Human Research Ethics Application

Application Management Information
Application ID: 2022/ETH02401
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**This is the earliest application from which this application (2022/ETH02401) was copied.*
Parent Application ID: 2022/ETH02401
**This is the immediate predecessor from which this application (2022/ETH02401) was copied.*
Version Number: 2
Application submitted to: Hunter New England Local Health District; Hunter New England Human Research Ethics Committee.

The applicant has requested that this ethics application be considered under the Low or negligible risk review pathway.

Section 1 – Core Information

Pre-application conditions

The applicant/s have acknowledged that:

1. The HREA has been designed for ethics review of human research, as defined in the National Statement.
2. Adequate resources must be available to conduct this research project.
3. All relevant institutional polices pertaining to the conduct of this research project should be considered and adhered to.
4. Research activities must not commence until ethics approval (and site authorisation, if appropriate) has been provided.

Project Overview

Q1.1 Project Title:

Acute PresentatiOn of CoLorectaL Cancer: an internatiOnal snapshot (APOLLO)

Q1.2 Summary of the research project:

APOLLO is an international, multi-centre, prospective observational study of acutely (i.e. unplanned and non-elective presentation to hospital for urgent or emergency reasons) presenting colorectal cancer. This study will adapt the student- and trainee-led collaborative research model. The primary aim of the APOLLO study is to describe the operative and non-operative management of emergency presentations of colon and rectal cancer in an international cohort. The secondary aims will be to describe 30-day and 90-day management outcomes, identify the risk factors for intraoperative, 30-day, and 90-day mortality and ostomy rates in patients deemed for active management (i.e., not for palliative management), and develop a mortality and ostomy risk prediction model for patients undergoing active management for colorectal cancer.

Q1.3 Which category/ies of research best describes the project?

Oncology and Carcinogenesis - 1112

Q1.4 In what environments will the research be conducted?

Hospital(s)

Q1.5 What organisation/entity has overall responsibility for this project?

Sponsor type: Collaborative group
Sponsor name: European Students Research Network (EuroSurg)

Q1.6 Describe how this research project is currently, or will be, funded.

No funding required

Q1.7 Anticipated starting date of the research project:

16/01/2023

Q1.8 Anticipated duration of the research project:

24 Months

Project Team

Name: **Associate Professor Amanda Dawson**

Q1.9.4 Email Address:

amanda.dawson@newcastle.edu.au

Q1.9.5 Is this person the contact person for this application?

Yes

Q1.9.5.1 Email Address:	amanda.dawson@newcastle.edu.au
Q1.9.5.2 Telephone Number:	+61419579368
Q1.9.5.3 Mailing Address	The University of Newcastle, Central Coast Clinical School, College of Health, Medicine and Wellbeing, Level 9 Building A, 77a Holden St, Gosford Hospital, GOSFORD NSW 2250

Q1.9.6 Is this person a student on this project?

No

Q1.9.7 Institutional affiliation and position:

Consultant Academic General Surgeon at Gosford Hospital, Wyong Hospital and Gosford Private Hospital.
Clinical Dean Central Coast Local Health District
Associate Professor of General Surgery at The University of Newcastle.
Director of the Surgical Trainee Organisation for Research Central Coast Collaborative (STORCC).

Q1.9.8 Staff ID *(optional)***:**

52814638

Q1.9.9 ORCID Identifier *(optional)***:**

0000-0003-2447-3251

Q1.9.10 Position on the research project:

Co-ordinating Principal Investigator/Researcher

Q1.9.12 Research activities Associate Professor Amanda Dawson will be responsible for:

Advising and supervising students and trainees in ethics applications and site specific applications, data collection and dissemination of results.

Q1.9.13 Expertise relevant to the research activity:

Associate Professor Dawson is an experienced clinical researcher with previous extensive experience in supervising as well as participating in international collaborative research. She has been an Australian colead, member of the Australasian steering committee, national surgical lead, NSW lead and CCLHD PI of internationally organised collaborative studies IMAGINE (2018) RECON (2019), Global Surg 3
(2019) SUNRRISE (2019), COVIDSURG (2020), Covidsurg Cancer (2020), GlobalSurg-Covidsurg

