Student Audit and Research in Surgery (STARSurg) Collaborative

REspiratory COmplications after abdomiNal Surgery (RECON)

A student-led observational prospective audit of postoperative pulmonary complications after major abdominal surgery

Study protocol V2.0

08 February 2019

Study video available: http://bit.ly/RECONvideo

e-Learning modules available: learning.starsurg.org

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Project Timeline

Dates	Description
17th Oct 2018	RECON Regional Lead recruitment opens
31st Oct 2018	Recruitment for RECON Regional Leads closes
23rd Nov 2018	Online launch of RECON Protocol and Training Materials
7th Dec 2018	RECON Project Launch at National Research Collaborative Meeting, Manchester
14th Jan 2018	RECON Investigator Training Meeting and Research Skills Event, Royal College of Surgeons in London
Jan 21st – 3rd Feb 2019	Start of data collection period 1 (30-day follow-up ends 5th Mar 2019).
4th – 17th Feb 2019	Start of data collection period 2 (30-day follow-up ends 19th Mar 2019).
18th Feb - 3rd Mar 2019	Start of data collection period 3 (30-day follow-up ends 2nd Apr 2019).
4th – 17th Mar 2019	Start of data collection period 4 (30-day follow-up ends 16th Apr 2019).
16th May 2019	REDCap database locked, final data submission deadline.
23rd – 25th Sept 2019	RECON results presented to European Society of Coloproctology meeting.

About STARSurg

Student Audit and Research in Surgery (STARSurg) is a student-led, national research collaborative empowering medical students and junior doctors to conduct high-quality, protocol-driven audit and research in a multicentre setting. Students contribute data to national studies whilst gaining an understanding of clinical academia, audit and research methodology, and ethical considerations in research[1].

The 'collaborative' trainee-led model for 'snapshot' audit has been pioneered from the West Midlands, developing from as regional networks of surgical registrars to national and international groups across specialties and around the world[2]. These networks have delivered major multicentre projects including cohort studies and randomised controlled trials. In accordance with National Research Collaborative (NRC) authorship guidelines[3], these studies typically use a single corporate author model, where all publications are listed under a single collaborative name with all contributing authors listed as PubMed-citable collaborators[4]. This seeks to democratise the publication process and flatten traditional research hierarchies.

STARSurg has now delivered five national audits of surgical and perioperative practice: STARSurg-1[5], Determining Surgical Complications in the Overweight (DISCOVER) [6], Outcomes after kidney injury in surgery (OAKS)-1[4], OAKS-2, and Ileus Management International (IMAGINE)[7]. To date, we have engaged 5,400 collaborators in our projects from over 170 centres in the UK and Ireland, with in data being collected on more than 20,000 patients. This has resulted in 15 peer reviewed papers published within high impact journals, including the British Journal of Surgery (BJS), British Journal of Anaesthesia and Anaesthesia. Members of the steering committee and Regional Leads have given over 80 presentations at regional, national and international conferences (see www.starsurg.org).

STARSurg is part of the Surgical Research Gateway (SURG) Foundation, a UK registered charity. We are also proud partners of the *BJS Society* who provide invaluable support for the day-to-day running of STARSurg activities and our infrastructure.

Introduction

Postoperative pulmonary complications (PPCs) are common after abdominal surgery, with a spectrum of severity. PPCs range from minor complications such as partial atelectasis, to life threatening complications such as pneumonia, pulmonary aspiration and adult respiratory distress syndrome[8, 9]. PPCs account for 3 to 30% of complications in all patients undergoing abdominal surgical procedures[10-13]. Various peri-operative risk factors have been found to increase the risk of PPCs, including smoking, surgery involving the thorax, presence of severe underlying respiratory disease, and intraoperative neuromuscular blockade[10, 11, 14-16]. PPCs remain an important focus for quality improvement projects and targeted research with a strong association with postoperative morbidity and mortality. In two studies to date, 30-day mortality patients with PPCs was up to six times higher than patients without them (18.5% versus 2.5%) [17, 18]. PPCs have also been found to be associated with worse long-term outcomes and increased costs to healthcare [19].

Despite the negative impact of PPCs on short and long-term outcomes being well recognised, there is a paucity of robust evidence regarding the risk factors, incidence, and outcomes in major abdominal surgery and anterior abdominal wall hernia surgery in the UK[19, 20]. Several trials have been conducted exploring preventive measures for PPCs[21-25], however there are currently limited specific UK guidelines regarding their prevention and/or management. The Royal College of Anaesthetists Guidelines for the Provision of Anaesthesia Services (GPAS) and Association of Anaesthetists of Great Britain and Ireland (AAGBI) provide a number of risk reduction strategies and standards within the pre-, intra- and post-operative periods. In addition, relevant Enhanced Recovery After Surgery (ERAS) protocols exist to minimise postoperative infective complications[26]. In 2018, an intervention bundle has been derived using a Delphi consensus process; POPC-CB (Post-Operative Pulmonary Complications – Care Bundle)[27], and formal evaluation of its effectiveness in underway.

A recent regional collaborative audit analysed PPCs across six UK hospitals[10], collecting data on 268 patients across a 2-week period, demonstrating feasibility of collecting PPC data using a snapshot audit model. RECON (REspiratory COmplications after abdomiNal Surgery) aims to increase our understanding of variability and adherence to risk reduction measures for PPCs following major abdominal and hernia surgery through a multi-centre audit across UK and Ireland.

Audit Standards

Relevant audit standards from Royal College of Anaesthetists, Association of Anaesthetists of Great Britain and Ireland and Enhanced Recovery After Surgery (ERAS) guidelines

Pre-operative Standards:	
1. Weight and BMI should be recorded.	**Royal College of Anaesthetists: Guidelines for the Provision of Anaesthesia Services 2018** • **Pre-operative Assessment and Preparation Recommendation 3.23:** Operating lists should include the patients' weight and body mass index (BMI).
2. Cardiopulmonary exercise testing for high-risk patients	**Royal College of Anaesthetists: Guidelines for the Provision of Anaesthesia Services 2018** • **Pre-operative Assessment and Preparation Recommendation 5.16**: Cardiopulmonary exercise testing or functional assessment for high-risk patients should be carried out.

Intra-operative Standards:	
1. WHO Surgical Safety Checklist should be used for all procedures.	**Royal College of Anaesthetists: Guidelines for the Provision of Anaesthesia Services 2018** • **Pre-operative Assessment and Preparation Recommendation 5.8**: The WHO's Surgical Safety Checklist should be used and is fully endorsed by the RCoA as the instrument for promoting team working and patient safety.
2. Operative long-acting NMBA should not be used routinely.	**ERAS for gastrointestinal surgery: consensus statement for anaesthesia practice** [28] • **Neuromuscular blockade (NMB) and neuromuscular monitoring**: Long-acting Neuromuscular blocking agents (NMBA) should be avoided. At the end of surgery, it is important to restore neuromuscular function to preoperative levels and avoid residual muscle paralysis.
3. Monitoring using quantitative peripheral nerve stimulators should be used in conjunction with NMB drugs	**Association of Anaesthetists of Great Britain and Ireland (AAGBI): Recommendations for standards of monitoring during anaesthesia and recovery 2015** [29] • A measure of neuromuscular blockade, using a peripheral nerve stimulator, is essential for all stages of anaesthesia when neuromuscular blockade drugs are administered. This is best monitored using an objective, quantitative peripheral nerve stimulator.

