Low or Negligible Risk Research Application for Ethical Review

This application form should be used by researchers seeking ethical approval for human research studies that present no more than low risk to research participants. (NS 2.1.6 – 2.1.7)

INSTRUCTIONS FOR THE PRINCIPAL INVESTIGATOR

Completing the Form:

The form will determine if your study is required to be submitted to a Low Risk Review panel or a full HREC committee. You will be notified if your study is not suitable for submission to a Low Risk Review panel and instructed how to proceed once you start completing the questions below. Studies that are ineligible for exemption from full HREC review are forwarded to the HREC for consideration and approval in the usual way. A full HREC application must be prepared using the online Queensland Health NEAF (https://au.EthicsForm.org/SignIn.aspx).

Upload any supporting documentation (through the "Documents" tab) such as Patient Information Sheet and Consent Forms, have the form signed (either electronically or manually) by the relevant authorities and submit via the "Submit" button. Record the "Submission code" and enter that into your cover letter.

Authorisations:

Please check that you have obtained all required signatures on the Declaration pages before submitting the application. This can be done electronically once the form is completed (please note: if the form is changed once the electronic signatures have been obtained, the form will need to be resigned as any changes to the form invalidate obtained signatures) or by printing the Declarations page, having the investigator sign the printed page and then uploading this as a PDF attachment.

Submitting the Application:

Submit the completed and signed original application and any attachments to the designated review personnel at your Institution / Health Service District if this is a single site study. **If it is a multi-centre study, please complete booking form at http://www.health.qld.gov.au/ohmr/html/regu/cen_coord_serv.asp and email to the Central Coordinating Service (QHCCS@health.qld.gov.au) for the study to be allocated to a reviewing panel.**

Do not commence research until written approval has been received from the District CEO or delegate.

Application for Ethical Review of Negligible or Low Risk Research

NHMRC "National Statement on Ethical Conduct in Human Research"
Sections 2.1.7, 5.1.18 – 5.1.23

1. Study details

1.1. Study Full Title

Efficiency of Snare-WithIn-The-scope-CHannel Technique (SWITCH trial) During Cold-Snare Polypectomy: A randomised controlled trial

1.2. Study Short Title

SWITCH study

1.3. HREC Reference No.

HREC/16/QPAH/395

1.4. Type of research

○ Multi-centre

◉ Single-centre

Once complete, submit the SSA to the local site ethical review body.

Name the sites this research study is going to be undertaken at:
Queen Elizabeth II Jubilee Hospital

1.5. Coronial material

Does the study require access to Coronial material?

○ Yes ◉ No

Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals. This also applies to clinical research studies where there is a component involving coronial material. In this context, examples of coronial material include tissues from coronial autopsies, slides and blocks, blood samples, autopsy reports and other documents and data relating to coronial autopsies.

For further information please refer to Research Involving Material from Coroner's Autopsies: Advice to Ethics Committees and Researchers: http://www.health.qld.gov.au/qhcss/qhss/fss/ethics-committee.asp

1.6. Participant details

1.6.1 Does the study include any of the ten following types of research and/or participants?

- New interventions and therapies, including clinical and non-clinical trials ○ Yes ◉ No
- Introduction of new treatment modalities ○ Yes ◉ No
- Human genetics ○ Yes ◉ No
- Human stem cells ○ Yes ◉ No
- Women who are pregnant and the human foetus ○ Yes ◉ No
- People who are highly dependent on medical care who may be unable to give consent ○ Yes ◉ No
- People with a cognitive impairment ○ Yes ◉ No
- People with an intellectual disability or a mental illness ○ Yes ◉ No
- Research specifically targeting Aboriginal or Torres Strait Islanders ○ Yes ◉ No
- People who may be involved in illegal activities ○ Yes ◉ No

1.6.2 Is the study a clinical audit / quality assurance activity? ○ Yes ◉ No

1.7. Research Topics, procedures, risks and participants

Are any of the following topics covered in part or in whole?