Week (2020), Cholecovid (2020), Covidsurg 3 (2021), POSTVenTT (2022), OPERAS (2022). All of these projects were completed successfully. She is the current Australian national lead for the ongoing collaborative trials, SNAP 3 - national surgical lead (2022) and APOLLO 2023 and is the current supervisor of a MPhil RCT. She has published and presented the results in peer reviewed meetings and journals. As immediate past chair of the Critical Literature Evaluation and Research Committee (CLEAR) for the Royal Australasian College of Surgeons she was also responsible for the management, curriculum and delivery of the CLEAR course across both Australia and New Zealand to teach trainee surgeons the understanding, design and implementation of surgical research. This research course is compulsory for all trainee surgeons in both countries and runs 20 times annually. She is a founding member of both the Clinical Trials Australia and New Zealand for the Royal Australasian College of Surgeons (2017) and the Surgical Trainee Organisation for Research
Central Coast Collaborative (2016).

Name: **Lorane Gaborit**

Q1.9.4 Email Address:

lorane.gaborit@anu.edu.au

Q1.9.5 Is this person the contact person for this application?

No

Q1.9.6 Is this person a student on this project?

No

Q1.9.7 Institutional affiliation and position:

Co-lead of the Trials and Audits in Surgery by Medical Students in Australia and New Zealand (TASMAN) Collaborative.
Will be an intern at Wagga Wagga Base Hospital in 2023 during the study.

Q1.9.8 Staff ID *(optional)***:**

Q1.9.9 ORCID Identifier *(optional)***:**

0000-0002-0044-1792

Q1.9.10 Position on the research project:

Associate/Assistant/Sub-/Co- Investigator/Researcher

Q1.9.12 Research activities Lorane Gaborit will be responsible for:

Coordination of ethics applications and site specific applications and recruitment of sites.

Q1.9.13 Expertise relevant to the research activity:

Previous experience in developing and delivering an international collaborative study (OPERAS), including coordinating ethics and site specific applications.

Name: **Dr Nagendra Dudi-Venkata**

Q1.9.4 Email Address:

drnags3@gmail.com

Q1.9.5 Is this person the contact person for this application?

No

Q1.9.6 Is this person a student on this project?

No

Q1.9.7 Institutional affiliation and position:

RACS General Surgical Trainee
Colorectal Research Fellow, Colorectal Unit, Royal Adelaide Hospital
Chair of the South Australian Trainees Audit & Research Collaborative (STARC)

Q1.9.8 Staff ID *(optional)*:

Q1.9.9 ORCID Identifier *(optional)*:

0000-0002-9775-3599

Q1.9.10 Position on the research project:

Associate/Assistant/Sub-/Co- Investigator/Researcher

Q1.9.12 Research activities Dr Nagendra Dudi-Venkata will be responsible for:

Advising and supervising students and trainees in ethics applications and site specific applications, data collection and dissemination of results. Providing expertise relevant to Colorectal surgery.

Q1.9.13 Expertise relevant to the research activity:

Extensive research experience both in Colorectal/General surgery and international collaborative research, including supervision and participating in IMAGINE (2018), GLOBALSurg3 (2018), RECON (2019), COMPASS (2020), SUNRRISE (2019-2022), Covid-Surg (2020-2021), DAMASCUS (2021) PoST VenTT (2021) and OPERAS (2022).

Name: **Kristy Atherton**

Q1.9.4 Email Address:

kristy.atherton@newcastle.edu.au

Q1.9.5 Is this person the contact person for this application?

No

Q1.9.6 Is this person a student on this project?

No

Q1.9.7 Institutional affiliation and position:

Research Coordinator, School of Medicine and Public Health, The University of Newcastle
Clinical Trial Coordinator, RACS Clinical Trials Australia and New Zealand Network

Q1.9.8 Staff ID *(optional)*:

Q1.9.9 ORCID Identifier *(optional)*:

Q1.9.10 Position on the research project:

Administration Contact

Q1.9.12 Research activities Kristy Atherton will be responsible for:

Advising and supervising students and trainees in ethics applications and site specific applications, data collection and dissemination of results.

Q1.9.13 Expertise relevant to the research activity:

Extensive collaborative research experience, including as the research coordinator of the OPERAS study which involved advising and supervising students and trainees in ethics applications and site specific applications.

Disclosure of interests

Q1.10 Do any members of the research team (including persons not listed in this application), have any financial or non-financial interests related to this research?

No

Restrictions

Q1.11 Are there any restrictions or limits on publication of data or dissemination of research outcomes of this project?