4. Recovery from blockade should be assessed as a train-of-four ratio > 0.9.	**Association of Anaesthetists of Great Britain and Ireland (AAGBI): Recommendations for standards of monitoring during anaesthesia and recovery 2015** [29] A more reliable guarantee of return of safe motor function is evidence of a train-of-four ratio > 0.9.
5. Patients at risk of PONV should receive at least two intraoperative antiemetic agents.	**ERAS for gastrointestinal surgery: consensus statement for anaesthesia practice** [28] • **Preventing and treating postoperative nausea and vomiting (PONV)**: Aggressive PONV prevention strategy should be included. All patients with 1 – 2 risk factors should receive a combination of two antiemetics. Patients with 3 – 4 risk factors should receive 2– 3 antiemetics.

Post-operative Standards:	
1. Opioid-sparing analgesic strategies should be used.	**ERAS for gastrointestinal surgery: consensus statement for anaesthesia practice** [28] • **Pain management**: Opioid-sparing analgesic strategies, including regional analgesia techniques, should be implemented in a context of a multimodal analgesic regimen.
2. Routine nasogastric decompression should be avoided in elective surgery	**ERAS for gastrointestinal surgery: consensus statement for anaesthesia practice** [28] • **Nasogastric (NG) intubation**: Routine nasogastric decompression following elective abdominal surgery should be avoided.
3. Early recognition of patients needing specialist postoperative input	**Royal College of Anaesthetists: Guidelines for the Provision of Anaesthesia Services 2018** • **Provision of Postoperative Care Recommendation 3.23:** Mechanisms for the early recognition of patients requiring specialist postoperative input from geriatrician-led services and/or critical care should be developed. These should include patients at risk of or presenting with delirium, multiple medical complications, functional decline or complex discharge planning.

The RECON audit is designed to be complementary to ongoing quality improvement efforts in acute and elective surgical care, for example the Perioperative Quality Improvement Project (PQIP: pqip.org.uk) and the UK National Emergency Laparotomy audit (NELA: www.nela.org.uk).

Methods

1. Summary:

Mini-teams of 1 to 2 medical students and one junior doctor per speciality group per data collection period, at each participating centre will prospectively collect data over a continuous 14-day period on consecutive patients undergoing major abdominal surgery, with follow-up to 30 postoperative days. All mini-teams should be supervised by a consultant in surgery and/or anaesthesia or critical care.

2. Study Aims:

- ***Primary Aim:*** To audit compliance to pre-, intra-, and postoperative Royal College of Anaesthetists (RCOA) and Enhanced Recovery After Surgery (ERAS) guidelines for reducing risk of postoperative pulmonary complications.
- ***Secondary Aims***
    - To characterise incidence of postoperative pulmonary complications following major abdominal surgery.
    - To identify risk factors associated with postoperative pulmonary complications.
    - To explore association of postoperative pulmonary complications with short term outcomes (mortality, critical care admission, length of stay).
    - To explore associations between perioperative preventative measures and rate of postoperative pulmonary complications.

3. Project Timeline:

- The suggested overall data collection period will be Monday 21st January 2019 to Saturday 16th April 2019. Each mini-team will collect data over a 2-week, consecutive period with subsequent 30-day follow-up:
    - Period 1: 00:00 21st Jan 2019 – 23:59 3rd Feb 2019 (+ 30 Day Follow-up)
    - Period 2: 00:00 4th Feb 2019 – 23:59 17th Feb 2019 (+ 30 Day Follow-up)
    - Period 3: 00:00 18th Feb 2019 – 23:59 3rd Mar 2019 (+ 30 Day Follow-up)
    - Period 4: 00:00 4th Mar 2019 – 23:59 17th Mar 2019 (+ 30 Day Follow-up).
- Patients should be included if their operation started (defined as 'knife-to-skin' time) within the time period during the data collection periods as specified above.

- Additional data collection periods may be added later in the study, to give flexibility to include further UK or international centres with logistical difficulties in study start up.

4. Centre Eligibility:

- RECON is open to any hospital in the UK and Ireland that performs both elective and emergency major abdominal surgery.
- All participating centres are required to register the RECON study according to local regulations. In the UK, RECON has been approved for registration as an audit of practice by NHS East of Scotland REC Committee.
- Internationally, individual study investigators are responsible for ensure the correct audit, ethical or departmental approval has been achieved prior to commencing data collection (this can be registered as an audit or service evaluation).
- Evidence of successful audit registration must be sent to their university's regional lead prior to commencement of data collection.
- Following completion of the RECON audit, it is a requirement of participation that mini-teams should **present the audit findings** to their local surgery and/or audit departments.

Providing feedback on the audit's findings to your department's clinicians is an essential step in the audit loop. Presenting local results will help collaborators develop analytical and presentation skills and will boost their CVs.

5. Patient Eligibility:

Summary: Consecutive adult patients undergoing emergency or elective abdominal visceral resection, reversal of stoma, open vascular surgery, anterior abdominal wall hernia repair, or transplant surgery through any operative approach.

Inclusion criteria:

- **Age**: Adult, 16 years or above.
- **Incision:** Any abdominal incision and configuration is eligible for inclusion.
- **Procedure:** A comprehensive list of included procedures can be found in **Appendix A**. RECON will include major abdominal surgery across multiple specialty groups, including one or more of the following operations:

- Visceral resection, defined as complete transection and removal of a segment of the oesophagus, stomach, small bowel, liver, pancreas, gallbladder, colon, appendix, rectum, kidney, bladder, ovary and/or uterus, including multivisceral resections.
- Reversal of stoma (ileostomy or colostomy).
- Open repair of abdominal aortic aneurysm or vascular bypass procedure including an abdominal incision.
- Anterior abdominal wall incisional hernia or parastomal hernia repair.
- Transplant surgery, including renal, liver or pancreas transplant and live donor nephrectomy.

- **Approach:** Open, laparoscopic, laparoscopic converted, robotic, robotic converted procedures are all eligible.
- **Urgency**: Patients undergoing planned (elective or expedited) or unplanned (emergency) surgery.

Exclusion criteria:

- **Procedures:** Abdominal surgeries without resection (e.g. anti-reflux surgery, rectopexy, sterilisation), and Caesarean sections (C-sections) are excluded. Groin (femoral, inguinal), and primary (i.e. not incisional) umbilical, paraumbilical and ventral hernia repairs are also excluded. Vascular surgeries that only have a groin and/or limb component only with no abdominal incision are not eligible.
- **Indication:** Procedures performed for a trauma indication (blunt or penetrating) are excluded.
- **Extent of surgery:** Resections without complete transection and removal of viscera are not eligible for inclusion (e.g. myomectomy, polypectomy, wedge resection of rectum).
- **Incision:** Any procedures performed without an abdominal incision (e.g. Natural Orifice Transluminal Endoscopic Surgery, transurethral surgery, transrectal endoluminal surgery, total vaginal hysterectomy) are not eligible.
- **Urgency:** Planned day case procedures (discharge home on the same day as surgery) are excluded.
- **Return to theatre**: Each patient should only be included in the study *once*. Patients returning to theatre due to complications following earlier surgery can be included, as long as their indexed procedure has not already been included in the RECON study.