- Research about parenting issues ○ Yes ◉ No
- Research investigating sensitive personal issues ○ Yes ◉ No
- Research investigating sensitive cultural issues ○ Yes ◉ No
- Explorations of grief, death or serious/traumatic loss ○ Yes ◉ No
- Mental Disorders eg Depression, mood states, anxiety ○ Yes ◉ No
- Gambling ○ Yes ◉ No

- Eating disorders ○ Yes ◉ No
- Illicit drug use ○ Yes ◉ No
- Substance abuse (prescribed or over the counter) ○ Yes ◉ No
- Self report of criminal behaviour ○ Yes ◉ No
- Any psychological disorder ○ Yes ◉ No
- Suicide risks ○ Yes ◉ No
- Gender identity ○ Yes ◉ No
- Sexuality ○ Yes ◉ No
- Race or ethnic identity ○ Yes ◉ No
- Any disease or health problem ○ Yes ◉ No
- Fertility ○ Yes ◉ No
- Termination of pregnancy ○ Yes ◉ No

Are any of the following procedures to be employed?

- Use of personal data obtained from Commonwealth or State Government Department/Agency with participant consent ○ Yes ◉ No
- Deception of participants ○ Yes ◉ No
- Concealing the purposes of the research ○ Yes ◉ No
- Covert observation (or minimal disclosure) ○ Yes ◉ No
- Audio or visual recording without consent ○ Yes ◉ No
- Recruitment of a third party or agency ○ Yes ◉ No
- Withholding from one group specific treatments or methods of learning, from which they may "benefit" (e.g. in medicine or teaching) ○ Yes ◉ No
- Psychological interventions or treatments ○ Yes ◉ No
- Involvement of any experimental manipulation or includes the presentation of any stimulus other than question-asking ○ Yes ◉ No
- Invasive physical procedures ○ Yes ◉ No
- Infliction of pain ○ Yes ◉ No
- Administration of drugs ○ Yes ◉ No
- Administration of other substances or devices ○ Yes ◉ No
- Exposure to ionising radiation ○ Yes ◉ No
- Tissue sampling or blood for pathological or genetic testing ○ Yes ◉ No
- Collecting body fluid (eg. saliva) ○ Yes ◉ No
- Use of medical records where participants can be identified or linked ○ Yes ◉ No

Does the research involve potential risks?

- Are there any potential risks to the researcher? (e.g. research conducted in unsafe environments or trouble spots) ○ Yes ◉ No
- Are there any potential risks to non participants in the research, such as, participant's family members and social community? (e.g. effects of biography on family and friends or infectious disease risk to the community) ○ Yes ◉ No

Select the categories that are targeted or likely to be included as participants in this research study.

- Suffers from a psychiatric / psychological disorder / emotional impairment ○ Yes ◉ No
- Suffering a physical disability or medical condition ○ Yes ◉ No

• Participants are aged less than 18 years	○ Yes	◉ No
• Children and/or young people without parental or guardian consent	○ Yes	◉ No
• Resident of a custodial institution	○ Yes	◉ No
• Unable to give freely an informed consent because of difficulties in understanding information provided (eg. Language difficulties, Non English Speaking Background)	○ Yes	◉ No
• Members of a socially identifiable group with special cultural or religious beliefs or political vulnerabilities	○ Yes	◉ No
• Participants specifically targeted belong to a cultural/minority group or any other collectivity	○ Yes	◉ No
• Those in a dependent relationship with the researchers (eg. Lecturer/student, doctor/patient, teacher/pupil and professional/client)	○ Yes	◉ No
• Participants are identifiable or re-identifiable	○ Yes	◉ No
• Participants are identifiable in the final report when specific consent for release has not been given	○ Yes	◉ No