No

Evaluations

Q1.12 Has the scientific or academic merit of the research project been evaluated?

No

Q1.13 Has this research project had prior ethics review?

No

Q1.14 Will any further or additional specialised review of this application be sought?

No

Setting of research

Q1.15 Will this project be conducted at multiple sites?

Yes

Q1.16 Will separate institutional approvals or authorisations be required prior to commencing research at each site?

Yes

Section 2 – Research Details and Participants

Q1.17 The following research methods will be used in the research project:

Research Method	Status
Action research	✗
Biospecimen analysis research	✗
Data linkage research	✗
Ethnographic research	✗
Epidemiological research	✗
Interventional/Clinical Trials research	✗
Observational research	✓
Survey/Interview/Focus Group research	✗
Textual analysis research	✗
None of the above	✗

Q1.18 The research will be conducted with the following:

Participation	Status
Human beings (via active participation), including their associated biospecimens and/or data.	✓
Human biospecimens only	✗
Data associated with human beings only (i.e. as the primary object of research)	✗

Q1.19 The research will involve the following participants:

Participants	Status
Women who are pregnant and the human fetus	✗
Children and young people	✗
People highly dependent on medical care who may be unable to give consent	✗
People with a cognitive impairment, intellectual disability or mental illness	✗
People in dependent or unequal relationships	✗
People who may be involved in illegal activities	✗
People in other countries	✗
Aboriginal and Torres Strait Islander peoples	✗

Method Specific Questions

Observational Research

M7.1 What type of observation will you be conducting?

APOLLO is a prospective observational study that aims to describe the operative and non-operative management of emergency presentations of colon and rectal cancer in an international cohort.

The secondary aims will be to describe 30-day and 90-day management outcomes, identify the risk factors for intraoperative, 30-day, and 90-day mortality and ostomy rates in patients deemed for active management (i.e., not for palliative management), and develop a mortality and ostomy risk prediction model for patients undergoing active management for colorectal cancer. This study will also aim to validate risk criteria of large bowel obstruction in patients with previously known colorectal cancer undergoing neoadjuvant chemotherapy or awaiting elective surgery. A full list of required data fields is available in the APOLLO Study Protocol (page 22).

This study will be completed through an observational audit of routine clinical practice of managing and follow up of consecutive patients presenting to hospital and meeting the eligibility criteria. criteria.

The information gathered is routinely captured in daily clinical practice and this will be recorded on a purpose build database using the REDCap (Research Electronic Data Capture) system. No additional telephone, in-person or questionnaire-based follow-up is required.

M7.2 What sampling strategy will you use?

Convenience sampling - Collaborators at each participating centre will prospectively collect data for all patients presenting acutely to hospital for symptoms of colorectal cancer and meeting the inclusion criteria (see protocol section 5, page 12) during a specified data collection period.

The data collection periods will be any 6 week period between 16 January and 13 June 2023, with 30 and 90 day follow up. All 90-day follow-up should be completed by 11 September, 2023. Data collectors will be able to participate in more than one data collection period, if these do not overlap and ensure follow up may be completed by 11 September 2023.

All patients who meet the inclusion criteria and are admitted to hospital within the study data collection dates defined above would be eligible for inclusion.

M7.3 How will you match and follow up participants?

All eligible patients during the study inclusion periods will be identified prospectively and given a unique ‘REDCap ID’ when entered into the study database.

No patient identifiable data will be uploaded or stored on the REDCap Database.

Local site hospital leads will keep a local cross-reference of patient identification numbers (hospital numbers) and REDCap IDs to enable follow up. This will be kept in a secure, encrypted spreadsheet on a hospital, password-protected computer.

M7.4 How will potential sources of bias be addressed, including consideration of both the direction and magnitude of bias?

All eligible prospective patients that meet the inclusion criteria will be included to minimise selection bias (see protocol section 5, page 12).

To minimise confounding bias additional data will be collected on participant demographics and comorbidities, preoperative diagnosis and procedure-specific details, and accounted for in the statistical analysis. A full list of required data fields is available in the APOLLO Study Protocol.

Information bias will be minimised by the data validation and quality assurance processes described in section 12 ‘Quality Assurance’ of the protocol. Specifically, only data sets with >95% data completeness will be accepted for pooled analysis.