*You should collect data on **all consecutive patients** operated at your centre during the data collection period. This means that all eligible patients should be included.*

Strategies to identify consecutive eligible patients could include:

- *Daily review of elective theatre lists.*
- *Daily review of handover sheets/ emergency admission and ward lists.*
- *Daily review of theatre logbooks (both elective and emergency).*

6. Covariates:

Data will be collected on audit standards, and confounding factors for risk of PPCs to permit accurate risk adjustment of outcomes. Without appropriately adjusting for risk factors, it is likely that any findings would be biased and unable to be appropriately analysed on a national scale. A full list of required data fields is available in **Appendix B**, and on the REDCap database.

7. Outcome Measures and Follow-up:

Primary outcome measure: Adherence to selected Royal College of Anaesthetists (RCOA) and Enhanced Recovery After Surgery (ERAS) guidelines for prevention of PPCs (percentage, %).

Secondary outcome measures:

- 7-day and 30-day PPC rate, defined according to (1) StEP (Standardized Endpoints for Perioperative Medicine) definition, including pulmonary complications of a common pathophysiological mechanism: atelectasis, pneumonia, aspiration, and adult respiratory distress syndrome[9] (see **Appendix C: Definitions of Key Outcomes**); (2) Clinical diagnosis only (included as a sensitivity analysis).
- 30-day other pulmonary complication rate.
- 30-day postoperative complication rate (defined according to the Clavien-Dindo classification: see **Appendix C: Definitions of Key Outcomes**).
- Critical care bed days up to 30 days postoperatively.
- Length of in-patient stay up to 30 days postoperatively.

Follow-up should be performed in line with current routine practice within each hospital settings. No additional telephone, in-person or questionnaire based follow-up is required. Source data may be acquired from hospital in-patient notes, clinical electronic systems, or outpatient letters.

Prior to collecting data, all collaborators will be required complete the **mandatory e-learning** *modules available from the RECON project online hub: www.starsurg.org/project*

These include: ***(1)*** *RECON Study protocol;* ***(2)*** *Surgical incisions;* ***(3)*** *Postoperative Pulmonary Complications;* ***(4)*** *Clavien-Dindo classification;* ***(5)*** *Data governance.*

8. Local Project Registration & Data Governance:

RECON should be registered in the UK and ROI as clinical audit or service evaluation. It is the responsibility of the local mini-team at each site to identify a local consultant surgeon to supervise them and ensure registration.

Confirmation that ethical review is not required for RECON within the UK is available in **Appendix D**. Examples of audit registration forms can be found at the online project hub. When registering RECON as a clinical audit or service evaluation you can emphasis that:

- RECON is a national audit/service evaluation, and all data collected will measure current practice in the UK and Ireland, and allow benchmarking against recognised standards.
- No changes to normal patient pathways/ treatment will be made, including no changes to follow-up for included patients.
- All RECON data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application [30]. REDCap allows collaborators to enter and store data in a secure system. Collaborators will be given secure REDCap project server login details, allowing secure data storage on the REDCap database.

Collaborators in the UK should seek their trust's Caldicott Guardian's permission to submit data to the REDCap system. **No data should be uploaded to REDCap prior to written (or electronic/email) approval from the Caldicott Guardian**. No patient identifiable information (e.g. NHS numbers) should be uploaded or stored on the REDCap database without explicit permission from the trust's Caldicott Guardian.

All data should be handled in accordance with local data governance policies, and the STARSurg Data Governance e-learning module (available on-line at: www.starsurg.org). This e-learning module sets out comprehensive guidelines on the management of data through all stages of the project. All collaborators should abide by these when participating in RECON.

REDCap accounts will not be issued until evidence is sent to your university's regional lead that the following approvals are in place at your centre:

- *Successful registration of RECON with the audit department.*
- *Caldicott Guardian permission for data to be submitted to REDCap.*

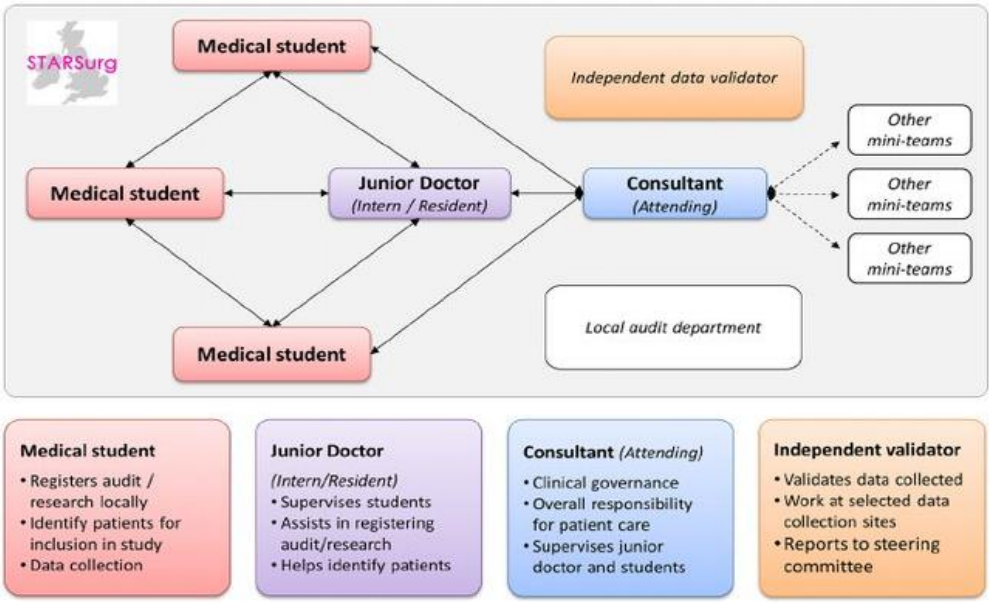
9. Quality assurance:

Design: This protocol was written with guidance from an expert cross-speciality advisory group. This has been informed by prior pilot research on this topic by the West Midlands Research Collaborative (WMRC) [10].

Training: The protocol will be formally launched at the National Research Collaborative Meeting on 7th December 2018. Investigators will be trained face-to-face in the study design and methodology at the Royal College of Surgeons RECON Investigator Meeting in London on 14th January 2019. RECON Regional Leads are encouraged to hold local meetings with collaborating teams at their medical school to brief them on the protocol, and to feedback any local issues or questions raised. To ensure collaborators understand the study topic and diagnosis of PPC, inclusion criteria, surgical incision, application of the Clavien-Dindo classification and the principles of data governance, they will all be asked to complete a series of online ***e-learning modules*** (pass mark is 100%) prior to starting data collection (online at: www.starsurg.org).

Project team structure: Medical students will take the lead in disseminating and delivering this study alongside junior doctors. These 'mini-teams' should be supervised by up to two consultants (one surgeon, one anaesthetist) at each site (**Figure 1**). Each team should include at least one qualified doctor to provide additional local support for participating medical students.

Figure 1: STARSurg "Mini-team" structure, roles, and responsibilities.



Data completeness: Following data collection, only data sets with >95% data completeness will be accepted for pooled national analysis. To emphasise the importance of data completeness to collaborators, data collection periods with >5% missing data points will be excluded from the study and collaborators from those periods withdrawn from the published list of citable collaborators.

Validation: This methodology for student-driven snapshot audit has been widely validated across multiple datasets both nationally in the UK and Ireland and internationally demonstrating high levels of case ascertainment (typically 90 to 95%) and data accuracy (96 to 98%) [4-6, 31, 32].

