Hammersmith Hospital, 72 Du Cane Road

London, United Kingdom

Post Code W12 0HS

Telephone [TELEPHONE]

Fax [FAX]

Mobile [MOBILE]

E-mail [EMAIL]

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

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

The primary outcome measure for this study is:

Identification of current training pathways for ESD and the techniques and methods used to perform ESD in the UK.

This outcome will be measured through the survey responses, which will collect data on:

1. The types of training and professional opportunities available for UK-based endoscopists performing ESD.
2. The specific techniques, tools, and methods used in current ESD practice in the UK.

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

The secondary outcome measures for this study are:

1. Barriers to the wider adoption of ESD in the UK.
2. Endoscopists' perspectives on the use of robotic devices to assist ESD.
3. Variation in ESD practice across different regions and specialties within the UK.

These secondary outcomes aim to provide a deeper understanding of the factors influencing ESD adoption and practice and help guide future training and policy developments.

**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:

Total international sample size (including UK):

Total in European Economic Area:

*Further details:*

Total UK sample size:

The exact sample size is unknown at this time, as it depends on the number of UK-based endoscopists who respond to the survey. However, we estimate that we will gather a minimum of 30 responses.

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

The study will focus on UK-based participants, so international sample size or EEA sample size is not applicable.

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

The sample size for this study has not been formally estimated. Since this is a survey-based study and the target population is a specific group of UK endoscopists, the exact number of participants is uncertain.

As the study is exploratory in nature, the main goal is to gather a broad range of responses from as many endoscopists as possible. The study will aim to reach a sufficient proportion of UK-based endoscopists to gain meaningful insights into ESD practices across the country.

**A61-1. 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.**

The data will be analysed using both quantitative and qualitative methods to address the study objectives.

**Quantitative Analysis:**

1. The quantitative data (e.g., multiple-choice questions, Likert scales) will be analysed using descriptive statistics to summarise trends and frequencies.
2. Measures such as mean, median, and standard deviation will be used where appropriate for numerical responses.
3. The distribution of responses will be visualised using bar charts, pie charts, and frequency tables to present the distribution of ESD practices, training pathways, and barriers.

**Qualitative Analysis:**

1. The qualitative data (e.g., open-ended responses, free-text answers) will be analysed using thematic analysis.
2. Thematic analysis will involve the following steps:  
Familiarisation with the data by reading through all open-ended responses.  
Coding the responses to identify recurring themes and patterns.  
Categorising the identified codes into broader themes (e.g., barriers to ESD adoption, training needs, views on robotic devices).  
Interpretation of the themes to draw conclusions and provide insights into the qualitative aspects of the study.
3. The qualitative analysis will be performed manually or using software such as NVivo or ATLAS.ti to help in managing and coding the text data efficiently.

**Integration of Quantitative and Qualitative Data:**

1. The quantitative and qualitative findings will be integrated to provide a comprehensive understanding of the ESD training landscape, practices, and barriers in the UK.
2. Key quantitative trends will be compared with the qualitative data to highlight specific challenges or insights in ESD adoption and training.

The combination of descriptive statistics for quantitative analysis and thematic analysis for qualitative responses will ensure a robust evaluation of the data to meet the study's objectives.

## 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

[TITLE] [FORENAME] [SURNAME]

Post Institute of Global Health Innovation; [ROLE]

Qualifications PC KBE FRS FMedSci HonFREng

Employer Imperial College London

Work Address Queen Elizabeth the Queen Mother Wing (QEQM)

St Mary's Campus

10 S Wharf Rd, London

Post Code W2 1PE

Telephone [TELEPHONE]

Fax [FAX]

Mobile [MOBILE]

Work Email [EMAIL]

Title Forename/Initials Surname

[TITLE] [FORENAME] [SURNAME]

Post

Qualifications BEng, MSc, DIC, PhD  
Employer Imperial College London  
Work Address Room 415B, 4th Floor, Bessemer Building  
South Kensington Campus  
London  
Post Code SW7 2BP  
Telephone [TELEPHONE]  
Fax [FAX]  
Mobile [MOBILE]  
Work Email [EMAIL]

Title Forename/Initials Surname  
[TITLE] [FORENAME] [SURNAME]

Post Research Associate in Soft Medical Robotics  
Qualifications PhD  
Employer Imperial College London  
Work Address 3rd Floor, Paterson Wing  
St Mary's Campus  
S Wharf Rd, London  
Post Code W2 1NY  
Telephone [TELEPHONE]  
Fax [FAX]  
Mobile [MOBILE]  
Work Email [EMAIL]