2. Study details

2.1. Coordinating Investigator / Chief Researcher

Title:	Dr
Forename/Initials:	Ammar
Surname:	Kheir
Mailing Address:	Endoscopy Unit, Queen Elizabeth II Jubilee Hospital, Cnr Kessels & Troughton Roads
Suburb/Town:	Coopers Plains
Postcode:	4108
Country:	Australia
Organisation name:	Queen Elizabeth II Jubilee Hospital
Department:	Gastroenterology Department(Endoscopy Unit)
E-mail:	ammarkheir@gmail.com
Phone (BH):	0424266194
Mobile:	0424266194
Is the chief researcher a student?	○ Yes ◉ No

** For single centred studies the principal investigator and the coordinating investigator will be the same person.*

2.2. Principal Investigator(s)

Principal Investigator 1

Title:	A/Prof
Forename/Initials:	David
Surname:	Hewett
Mailing Address:	Endoscopy Unit, Queen Elizabeth II Jubilee Hospital, Cnr Kessels & Troughton Roads
Suburb/Town:	Coopers Plains
Postcode:	4108
Country:	Australia
Organisation name:	Queen Elizabeth II Jubilee Hospital
Department:	Gastroenterology Department(Endoscopy Unit)
E-mail:	d.hewett@uq.edu.au
Phone (BH):	0414968179
Mobile:	0414968179

Is the principal Investigator a student?	○ Yes ◉ No

Principal Investigator 2

Title:	Dr
Forename/Initials:	Nicholas
Surname:	Tutticci
Mailing Address:	Endoscopy Unit, Queen Elizabeth II Jubilee Hospital, Cnr Kessels & Troughton Roads
Suburb/Town:	Coopers Plains
Postcode:	4108
Country:	Australia
Organisation name:	Queen Elizabeth II Jubilee Hospital
Department:	Gastroenterology Department(Endoscopy Unit)
E-mail:	nick_tutticci@yahoo.com.au
Phone (BH):	0412530925
Mobile:	0412530925
Is the principal Investigator a student?	○ Yes ◉ No

2.3. Associate Investigator(s)

Associate Investigator 1

Title:	Dr
Forename/Initials:	Shinichro
Surname:	Sakata
Mailing Address:	Endoscopy Unit, Queen Elizabeth II Jubilee Hospital, Cnr Kessels & Troughton Roads
Suburb/Town:	Coopers Plains
Postcode:	4108
Country:	Australia
Organisation name:	Queen Elizabeth II Jubilee Hospital
Department:	Gastroenterology Department(Endoscopy Unit)
E-mail:	shin.sakata@gmail.com
Phone (BH):	
Mobile:	0423892628

Associate Investigator 2

Title:	Dr
Forename/Initials:	Antonio
Surname:	Lee
Mailing Address:	Endoscopy Unit, Queen Elizabeth II Jubilee Hospital, Cnr Kessels & Troughton Roads
Suburb/Town:	Coopers Plains
Postcode:	4108
Country:	Australia
Organisation name:	Queen Elizabeth II Jubilee Hospital
Department:	Gastroenterology Department(Endoscopy Unit)
E-mail:	antonio.lee@uqconnect.edu.au
Phone (BH):	
Mobile:	0422790414

2.4. Contact person for the study

Title:	Dr
Forename/Initials:	Ammar
Surname:	Kheir
Mailing Address:	Endoscopy unit
Suburb/Town:	Coopers Plains
Postcode:	4108
Country:	Australia
Organisation name:	Queen Elizabeth II Jubilee Hospital
Department:	Gastroenterology Department (Endoscopy Unit)
E-mail:	ammarkheir@gmail.com
Phone (BH):	0424266194
Mobile:	0424266194

2.6. Researcher/s Qualification, Experience and Skills

List academic qualifications and outline experience and skills relevant to the study that researcher/s and any supporting staff have in undertaking the research. (100 words max)
Ammar Kheir: Bachelor of Medicine and Surgery, Membership of the Royal College of Physician (UK), Final year gastroenterology advanced trainee working at QEII hospital. Has research experience and presented in national and international gastroenterology meetings.