Patient and service user involvement: The James Lind Alliance (JLA) is a non-profit initiative established in 2004 [33]. It brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs) to identify and prioritise unanswered questions or evidence uncertainties that they agree are the most important. RECON will collect data to address the following JLA priority areas in Perioperative Care:

- How can patient care around the time of emergency surgery be improved?
- What outcomes should we use to measure the 'success' of anaesthesia and perioperative care?
- How can we improve recovery from surgery for elderly patients?
- How can pre-operative exercise or fitness training, including physiotherapy, improve outcomes after surgery?

10. Authorship:

In accordance with National Research Collaborative (NRC) authorship guidelines [3], all research outputs from RECON will be listed under a single corporate authorship ("STARSurg Collaborative"). All collaborators will be listed as PubMed-citable collaborators within the STARSurg Collaborative in accordance with the roles defined below (so long as the minimum requirements for authorship are met).

- **Writing Group:** A group of medical students, junior doctors and external advisory board members responsible for the overall scientific content, data analysis, and preparation of research manuscripts.

- **Steering Committee**: A core group of medical students and junior doctors who have overall responsibility for protocol design, project co-ordination, and data handling.

- **Statistical Analysis**: A small team of dedicated statisticians who take overall responsibility for the statistical analysis plan and quality assurance of data analysis.

- **External Advisory Group**: A panel of cross-disciplinary field experts who are able to ensure contextual and scientific relevance of the protocol design, data fields and data interpretation.

- **Regional Leads**: A network of medical students across all medical schools. They are responsible for co-ordinating mini-teams at local hospitals, and act as a link between mini-teams / hospital leads, and the steering committee. Requirements for authorship on RECON outputs include:
    - Active engagement with dissemination of RECON and other STARSurg activities at their local medical school.
    - Effective and responsive communication with the STARSurg steering committee, and with local collaborators throughout their time as Regional Leads.
    - Recruitment of at least two mini-teams at each centre where students from their medical school have surgical placements, with a minimum of one centre meeting the criteria for inclusion within the RECON dataset.
    - Responsible for representing STARSurg at regional educational and research meetings.

- **Local (Hospital) Leads**: A single lead point of contact for data collection at each site who has overall responsibility for site governance registration and coordinating handover between local collaborator teams. Local Leads should be prospectively identified by Regional Leads (although remain an optional role), and these are recommended to be the junior doctor or a senior medical student within the mini-team, and only one person can fulfil this role. Minimum requirements for authorship on RECON outputs include:
    - Primary person responsible in obtaining local approvals for conduct of the RECON audit (e.g. registration of the audit, seeking Caldicott guardian permission to upload data to REDCap).
    - Active involvement in a mini-team during a data collection period at the centre which meets the criteria for inclusion within the RECON dataset.
    - Co-ordination of handover between all local collaborator teams at the centre, and involvement in local dissemination of RECON and other STARSurg activities.
    - Presentation of local results at their centre from the RECON audit (or otherwise arranges another collaborator to present on their behalf).

- **Local collaborators (data collectors)**: A team of up to 3 people responsible for data collection per specialty group over a specific 2-week period at a particular centre. This should ideally be formed by 1-2 medical students collaborating with a junior doctor (FY1 to senior registrar grade). Reflecting the cross-specialty nature of the RECON study, up to one mini-team (3 members) will be permitted *per specialty group* (if these surgeries are conducted by separate speciality teams at the centre), defined as:

  (1) Gastrointestinal and hepatopancreatobilary surgery
  (2) Vascular and transplant surgery
  (3) Urological surgery
  (4) Gynaecological surgery

  This gives a *maximum* of 12 collaborators per data period per hospital. Please note that, mini-team size and the total number of collaborators required at each site will be at the discretion of the regional lead according to the specialty organisation and case load of each hospital. Minimum requirements for authorship on RECON outputs include:
    - Compliance with local audit approval processes and data governance policies.
    - Active involvement in data collection over at least one data collection period at a

centre which meets the criteria for inclusion within the RECON dataset.

- Collaboration with the regional / local lead to ensure that the audit results are reported back to the audit office / clinical teams.

- **Supervising Consultant**: Data collection in each hospital must be supervised by up to two consultants, one in a surgical specialty, and one in anaesthesia or critical care. Minimum requirements for authorship on RECON outputs include:
  - Sponsorship of local audit registration, and responsible to ensure local collaborators act in accordance with local governance guidelines.
  - Inclusion of at least one data collection period at their centre which meets the criteria for inclusion within the RECON dataset.
  - Facilitation of local audit results presentation and support of appropriate post-audit interventions.
  - Completion of workplace-based assessments for students or trainees (ePortfolio/ISCP), if requested.

Criteria for centre inclusion within RECON:

- Obtain of all appropriate local approvals for conduct of the RECON audit.
- Successful completion of at least one data collection period at the centre (with a minimum of one eligible patient per period included). Individual data collection periods will only be included when:
  i. >95% data completeness has been achieved.
  ii. All data for the period has been uploaded within the specified deadlines.

Please note if these criteria are not met, then the contributing mini-team and/or the centre may be removed from the dataset and authorship list (please get in contact as soon as potential issues arise so we can support as many centres to be included as possible). See **Appendix E** for advice to help ensure for successful inclusion of your centre in the RECON audit.

11. Bolt-On Project:

The RECON audit will provide opportunities for a select number of sites participating the main project to take part in an enhanced “Bolt-On” audit. This project will have the same patient eligibility criteria and recruitment periods as the main RECON project, and this will involve collection of additional perioperative data fields (see the project hub for the “Bolt-On” protocol: https://starsurg.org/recon-project-18-19). Collaborators must have engagement of a local anaesthetic trainee (core trainee or specialist registrar) and anaesthetic consultant as part of the mini-team(s) in collecting the required data fields for the RECON “Bolt-On”.

One additional mini-team member will be permitted per specialty group, per data collection period, per centre where the “Bolt-On” Audit Form is completed.

It is anticipated that this “Bolt-On” audit will take place in approximately 10-15% of all RECON centres. Please contact your regional lead if interested to take part.

Appendix A: Included Operative Procedures

Upper gastrointestinal	• Oesophagogastrectomy (excision of oesophagus and stomach) • Oesophagectomy (excision of oesophagus). • Gastrectomy (excision of stomach). • Duodenectomy / Small bowel resection (excision of small bowel).
Hepatopancreatobilary	• Cholecystectomy (total or partial excision of gallbladder). • Hepatectomy (segmental or partial excision of liver) • Excision of bile duct • Pancreatectomy (total or partial excision of pancreas, including Whipple's procedure). • Splenectomy (total or partial excision of spleen).
Lower gastrointestinal	• Appendicectomy (Total or partial excision of appendix). • Panproctocolectomy (total excision of colon and rectum). • Pancolectomy (total excision of colon). • Right colectomy (excision of right colon). • Transverse colectomy (excision of transverse colon). • Left colectomy (excision of left colon). • Sigmoid colectomy (excision of sigmoid colon). • Excision of rectum (including anterior resection or Hartmann's procedure).
Stoma	• Reversal or closure of ileostomy. • Reversal or closure of colostomy (include reversal of Hartmann's).
Vascular	• Open replacement or repair of aneurysmal segment of aorta. • Vascular bypass surgery including abdominal component (e.g. aortobifemoral or aortounifemoral bypass)
Endocrine	• Adrenalectomy (excision of adrenal gland).
Transplant	• Transplantation of liver • Transplantation of pancreas (or islet cell transplantation) • Transplantation of kidney • Live donor nephrectomy (excision of kidney for transplant indication)
Gynaecology	• Trachelectomy or cervicectomy (excision of cervix uteri). • Hysterectomy (total or partial excision of uterus). • Salpingo-oophorectomy (total or partial excision of fallopian tube or ovary).
Urology	• Nephrectomy (total or partial excision of kidney). • Ureterectomy (excision of ureter). • Cystectomy (total or partial excision of bladder). • Prostatectomy (total or partial excision of prostate).
Hernia	• Anterior abdominal wall Incisional hernia repair. • Parastomal hernia repair.
Other	• Multivisceral resection (resection of several viscera in combination) • Other (free text)