Title Forename/Initials Surname  
[TITLE] [FORENAME] [SURNAME]

Post  
Qualifications  
Employer Imperial College London and Imperial College Healthcare NHS Trust  
Work Address Imperial Centre for Translational and Experimental Medicine (ICTEM)  
72 Du Cane Rd London  
Post Code W12 0NN  
Telephone  
Fax  
Mobile  
Work Email

Title Forename/Initials Surname  
[TITLE] [FORENAME] [SURNAME]

Post  
Qualifications  
Employer Kings College London NHS Foundation Trust  
Work Address King's College Hospital  
Denmark Hill  
London  
Post Code SE5 9RS  
Telephone [TELEPHONE]  
Fax [FAX]

Mobile [MOBILE]  
Work Email [EMAIL]

**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)☐ OtherCommercial status: ☐ Non-Commercial*If Other, please specify:* Imperial College London**Contact person**

Name of organisation Imperial College London

Given name [FORENAME]

Family name [SURNAME]

Address 5th Floor, Sherfield Building, South Kensington Campus

Town/city London

Post code SW7 2BB

Country United Kingdom

Telephone [TELEPHONE]

Fax [FAX]

E-mail [EMAIL]

**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:

**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

[TITLE] [FORENAME] [SURNAME]

Organisation Imperial College London

Address Level 5 Sherfield Building, Imperial College Union,  
Prince Consort Rd, South Kensington  
London

Post Code SW7 2BB

Work Email [EMAIL]

Telephone [TELEPHONE]

Fax [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:01/05/2025

Planned end date:01/11/2025

Total duration:

Years:0 Months:6 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☐ 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)

The study is online, and we will recruit participants from all 4 countries of the UK.

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?**

Internal Monitoring: The study will be monitored by [NAME] and [NAME] with regular check-ins to ensure adherence to the protocol.

Data Monitoring: Survey responses will be regularly checked for quality and completeness.

Institutional Oversight: Imperial College London will provide oversight to ensure compliance with research governance.

These measures ensure ethical conduct and proper monitoring of the study.

**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)

1. Since this is an academic study conducted under Imperial College London, which is the sponsor, the institution's standard academic research insurance will apply.
2. Imperial College London provides insurance coverage for academic research through its internal policies, which are designed to cover any potential legal liabilities related to the research, including harm to participants.
3. No NHS indemnity scheme is required, as the study is not being sponsored by an NHS organisation.

The institution will ensure that appropriate insurance or indemnity arrangements are in place for any potential legal liability related to the design of the study. If required, evidence of this coverage can be provided upon request.

*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)

1. Since this study is designed by an academic researcher ([NAME]) and is being conducted under Imperial College London, the institution provides insurance coverage for academic research through its internal policies.

2. Imperial College London holds responsibility for the design and conduct of the research, and the insurance arrangements cover any potential legal liabilities arising from the study's design, including harm to participants.

3. As the study is not sponsored by an NHS organisation, NHS indemnity schemes do not apply.

The institution will ensure that appropriate insurance or indemnity arrangements are in place for any potential legal liability related to the design of the study. If required, evidence of this coverage can be provided upon request.

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)

1. Since this study is based on survey data collection and does not involve direct patient interaction or clinical procedures, there is no direct risk of harm to participants in the conduct of the research.

2. The study is focused on survey responses from UK-based endoscopists, and participants will be recruited through professional networks, with no involvement of NHS patients or clinical environments.

3. Imperial College London, as the sponsor and institution conducting the research, provides insurance coverage for the investigators and collaborators involved in the study through its internal academic research insurance policy. This coverage extends to all research activities carried out by the investigators and collaborators associated with the study.

Therefore, the insurance and indemnity arrangements provided by Imperial College London will cover any potential liability arising from the conduct of the research. Since the study is not based in NHS settings or private practices, no separate NHS indemnity scheme is required. Evidence of insurance coverage can be provided upon request.

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 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

IN2

- ☐ NHS/HSC Site  
☒ Non-NHS/HSC Site

Institution name Imperial College London  
Department name Department of Surgery and Cancer  
Street address 10 S Wharf Rd, London  
Town/city W2 1PE  
Post Code SW7 2AZ  
Country United Kingdom

Forename [FORENAME]  
Middle name  
Family name [SURNAME]  
Email [EMAIL]  
Qualification [QUALIFICATIONS]  
(MD...)  
Country United Kingdom