Participant Specific Questions

Recruitment Questions

Q2.1.1 Indicate how you will identify and recruit participants for your research, referencing any relevant sections of your Project Description/Protocol as appropriate.

All patients who meet the inclusion criteria and are admitted to hospital within the defined study period dates are included.

Patients must fulfil all of the following criteria to be included in the study:

- Adult patients (greater than or including 18 years of age)
- Patients presenting to the hospital acutely with colon AND/OR rectal cancer and referred to general/colorectal surgical departments
- Any extent of cancer (including extra-abdominal metastatic, intra-abdominal metastatic and non-metastatic disease)
- Patients presenting with both known or unknown colorectal cancer
- Symptomatic presentation (e.g. large bowel obstruction, haemorrhage, perforation)

The exclusion criteria is as follows:

- Paediatric patients (below 18 years of age)
- Presenting for side effects of cancer treatment such as chemotherapy/radiotherapy
- Each individual patient should only be included once in the APOLLO study. Readmission is regarded as a complication and should not form a duplicate entry onto REDCap.

All eligible patients during the study inclusion periods will be included prospectively, as identified from daily review of theatre lists, handover lists, new inpatient referrals etc. As this is an observational audit of usual routine clinical practice, patient consent is not required.

We will include people with disabilities and people from culturally and linguistically diverse backgrounds, although these groups will not be specifically targeted.

Q2.1.2 How will your recruitment strategy take account of the ethical considerations relevant to the specific people you are recruiting?

This is an international audit and no changes to usual practice (including normal patient pathways/ management) will take
place. All data collected will measure current practice.

(Observational specific question)

Q2.1.M7.1 How will you distinguish between participants and non-participants in your research, and how will you manage that distinction?

Participants will be identified from lists produced using hospital systems with data collectors encouraged to undertake daily review of relevant theatre lists, handover meetings/sheets and ward lists, theatre logbooks, inpatient referrals to the surgical team, and multidisciplinary team meetings. This will be used to identify participants admitted to hospital and meeting the inclusion criteria.

Once identified as being eligible for the APOLLO Study, the site data collection team will record the patient on an electronic patient identification log (which is stored in a password-protected hospital computer in a secure location at each site). The only
purpose of the log is to manage the data entry process at the site level. The patient identification log will not be uploaded
or transferred electronically.

(Observational specific question)

Q2.1.M7.2 How will you determine whether it is appropriate to obtain consent from the people whom you are observing?

This audit requires data associated with human beings only, collected prospectively with no active participation from
participants.

This study is requesting a waiver of consent, therefore, no formal recording of consent or patient withdrawal process would be obtained.

The participant will not be aware that their data has been reviewed and will not be able to withdraw from the study. Eligible patients will have no change to standard medical care, no interventions and access to their medical record for the purpose of this study will be limited to the collection of data relevant to this observational study (as outlined in the APOLLO Study Protocol). All data required for this study will be available in the medical record as standard data recorded during the treatment of the patient. All data collected for this project will be entered into the study database in a de-identified format, and reported in an aggregate format.

Consent Questions

Q2.2.1 Indicate by reference the relevant section/s of your Project Description/Protocol that address/es consent.

Section 3 'Setting' of the APOLLO Study Protocol identifies that the study is an audit of practice with no requirement for any change to normal patient management.

Individual study investigators are responsible for ensuring the correct approvals have been achieved prior to commencing data collection. As part of the site specific approval (SSA) process individuals who will be involved in data collection and looking at patient health records will be named on the local SSA application. The principle investigator/ site data custodian will oversee data collection and be responsible for ensuring that all data entered into the REDCap database is de-identified.

All information uploaded or stored on the REDCap database will be de-identified. Any local site cross-reference of hospital numbers and REDCap IDs created to facilitate data collection will be destroyed after the end of data collection (i.e. the nominated data-lock date). Therefore, no identifying information will be retained.

We consider it is appropriate for this study to have a waiver of consent given its nature as an observational audit which audits routinely collected data which will be de-identified and aggregated. Further information is provided in section 'Alternatives to Consent' of this document.

Q2.2.2 Will you be obtaining consent from some or all participants to participate in the research?

Not for any participants

Q2.2.3 Are family members, authorised representatives or any others involved in the participants' decision to participate in the research?

No

Q2.2.4 Will there be an opportunity to confirm or re-negotiate consent during the research project?