Appendix B: Data Dictionary

Pre-operative Data Fields	Required data (definition / comment)	Suggested source(s)
1. Patient age	**Years** (whole years at the time of operation)	– Clinical notes
2. Patient gender	**Male** / **Female**	
3. Patient height	**Meters** (record to two decimal places)	– Drug charts – Clinical notes
4. Patient weight	**Kilograms** (record to one decimal places)	
5. Patient ASA grade	**Grade I-V** (Full ASA classification available at: https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system).	– Anaesthetic notes
6. History of cardiac disease	**Yes** (myocardial infarction, angina, congestive cardiac faiure, hypertension) / **No**	– Admission clerking – Anaesthetic notes – Outpatient letters
7. History of chronic respiratory disease	**Yes** (asthma, chronic obstructive pulmonary disease, bronchiectasis, pulmonary fibrosis, lung cancer, obstructive sleep apnoea, other) / **No**	
8. History of immunosuppression	**Diabetes** (diet controlled, tablet controlled, insulin controlled), **HIV** (antiretroviral therapy, no/unknown), **Steroids** (yes: oral, intravenous or topical e.g. prednisolone, fludrocortisone, dexamethasone, no), **Other immunosuppressive drug** (yes, e.g. azathioprine, methotrexate, biologic agents, no), **Chemotherapy** (yes, current chemotherapy or if the last cycle was within 12 weeks of operation, no).	
9. History of neurological disease	**Yes** / **No**	
10. History of liver disease	**Yes** / **No**	
11. Previous lung surgery	**Yes** / **No**	
12. Bowel obstruction at time of admission	**Yes, small bowel** / **Yes, large bowel** / **No.** ***If Yes:*** Was an NG tube inserted pre-operatively; **Yes** / **No**	
13. Recent upper or lower respiratory tract infection	**Yes** (present on admission) / **Yes** (within past 1 month, but recovered by time of admission) / **No** *Diagnosis requires clinical/radiological diagnosis, fever ≥ 38°C* ***AND*** *antibiotic treatment given*	– Clinical notes – PACS software
14. Pre-operative oxygen saturation (SaO2)	**>96%** / **91-95%** / **≤90%** (as measured by pulse oximetry, on 21% Fraction of Inspired Oxygen (room air))	– Observation charts
15. Last pre-operative blood test values	**Haemoglobin** (grams / litre) / **Albumin** (grams / litre) / **estimated Glomerular Filtration Rate** (ml / min)	– Pathology systems
16. Smoking status	**Current** (includes those who stopped smoking within 6 weeks), **Previous**, **Never**.	– Admissions clerking – Clinical notes
17. Pre-operative smoking cessation referral	**Yes – intensive** / **Yes – one-off** / **No or unknown**	
18. Pre-operative assessment	***If elective***: Pre-admission anaesthetic assessment clinic (**Yes** / **No**) or cardiopulmonary exercise testing (**Yes** / **No**). ***If emergency:*** **Yes** (inpatient perioperative or elderly medicine, including physician or nurse specialist) / **No**	– Clinical letters – Clinical notes
19. Formal pre-operative prehabilitation	**Supervised exercise programme** (home or in hospital) / **Inspiratory muscle training** (physiotherapist) / **No**	– Admissions clerking
Abbreviations: ASA = American Society of Anaesthesiologists; Hb = Haemoglobin; PACS = Picture Archiving and Communication; SpO2 = Peripheral capillary oxygen saturation.		

Intra-operative Data Fields	Required data (definition / comment)	Suggested source(s)
1. Operative urgency (NCEPOD Classification of Intervention)	**Immediate** (Immediate life, limb or organ-saving intervention – resuscitation simultaneous with intervention. Normally within minutes of decision to operate). **Urgent** (Intervention for acute onset or clinical deterioration of potentially life-threatening conditions, for those conditions that may threaten the survival of limb or organ, for fixation of many fractures and for relief of pain or other distressing symptoms. Normally within hours of decision to operate) **Expedited** (requiring early treatment where the condition is not an immediate threat to life, limb or organ survival. Normally within days of decision to operate). **Elective** (Intervention planned in advance of routine admission to hospital).	– Operative note – Admissions clerking – Clinical notes
2. Primary indication	**Malignant / Benign**	
3. Operative procedure	**Select main procedure** from Appendix C (closest option from the drop-down list or enter as free text by selecting "other").	
4. Operative approach	**Open** (performed exclusively using instruments inserted in to the abdomen through a surgical incision). **Laparoscopic** (performed exclusively using instruments inserted in to the abdomen through small ports) or **Laparoscopic-assisted** (laparoscopic surgery in which an incision is enlarged to deliver a specimen or to insert a gloved hand into the abdomen). **Laparoscopic converted to open** (surgery planned to be performed laparoscopically but for unforeseen reasons the decision was made to change to an open approach). **Robotic** (robot-assisted surgery with no conversion to either laparoscopic or open approaches). **Robotic converted to open** (surgery planned to be performed robotically but for unforeseen reasons the decision was made to change to an open approach).	– Operative note – Clinical notes – Theatre records
5. Operative incision(s)	**Select the picture(s) which best represent the incision made (**see REDCap for pictures).	
6. Operative contamination	**Clean** (Gastrointestinal (GI) and genitourinary (GU) tract not entered). **Clean-Contaminated** (GI or GU tracts entered but no gross contamination). **Contaminated** (GI or GU tracts entered with gross spillage or major break in sterile technique). **Dirty** (There is already contamination prior to operation, e.g. faeces or bile).	
7. Type of intubation	**Endotracheal (ET) Tube** (a tube placed into the trachea to ventilate the lungs during surgery) **Laryngeal Mask Airway (LMA) or I-Gel™** (a tube with a cuff which sits in the larynx above the glottis).	– Anaesthetic notes
8. Pre-induction provision of chlorhexidine mouthwash	**Yes / No**	– Clinical notes
9. Dexamethasone on induction	**Yes / No**	– Anaesthetic notes
10. Neuromuscular blocking drug use	**Yes, short acting** (Suxamethonium (succinylcholine), Mivacurium, Atracurium, Vecuronium) / **Yes, intermediate acting** (Rocuronium, Cisatracurium) / **Yes, long acting** (Pancuronium, Pipecuronium) / **No**	– Anaesthetic notes

11. Neuromuscular reversal agent use	**Yes** (sugammadex or neostigmine) / **No**	– Anaesthetic notes
12. Number of intra-operative anti-emetics used	**1**, **2**, **3**, **4**, **>4** (See examples of antiemetic drugs on REDCap - exclude any dexamethasone given at induction).	– Anaesthetic notes
13. Was the WHO checklist used?	**Yes** / **No**	– Clinical notes
14. Duration procedure	**Minutes** (from knife-to-skin to closure of skin).	– Theatre records – Anaesthetic chart
15. Intraoperative blood transfusion	**Yes** / **No**	– Anaesthetic chart
Abbreviations: NCEPOD: National Confidential Enquiry into Patient Outcome and Death. WHO = World Health Organisation		