A/Prof David Hewett: is a gastroenterologist, therapeutic colonoscopist and health services researcher. He is well published in effectiveness of colonoscopy for the bowel cancer screening, and he has published widely on new colonoscopic techniques and methods to improve physician performance of colonoscopy. He has parallel interests in health systems research and medical education, including quality of patient care, intergroup relations, and procedural skills training. Dr Hewett is active in national colorectal cancer policy and training initiatives. He is a member of national advisory boards for the National Bowel Cancer Screening Program and Lynch Syndrome Australia. He has served as Director of Training for the Gastroenterological Society of Australia and as a member of the Specialist Training Committee in gastroenterology with the Royal Australasian College of Physicians.

Dr Nicholas Tutticci: is a consultant interventional gastroenterologist at QEII hospital and has published research in colonoscopy and colonic polyps at major gastroenterology journals.

3. Study Specific Details

3.1. Study type, NHMRC Group and Field of Research (FOR)

3.1.1. Please select the study type (one only)

- (•) Clinical research
- ( ) Health research / social science
- ( ) Other

3.1.2. Please select the NHMRC Group and Field of Research from the drop down boxes

NHMRC Group	OTHER MEDICAL AND HEALTH SCIENCES 1199
NHMRC Field of Research	Medical and Health Sciences not elsewhere classified 119999

3.2. Lay Description

Briefly outline in simple terms the study's focus, aim(s), justification, participant group(s), method and possible outcomes. (150 words max.)
There is a perception among some colonoscopists that time required for inserting and removing a snare after each polypectomy, to allow for polyp suctioning and retrieval, increases the total polypectomy time and procedure time. Instead, some colonoscopists would leave the snare inside the scope channel and suction resected polyps and then continue inspecting the colon while the snare sheath is partially withdrawn inside the scope channel, to improve efficiency. Both practices are considered a standard of care. In fact, our local endoscopist use both

techniques on daily bases. However, the efficiency of the snare-within-the-scope-channel (SSC) technique and conventional polypectomy technique has not been studied. Our aim is to study the efficiency of both polypectomy techniques.

Hypothesis:
Snare-within-the-scope-channel technique reduces mean total polypectomy time by 30% compared with conventional polypectomy technique.

3.3. Research Methodology

Outline the proposed method, including data collection techniques, tasks participants will be asked to complete; estimated time commitment required of them; and how data will be analysed. Give a justification of your proposed sample size, including details of statistical power of the sample where appropriate. (600 words max)

Type of research
Clinical

Research design
Prospective Randomised controlled trial

Inclusion criteria:
- All patients undergoing elective colonoscopy (screening, surveillance and diagnostic)
- Polyps ≤9mm

Exclusion criteria:
- Patients under 18 years
- Complex cases for advanced therapeutic colonoscopy (endoscopic mucosal resection, endoscopic submucosal dissection, colonic stenting, colonic dilatation, colonic strictures).

Setting (No change to standard colonoscopy practice at QEII endoscopy unit:
- Split dose bowel preparation using polyethylene glycol.
- High-definition colonoscopes (CF-HQ190L, Olympus, Japan).
- Anaesthesiologist administered propofol sedation.
- Carbon dioxide insufflation during colonoscopy.
- Using standard snares for polypectomy (Boston Scientific Captivator II 10mm snare or US Endoscopy Exacto 9mm snare, both have similar 2.4mm sheath).
- Standard polyp retrieval through suctioning polyp into working channel of the colonoscope into the polyp suction trap.

Investigators:
- Two experienced colonoscopists (DH & NT) at a single centre (Endoscopy unit, QEII hospital)
- A research assistant will use a stop watch to time: Total procedure time, total polypectomy time for each polyp.