No

Q2.2.6 Describe any ethical considerations related to the approach to consent that you will be seeking and your strategies for addressing and managing these issues.

We consider this study to post negligible risk to patients, and the benefits justify any potential risk of harm. This study is a prospective observational study. All data is based on routinely collected data as part of the clinical care and there will be no change to usual practice. This data will be de-identified and appropriately stored and analysed using secure systems to ensure patient confidentiality.

Q2.2.7 Are you proposing to use an opt-out approach with respect to some or all of the participants?

No

Q2.2.8 Are you requesting a waiver of the requirement for consent with respect to some or all participants?

Yes

Q2.2.8.1 How will you ensure that the research satisfies the guidance for waiving consent as listed in National Statement 2.3.10?

Specifically, with regards to the National Statement of Ethical Conduct on Human Research:

Involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants

We consider that this study poses negligible risk to participants given it is an observational audit which audits routinely collected data which will be de-identified and aggregated, and in which there is no change to usual practice. There will be no change to the care that a patient will receive whether they were/were not included in the audit.

The benefits from the research justify any risks of harm associated with not seeking consent

We consider the benefits from this research justify any potential risk of harm, as explained in further detail in the risks and benefits section of this application. This study will capture prospective outcome data and describe the variation in management of acutely presenting colorectal cancer globally, which could improve understanding of risks of complications in this cohort and guide management recommendations.

It is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)

It is impractical to obtain consent given the volume of patients anticipated to be recruited (>5000 patients based on previous GolbalSurg/ CovidSurg studies), no patient contact planned between researchers and patients, and the use of consecutive recruitment to reduce bias.

There is no known or likely reason for thinking that participants would not have consented if they had been asked
This study is a prospective observational audit of usual practice: there will be no changes to usual practice for participants and all data obtained is routinely collected data as part of the clinical care of the participants. We believe based on previous audit studies that there is no known or likely reason for thinking that participants would not have consented if they had been asked. The relevance of this topic has been discussed with and a Patient and Public Involvement lead of ACPGBI and ESCP (Sue Blackwell) and was informed by an open public survey of patients with acutely presenting colorectal cancer. We will produce patient facing materials after analysing the data.

There is sufficient protection of their privacy
Data will be de-identified (age recorded in years) and appropriately stored and analysed to ensure patient confidentiality and privacy using secure systems.

There is an adequate plan to protect the confidentiality of data
Data will be de-identified and appropriately stored and analysed to ensure patient confidentiality and privacy using secure systems. Specifically, data will be collected and stored online via the Research Electronic Data Capture (REDCap) web application, hosted and managed by the Birmingham Surgical Trials Consortium (BSTC), United Kingdom. No patient identifiable data will be uploaded or stored on the REDCap database. See the 'Data and Privacy' section of this document for further information.

In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
At the end of the study, regarding dissemination as the patient data is de-identified we will be unable to feed back to individual patients. EuroSurg has consulted a patient representative within their project team, and this patient representative will be involved in the dissemination of results including through the media and organisations such as the European Society of Coloproctology. At a hospital level, audit results may be used to inform site-specific reports for service evaluation purposes at the hospital level and with local stakeholders. At the national level, results will be disseminated to the media and at medical meetings to educate/inform fellow doctors

The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
There are no anticipated possibilities of commercial exploitation or financial benefits from this research. Results will be shared at conference presentations and submitted for peer review publication. Research output presented in non-technical language including visual abstracts will be shared on social media and through the NIHR Global Unit on Surgery. Publications are submitted under an open access policy.

The waiver is not prohibited by State, federal, or international law.
To our knowledge, application for a waiver of consent for this study design and topic is not prohibited by state, federal or international law.

Risk Questions

Q 2.3.1 Describe the risks and burdens associated with your research, referencing any relevant sections of your Project Description as appropriate.

This project is designed to audit international clinical practice and outcomes. As a prospective observational study, this protocol is considered by the investigation team to pose negligible risk to patients.

No changes to standard practice will be applied and no patient data beyond routinely collected data will be audited. All data transferred to a central dataset will be de-identified and appropriately stored and analysed to ensure patient confidentiality using secure systems.

Although no identifiable data will be transferred centrally, in the process of auditing clinical records data collectors will have access to patient records.

Q 2.3.2 Describe how these risks will be mitigated and managed.