Post-operative Data Fields	Required data (definition / comment)	Suggested sources
1. Critical care admission	**Yes, direct admission from theatre to critical care** (including intensive care and high dependency units) / **Yes, admission from ward to critical care** / **No** ***If Yes,*** *direct admission from theatre to critical care:* **Transferred intubated and ventilated** / **extubated before transfer**	– Clinical notes
2. Critical care bed days *(if yes)*	**Number** (days from first post-operative day to day of discharge from critical care. If the patient has not been discharged prior to the end of 30-day follow-up, enter '31').	
3. Prophylactic use of continuous positive airway pressure (CPAP) in the first 24 hours postoperatively	**Yes** (full face CPAP mask, or nasal high-flow CPAP mask) / **No**	
4. Nasogastric tube present in first 24 hours	**Yes, wide bore** (i.e. for decompression of GI tract) / **Yes, fine bore** (i.e. for Enteral Nutrition) / **None**	
5. Analgesia use in the first 24 hours *(select all that apply)*	**Local analgesia** (anaesthetic that acts at the surgical wound or peri-wound site to provide analgesia e.g. wound catheter). **Regional analgesia** (continuous infusion of anaesthetic into the spinal epidural / subarachnoid space to provide analgesia e.g. epidural / spinal analgesia). ***If yes*** – number of days from first post-operative day to day that regional analgesia was stopped. **Continuous intravenous opioid infusion** (e.g. alfentanil infusion). **Patient controlled analgesia** (PCA). **Long-acting oral or transdermal opioid analgesia**. **Paracetamol** **Non-steroidal anti-inflammatory drugs** (NSAIDs. This includes non-selective and COX-2 selective medications). **Other analgesia**	– Clinical notes – Drug chart
6. Time to oral analgesia switch	**Number** (days from first post-operative day to day that the patient received oral analgesia only).	
7. Postoperative administration of anti-reflux medication	**Yes *** (proton pump inhibitor) / **Yes *** (H2 receptor antagonist) / **No.** ***If yes:*** **Regular administration pre-operatively** / **Started post-operatively**	– Drug chart
8. Physiotherapy review in the first 24h	**Yes, in the first 24h** (documentation of review by physiotherapist) / **Yes, during inpatient stay** / **No**	– Clinical notes – Physiotherapy notes
9. Documented provision of lung expansion techniques	**No** / **Yes** (incentive spirometry) / **Yes** (deep breathing exercises) / **Both** Provision of advice can be from the physiotherapist, nursing staff, or clinical team	
10. Mobilisation to chair	**Number** (post-operative day the patient was first mobilised to a chair). If the patient has not been mobilised prior to the end of 30-day follow-up, enter '31'.	
11. Mobilisation via walking	**Number** (post-operative day the patient was first mobilised to walk, aided or unaided). If the patient has not been mobilised prior to the end of 30-day follow-up, enter '31'.	

12. Post-operative assessment	Was the patient assessed by a specialist from Elderly or General Internal Medicine before discharge? *(Can include physician, trainee (e.g. registrar or core trainee) or nurse specialist).*	– Clinical notes
13. Post-operative pulmonary complications (PPCs) at 7-days and 30-days	**None** / **Atelectasis** / **Pneumonia** / **Pulmonary aspiration / ARDS** *(select all that apply)* – see **Appendix D** for definitions. ***If yes:*** Does the diagnosis fulfil the StEP criteria for PPC? (see **Appendix D**): **Yes** (incorporating radiological evidence) / **No** (clinical diagnosis only). *(30-day complications include all those between day 0 and day 30)*	– Clinical notes – Imaging software
14. Severity of PPC	**Not clinically significant** (planned use of supplemental oxygen or mechanical respiratory support as part of routine care, but not in response to a complication or deteriorating physiology. Therapies which are purely preventive or prophylactic, for example high flow nasal oxygen or continuous positive airways pressure (CPAP) should be recorded as none). **Mild** (therapeutic supplemental oxygen <0.6 FiO2 e.g. use of standard Nasal Cannula; Simple Mask or Venturi Mask only). **Moderate** (therapeutic supplemental oxygen ≥0.6 FiO2 (8L flow of oxygen or greater through a non-rebreathing mask with a reservoir) **Severe** (unplanned non-invasive mechanical ventilation, CPAP, or invasive mechanical ventilation requiring tracheal intubation).	– Clinical notes – Intensive care notes
15. Clinically significant organism(s) identified from respiratory sample.	**Yes** (see REDCap for groups of organisms, or enter as free text by selecting "other") / **No**	– Microbiology system – Clinical notes
16. Post-operative length of stay (hospital)	**Number** (days between from the first post-operative day to day of discharge. If the patient has not been discharged prior to the end of 30-day follow-up, enter '31').	– Discharge letter – Clinical notes
17. Other post-operative pulmonary complication	**Yes** (pleural effusion, pulmonary oedema, pneumothorax, pulmonary embolism, pulmonary collapse, other) / **No**	
18. Highest 30-day complication grade	**None / Clavien-Dindo Grade I-V** (see **Appendix D** for the full 7-point Clavien-Dindo scale).	

Appendix C: Definitions of Key Outcomes

1. Post-operative pulmonary complications:

Some of the most common postoperative complications affect the respiratory tract. There are several factors which can increase the risk of these post-operative pulmonary complications (PPC) in the perioperative content, particularly in patients with pre-existing respiratory disease. These can include anaesthetic agents (causing central respiratory depression, altered respiratory muscle tone, etc), ventilator-associated lung injury, surgical manipulation (restricted ventilatory capacity, postoperative pain, etc).

There are heterogenous definitions with the medical literature regarding which conditions should be considered post-operative pulmonary complications (and how these should be defined). This makes it difficult to interpret new studies in the context of the existing literature, and so means it often isn't possible to pool the data within systematic reviews.

A recent systematic review and international consensus process [9] recommended redefining PPCs by common pathophysiological mechanisms (including pulmonary collapse and airway contamination), each with standardised definitions (below). Importantly, this excludes other historically included conditions that do not share a common biological mechanism (e.g. pulmonary embolism, pleural effusion, cardiogenic pulmonary oedema, pneumothorax, bronchospasm). The following four conditions are included within the new PPC definition:

1. **Atelectasis**:

Definition: The collapse or closure of a lung resulting in reduced or absent gas exchange. It may affect part or all of a lung.
Diagnosis: Radiological (via CT scan or chest X-Ray).

2. **Pneumonia**:

Definition: An infective form of pneumonitis (inflammation of the lung parenchyma) typically secondary to a pathogenic bacteria or virus. This can be community- or hospital-acquired.
Diagnosis: US Centers for Disease Control criteria.

US Centers for Disease Control definition of pneumonia:	
CXR evidence of:	• New or progressive and persistent infiltrates. • Consolidation. • Cavitation.
AND one of:	• Fever (>38°C) with no other recognised cause. • Leucopenia (WCC <4 × 10^9 / L) or Leucocytosis (WCC >12 × 10^9 / L). • Age >70 years AND altered mental status (no other recognised cause).
OR two of:	• New onset purulent sputum or change in character of sputum. • Increased respiratory secretions. • Bronchial breath sounds. • New onset cough, dyspnoea or tachypnoea. • Worsening gas exchange (hypoxaemia, increased oxygen demand).

3. **Pulmonary aspiration:**

Definition: The inhalation of foreign material into the airways into the tracheobronchial tree (e.g. food or drink, pharyngeal secretions, or gastric contents).

Diagnosis: Clear history **AND** radiological evidence.

4. **Acute Respiratory Distress Syndrome**:

Definition: "An acute diffuse, inflammatory lung injury, leading to increased pulmonary vascular permeability, increased lung weight, and loss of aerated lung tissue…[with] hypoxemia and bilateral radiographic opacities, associated with increased venous admixture, increased physiological dead space and decreased lung compliance" [34].

Diagnosis: Berlin consensus definition.

Berlin consensus definition of ARDS (ALL 4 CRITERIA REQUIRED):			
1. Timing	Within 1 week of known clinical insult or worsening respiratory symptoms		
2. Chest imaging	Bilateral opacities (not fully explained by effusions / collapse / nodules).		
3. Origin	Respiratory failure (not fully explained by cardiac failure / fluid overload).		
4. Oxygenation	**Severity**	**FiO_2**	**With PEEP** (* or CPAP)
	Mild	26.7 - 40.0 kPa (200–300 mmHg)	≥5 cm H_2O *
	Moderate	13.3 - 26.6 kPa (100–200 mmHg)	≥ 5 cm H_2O
	Severe	≤13.3 kPa (≤ 100 mmHg)	≥ 5 cm H_2O

2. Clavien-Dindo Classification System:

Adverse post-operative events may be classified in different ways:

- **Failure of treatment** – This occurs when the original surgery fails to achieve its intended benefits; for example, persistent pain following laparoscopic cholecystectomy or tumour recurrence following cancer surgery.
- **Sequelae**: The recognised consequences of a given procedure; for example, gut malabsorption following a large small bowel resection or immune deficiency following splenectomy.
- **Complication**: Any deviation from the normal post-operative course that has an adverse effect on the patient and is not either a treatment failure or sequel.

In the Clavien-Dindo classification [35], the factor determining the severity of a complication is the treatment required. Consequently, a given complication may be graded differently depending on how it has been managed. For example, an anastomotic leak may be managed just with antibiotics if it is contained (grade II) or it may require re-operation under anaesthetic (grade IIIb).

Some other considerations:

- Intra-operative complications are not considered unless they have an adverse effect on the patient post-operatively. The only exception to this is intra-operative death; this is classified as grade V.
- All post-operative adverse events are included, even when there is no direct relationship to the surgery.
- All adverse events within the follow-up period (30 days) are included, even after following discharge.
- Diagnostic procedures are not included. For example, a diagnostic oesophagoduodenoscopy (OGD) to look for a source of bleeding without any intervention would not be considered a complication, but a therapeutic OGD with clipping of a bleeding vessel would be considered a grade IIIa complication. Since negative exploratory laparotomies are considered to be diagnostic procedures, they should not be recorded as complications.

Grade	Definition (examples listed in italics)
I	Any deviation from the normal postoperative course without the need for pharmacological (other than "allowed therapeutic regimens"), surgical, endoscopic or radiological intervention. Allowed therapeutic regimens are: selected drugs (antiemetics, antipyretics, analgesics, diuretics and electrolyte replacement), physiotherapy and wound infections opened at the bedside but not treated with antibiotics. ***Examples**: Ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.*
II	Requiring pharmacological treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included. ***Examples**: Surgical site infection treated with antibiotics; myocardial infarction treated medically; deep venous thrombosis treated with enoxaparin; pneumonia or urinary tract infection treated with antibiotics; blood transfusion for anaemia.*
IIIa	Requiring surgical, endoscopic or radiological intervention, not under general Anaesthetic (GA). ***Examples**: Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedures.*
IIIb	Requiring surgical, endoscopic or radiological intervention, under GA. ***Examples**: Return to theatre for any reason.*
IVa	Life-threatening complications requiring critical care management with single organ dysfunction, or neurological complications including brain haemorrhage and ischemic stroke (excluding TIA). ***Examples**: Single organ dysfunction requiring critical care management, e.g. pneumonia with ventilator support, renal failure with filtration; SAH; stroke*
IVb	Life-threatening complications requiring critical care management with multi-organ dysfunction.
V	Death of a patient

Appendix D: Ethics Waiver

South East Scotland Research Ethics Service

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG

NHS Lothian

Date: 02/11/2018

Direct Line: 0131 465 5678

Kenneth McLean

Academic Foundation Doctor
Department of Clinical Surgery
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
EH16 4SA

Dear Mr McLean,

Project Title: REspiratiry COmplications after abdomiNal surgery (RECON)

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer and you are advised that, based on the email correspondence, it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition).

The advice is based on the following:

- *The project involves NHS staff and is an audit of current or past practice concerning a healthcare issue*

If the project is considered to be health-related research you will require a sponsor and ethical approval as outlined in The Research Governance Framework for Health and Community Care. You may wish to contact your employer or professional body to arrange this. You may also require NHS management permission (R&D approval). You should contact the relevant NHS R&D departments to organise this.

For projects that are not research and will be conducted within the NHS you should contact the relevant local clinical governance team who will inform you of the relevant governance procedures required before the project commences.

This letter should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that NHS ethical approval is not required. However, if you, your sponsor/funder feel that the project requires ethical review by an NHS REC, please write setting out your reasons and we will be pleased to consider further. You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

Helen Newbery
Scientific Officer
South East Scotland Research Ethics Service

Appendix E: Steps for successful inclusion of your centre

1. Contact your local lead about participation in the RECON study at the centre of your choice. They will connect you to any other interested medical students and foundation doctors.

2. Form a mini-team of up to three collaborators, per specialty group (see **RECON** protocol). One or two medical student should be co-ordinating the team and leading audit registration and data collection. The student should be supported by at least one motivated doctor. This can be any doctor from FY1 to senior registrar grade. The collaborating doctor could be:

   - A junior (e.g. FY1, FY2, CT1, CT2) you know on rotation in the surgical department.
   - If you don't know any juniors working in the surgical teams, try walking onto the ward to find an FY1 to ask who the best FY1/2 to help the audit is; this approach often succeeds. If there is an FY1/2 on an academic rotation, they may be well placed to help you.
   - A member of your local or regional registrar-led research collaborative (asit.org/resources/collaboratives).

3. In RECON, one mini-team *per specialty group* can cover each consecutive 2-week period, working together to deliver 30-day follow-up, at the discretion of your regional lead. Smaller hospitals may not provide every type of included surgery, or surgical disciplines may be grouped together (e.g. general surgery, rather than lower GI, upper GI and HPB). The number of teams is therefore at the discretion of your regional lead. Discuss with your regional lead to establish a 14-day consecutive data collection period from below to suit your availability:

   - Period 1: 00:00 21st Jan 2019 – 23:59 3rd Feb 2019 (+ 30 Day Follow-up)
   - Period 2: 00:00 4th Feb 2019 – 23:59 17th Feb 2019 (+ 30 Day Follow-up)
   - Period 3: 00:00 18th Feb 2019 – 23:59 3rd Mar 2019 (+ 30 Day Follow-up)
   - Period 4: 00:00 4th Mar 2019 – 23:59 17th Mar 2019 (+ 30 Day Follow-up).

4. Ensure that you secure formal audit approval from your hospital's clinical audit department prior to commencing data collection. This may seem daunting at first but is in fact quite straight forward. Every hospital has an audit department and it is a simple case of approaching them with the information we have prepared in this protocol and applying this to the local audit registration form. You will need a local consultant to support you and sign the hospital's audit form (this should be the same consultant which is supervising the mini-teams). Ensure that

the audit department know that this is part of a national project and that you will enter data on REDCap.