All data collected for this project will be de-identified (patient age will be stored as years not d/m/y). No hospital-level sub analyses will be conducted by EuroSurg.

Data collectors will be provided with appropriate training on maintaining patient confidentiality, appropriate access of medical records, and comply with site-specific guidelines and regulations.

Study supervisors will be available at all times to provide overarching supervision to the project, and provide support and advice to data collectors about ethical conduct.

Benefit Questions

Q2.4.1 Describe the benefits associated with your research, referencing any relevant sections of your Project Description as appropriate.

Colorectal cancer presents as an emergency in as many as a third of patients worldwide and emergency surgery for CRC is associated with high rates of morbidity, mortality, higher ostomy rates, and poorer health related quality of life. Existing guidelines on the optimal management of such cases are based on predominantly low grade evidence and current series remain small.

This study will capture prospective outcome data and describe the variation in management of acutely presenting colorectal cancer globally. This study aims to develop a mortality and ostomy risk prediction model for patients undergoing active management for colorectal cancer and

validate risk criteria of large bowel obstruction in patients with previously known colorectal cancer undergoing neoadjuvant chemotherapy or awaiting elective surgery. This could improve understanding of risks of complications in this cohort and guide management recommendations. Additionally, this could be useful to externally validate ongoing trials, and identify new research gaps to power new trials.

Q2.4.2 Explain how benefits of this research justify any risks or burdens associated with the research.

There will be no changes to usual clinical care in this study, and risks to patients are minimal.

Patients have been involved in the development of this study as part of the steering committee and and have helped to identify the outcomes that are important to patients living with colorectal cancer after presenting to hospital in an emergency with colorectal cancer.

Improving the management of acutely presenting colorectal cancer is important for patients affected by this debilitating disease and the potential benefits of this research may inform recommendations and guidelines to manage these patients in the future and also in addition, may have flow on effects by adding to the literature and help conduct new trials. Unit level data for comparison will be fed back to collaborators to support local service improvement upon request.

Q2.4.3 How will you manage participants' expectations of the perceived benefit of participating in the research?

Patient consent will not be required for the audit, and therefore there should be no expectation of perceived benefit from patients who are included in the study.

Patients participating in the steering committee will be consulted for their recommendations and advice regarding study design, analysis and dissemination.

In regards to collaboration with the site and other clinicians, Data collectors will make it clear that the potential benefits of the service evaluation for the hospital are dependent on what the results of the audit find, which may be compared to the international dataset after conclusion of the study.

Section 3 – Data and Privacy

Data Characteristics

Q3.1 Indicate the type of information/data you will be collecting for this project.

Personal information

Health information

Q3.2 Indicate the type of information/data you will be using in this project:

Personal information

Health information

Q3.3 Indicate the degree of identifiability of information/data you will be collecting for this project.

Re-identifiable (coded) information

Q3.4 Indicate the degree of identifiability of information/data you will be using in this project.

Non-identifiable information

Q3.5 Describe any ethical considerations relating to the collection and/or use of the information/data in this project.

Data will be maintained in a purpose build database using the REDCap (Research Electronic Data Capture) system. REDCap is the industry standard secure clinical research database.

De-identified study data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application, allowing safe anonymised data storage by collaborators internationally.

The service will be hosted and managed by the Birmingham Surgical Trials Consortium (BiSTC) REDCap system hosted at the University of Birmingham, United Kingdom. Kingdom. The security of the study database system is governed by the policies of the University of Birmingham. These include appropriate best practices such as network firewalls, system and security monitoring and two factor authentication. REDCap access privileges will be managed and maintained by EuroSurg to ensure that users can only access data relevant to their site. That is, each site user will only have access to their site's data.

Each collaborator will have their own unique login which will only give them access to the participant data for which they are responsible. No participant identifiable data will be entered into the main database. Each site will maintain records of which participant is recruited into the study and their unique REDCap identifier through the use of a local cross-reference of hospital numbers and REDCap IDs. This will be kept in a secure, encrypted spreadsheet on a hospital, password-protected computer. Any local site cross-reference of hospital numbers and REDCap

IDs created to facilitate data collection will be destroyed after the end of data collection (i.e. the nominated data-lock date).

Q3.6 Identify the source/s of the information/data that you will be collecting and/or using in this project.