*It is essential that you begin this process **immediately**; approval can take up to a month or more. You may have to contact or even visit the hospital before your placement starts to ensure that you will be ready. If you have any difficulties contact your regional lead, your supervising junior doctor/consultant or the steering committee.*

5. Contact your hospital's Caldicott Guardian (often the medical director – the audit department can help you find out who this is) to request permission to submit data to REDCap. You need additional permission from the Caldicott Guardian to store any patient numbers on REDCap.

6. Agree with your audit office and Caldicott Guardian how you will facilitate 30-day follow-up. You will require the hospital number for each patient to undertake follow-up, and so this needs to be stored in a safe and secure manner until accessed for 30-day follow-up, in line with local and national data governance guidance. This can be within the hospital site (paper or computer), or on REDCap (if permission from the Caldicott Guardian has been obtained).

7. Once the audit is registered and you have Caldicott Guardian approval, please forward evidence of this to your regional lead. REDCap accounts will not be issued until proof of audit registration AND Caldicott approval has been received.

8. Arrange to meet with the other members of your mini-team, including the junior doctor and, if possible, supervising consultant. it is also highly recommended to meet with the preceding mini-team at your centre (this would ideally include ***a one or two-day period of shadowing***):
    - They will have a lot of helpful advice regarding what worked well. In your mini-team, agree in advance who will be responsible for each stage of the project (e.g. identifying patients, collecting baseline data, completing follow-up, data entry to REDCap).
    - Talk through how you will identify patients and collect required data, it will be particularly helpful if the consultant is present to offer guidance regarding this. Agree who will access blood test results; will students have a login or will the junior doctor check the results?

9. Identify all patients fitting the inclusion criteria within your specified two-week window. Contact your regional lead with any questions or issues that may arise over your data collection period.

10. Regularly follow-up for information on complications over the 30-day post-operative period. This study is prospective, so you should not wait until the end of the post-operative period to follow-up patients (this would be retrospective). Discuss the best way to follow up patients with the consultant supervising your audit, as this will vary from centre to centre.

Be proactive in identifying post-operative adverse events, as this will prevent under-estimation of true complication rates. Remember that in this audit no changes to normal patient follow-up should be made.

Strategies for identifying complications in the follow-up period include:

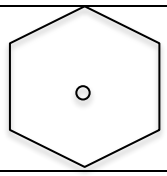
- *Regularly reviewing patient notes to identify in-hospital complications.*
- *Reviewing clinic notes and clinic letters, if seen in clinic by 30 days.*
- *Checking electronic systems and handover lists for re-admissions.*
- *Checking for A&E re-attendances.*

If case notes are reviewed shortly prior to discharge they do not be need to be requested/retrieved again for follow-up at 30-days, but do check electronic records for discharge letters, clinic letters, re-admissions.

11. Ensure all data has been uploaded to the REDCap system by the data collection deadline, and you have completed all fields, avoiding missing data points. If more than 5% of patients at your centre have missing data, your centre cannot be included in the RECON dataset and your name will be withdrawn from the author list.

12. It is a condition of participation in RECON that following completion of the audit at your centre you must ensure that your local results are presented to your hospital's surgical department and/or reported back to the audit department. You may also like to return to present again at a later date, when the final national results of RECON become available.

Appendix F: Case Report Form (CRF)

		REDCap Unique ID	_____
Pre-operative data fields			
Age (years)	_ _ _ (nearest year)	Gender	Male / Female
Height (meters)	_ . _ _ (2dp)	Weight (kg)	_ _ _ . _ (1dp)
ASA grade	I / II / III / IV / V	Smoking status	Current / Previous / Never
Cardiac disease	Yes: _____/ No	Chronic respiratory disease	Yes: _____/ No
Neurological disease	Yes / No	Liver disease	Yes / No
Previous lung surgery	Yes / No	Bowel obstruction	Small bowel / Large bowel / No *If yes:* NG tube preoperatively: Y / N
Immunosuppression	Diabetes / HIV / Steroids / Immunosuppressive drug / Chemotherapy	Recent upper or lower respiratory tract infection	Yes (on admission) / Yes (past month) / No
Pre-operative oxygen saturation	>96% / 91-95% / ≤90%	Last pre-operative blood tests	Hb _ _ . _ g/dL (1dp) Albumin _ _ . _ g/dL (1dp) eGFR _ _ _ ml/min
Smoking status	Current / Previous / Never		
Smoking cessation advice	Intensive / One-off / None		
Pre-operative assessment (anaesthetic, perioperative or elderly care medicine)	Elective: Yes (clinic) / (CPET) /No Emergency: Yes (inpatient) / No	Formal prehabilitation	Supervised exercise therapy / Inspiratory muscle training / No
Intra-operative data fields			
Urgency	Immediate (within minutes) / Urgent (within hours) / Expedited (within days) / Elective	Contamination	Clean / Clean-contaminated / Contaminated / Dirty
Operation	*See REDCap and Appendix C for list of operation types (select all that apply)*		
Approach	Open Laparoscopic/assisted Laparoscopic converted Robotic Robotic converted	Incision(s) – see REDCap for example pictures	
Indication	Malignant / Benign	Type of intubation	ET Tube / LMA or I-gel
Pre-induction chlorhexidine mouthwash	Yes / No	Dexamethasone on induction	Yes / No
Neuromuscular blockade	Yes, short acting / Yes, intermediate acting / Yes, long acting / No	Neuromuscular reversal agent	Yes / No
Number of antiemetics given at induction	1 / 2 / 3 / 4 / >4	Duration of procedure	_ _ _ mins
WHO checklist	Yes / No	Intraoperative blood transfusion	Yes / No
Post-operative data fields			
Critical care admission	Direct from theatre (intubated / extubated) / from ward / None	Critical care bed days	_ _ days
Prophylactic CPAP (first 24h)	Yes / No	Nasogastric tube (first 24h)	Wide bore / Fine bore / None
Physiotherapy review (first 24h)	Yes / No	Days until oral analgesia 'switch'	_ _ days
Anti-reflux medication	PPI / H2 receptor antagonist / No *If yes:* Regular pre-operatively / Started post-operatively	Analgesia in first 24h (*select all that apply*)	Local analgesia / Regional analgesia / Continuous intravenous opioid infusion / PCA / Long-acting opioid / Paracetamol / NSAIDs / Other
Lung expansion techniques	Yes (incentive spirometry) / Yes (deep breathing) / No		
Mobilisation to chair	_ _ days	Mobilisation via walking	_ _ days
Postoperative pulmonary complications	Day 7: Clinical diagnosis / StEP-COMPAC	Atelectasis / Pneumonia / Aspiration / ARDS	Not significant / Mild / Moderate / Severe
	Day 30: Clinical diagnosis / StEP-COMPAC	Atelectasis / Pneumonia / Aspiration / ARDS	Not significant / Mild / Moderate / Severe
Other pulmonary complications (	Pleural effusion / Pulmonary oedema / Pneumothorax / Pulmonary embolism / Pulmonary collapse / Other		
Pathogenic bacteria (sputum)	*See REDCap for list of bacteria (select all that apply)*		
Drug resistance (sputum)	*See REDCap for list of antibiotics (select all that apply)*		
Length of stay	_ _ days	Highest Clavien – Dindo grade	None / I / II / IIIA / IIIB / IV / V

Appendix G: References

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