Medical/health/mental health record

Q3.7 Describe any ethical considerations relating to the source of information/data as indicated in the response to the previous question.

None

Q3.8 Was the information/data that you are using previously collected for a purpose other than research?

Yes

Q3.8.1 Provide a rationale for your use of information/data for a purpose other than that for which it was originally collected.

Data was previously collected routinely for health care related reasons in the medical record. This record will be accessed to find information such as demographic information, procedure-specific information, and complications. This will allow information to be collected with negligible risk to the patient (i.e. no change to usual practice, no additional information collected beyond what would be routinely collected).

Activities Planned for/with Data

Q3.9 Do you plan to disclose any personal information/data in this project to a third party?

No

Q3.10 How will you protect the privacy of participants and non-participants in any notes and/or publications arising from your research?

Data will only be presented at an amalgamated level of participants. The study is expected to include more than 5000 participants internationally so no individual patient will be identifiable from the published records.

Q3.11 Are there any restrictions on your ability to assure the confidentiality of participants?

No

Q3.12 Do you plan to share any individual research results obtained during this research to the participants?

No

Q3.13 Describe how you will handle any secondary or incidental findings that arise from the analysis of personal information/data.

Any secondary or incidental findings will be discussed with the local site principal investigators, and appropriate members of the local research team. All local research teams will include at least one general surgical trainee, who will be able to appropriately follow up any secondary or incidental findings.

Q3.14 Describe how the information/data will be stored, accessed, archived and/or destroyed.

Data will be collected and stored online via the Research Electronic Data Capture (REDCap) web application, hosted and managed by the Birmingham Surgical Trials Consortium (BiSTC) REDCap system hosted at the University of Birmingham, United Kingdom. No patient identifiable data will be uploaded or stored on the REDCap database. Data will be stored for 15 years and then destroyed using approved file deletion techniques.

Q3.15 Describe any ethical considerations relating to the storage of, access to or destruction of information/data in this project.

None

Q3.16 Will the outcomes of this project be disseminated to the participants?

No

Q3.16.2.1 Justify why the outcomes of this project will not be disseminated to the participants.

The participants will be de-identified, and given a waiver of consent is requested, it will not be practical to relay information directly to participants.

However, the APOLLO steering committee and national leads will actively disseminate results. National co-leads for previous collaborative studies such as Covidsurg and Globalsurg have used the media to target national newspapers, radio and television to enable broad distribution of study findings to the broder community. They have also represented the EuroSurg collaborative at regional educational and research meetings which will influence the education of health practitioners. This project protocol has already been presented at the Annual Surgical Research Conference of the Royal Australasian College of Surgeons.

We envisage that results will be shared at conference presentations and submitted for peer review publication. Research output presented in non-technical language including visual abstracts will be shared on social media and through the European Society of Coloproctology. Analysis and publication of data collected will be attributed to eligible collaborators using a shared authorship model.

Q3.17 Describe any foreseeable future activities for which information/data collected and/or used in this project may be made available.

It is possible that this study will generate research questions from the data gathered and analysed. Other researchers, including collaborators in this project, can approach the study management group for access to the data if, and only if, they have prior approval for their study from a properly constituted Human Research Ethics Committee.

Q3.18 Describe any ethical considerations relating to the planned or possible future use of information/data in this project.

The study management group European student research network (EuroSurg) will be the steward of the data collected. They will consider making the data available to any collaborator who has an appropriate study that depends upon the data as long as, and only, that study has received prior approval by a properly constituted Human Research Ethics Committee.

Section 4 – Attachments and Declarations

Attachments

The following documents have been attached to this HREA.

Project Description/Protocol

See attachment *APOLLO Protocol v2 20122022.pdf*

Other attachments

Type	Attachment File Name	Attachment Description
More Information Required	*LG_2022ETH02401 More Information Required Decision Pending - Response to HREC Form V2.docx*	Response to Committee Form 1
Study Protocol	*APOLLO Protocol v2 20122022 TRACK CHANGES.pdf*	APOLLO Protocol v2 20122022 TRACK CHANGES
	Project Registration	The output from the Project Registration

Investigator Team Declarations

The research team has certified that:

- All information in this application and supporting documentation is correct and as complete as possible;
- I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
- I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
- All relevant financial and non-financial interests of the project team have been disclosed; and
- In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.

Associate Professor Amanda Dawson as CPI ☑ Certified