Methods used to achieve aims
All procedures will be performed by two experienced colonoscopists (David Hewett and Nick Tutticci). Eligible patients will be consented. Patients with one or more diminutive (5mm or less) or small (6-9mm) will be randomised in the study. Endoscopist will be given a sealed envelope (randomisation envelope for eligible patients) before starting the procedure assigning his method of cold polypectomy (either conventional technique or snare-within-the-scope-channel technique). Resection of colorectal polyps (polypectomy) will be performed using dedicated cold snare polypectomy (Boston Scientific Captivator II 10mm snare or US Endoscopy Exacto 9mm snare).

Conventional technique: As soon as a polyp is found by the endoscopist he will say "Polyp". An independent observing research assistant will use a stopwatch to measure the total polypectomy time from when the endoscopist announces "Polyp" until the resected polyp has been suctioned into the suction trap. This includes snare insertion time into the scope channel, polyp transection time, polyp retrieval time and polyp suction time. The endoscopist will remove the snare out of the scope channel prior to commencing suctioning.

Snare-in-the-scope-channel technique: As soon as a polyp is found by the endoscopist he will say "Polyp". An independent observing research assistant will use a stopwatch to measure the total polypectomy time from when the endoscopist announces "Polyp" until the resected polyp has been suctioned into the suction trap. This includes snare advancement time into the scope channel, polyp transection time, polyp retrieval time and polyp suction time. The endoscopist will suction the resected polyp while the snare is inside the scope channel.

The total procedure time will be measured form the time the colonoscope tip has been inserted into the patient's anus until the procedure has been completed by the endoscopist withdrawing the colonoscope tip outside of the patient's anus.

Primary outcome measurement: Mean polypectomy time per patient.

Secondary outcome measurement: Mean polypectomy time per polyp and mean procedure time per patient.

Definitions:
Snare feeding time: time from when a polyp is detected and the endoscopist requests a snare (conventional polypectomy technique) or when the endoscopist advances the snare sheath (SWITCH technique), until the snare or sheath appears on the monitor.

Polypectomy time: From the time the snare appears in the monitor (endoscopic field), that is end of snare feeding time until the polyp has been transected.

Polyp retrieval time: From the end of polypectomy time until the polyp has been suctioned and disappeared form the monitor (endoscopic filed). For the conventional polypectomy arm, the polyp will be suctioned after the snare has been removed out of the scope channel.

Polyp suction time: is the time from the end of polyp retrieval time until the polyp has reached the polyp suction trap, confirmed by the nursing staff.

Total polypectomy time: is the sum of snare feeding time, polypectomy time, polyp retrieval time and polyp suction time.

Statistical methodology (including sample size)
Assuming a 30% difference (reduced mean of total polypectomy times for snare-within-the-scope-channel technique over conventional technique) we will need 352 patients (176 each arm) with 5% drop rate (18 patients). So the total number of patients in the study is 370 patients.

alpha=0.05, power=80%, delta -30%, sd=1, estimated sample size: N=352 (N per group = 176), 5% drop rate=18.

Data collection techniques
Patient demographic, colonoscopy indication and endoscopist's name will be recorded using the study data collection form.

Polyp location, size, snare used, snare feeding time, polypectomy sime, polyp retrieval time, polyp suction time, total polypectomy time and total procedure time will be recorded on a standardised form. No patient identifiable information will be recorded.

Participant tasks and time involved
An independent research assistant will be present to record total polypectomy time. All other data are routinely collected as part of a standard colonoscopy procedure. There is no anticipated extra time by this study as both techniques are routinely practised by both endoscopists, specially the snare-within-the-scope-channel technique.

Data analysis
Data analysis will be performed using a statistician using STATA13.
Measures for both (conventional and SWITCH polypectomy technique):
Mean total polypectomy time per patient
Mean total polypectomy time per polyp
Mean total procedure time per patient
Regression analysis of primary and secondary outcomes
Summarising study demographics.

Other comments

3.4. Research Aims and Significance

State the aims, research objectives, key research questions, and significance of the study. Where relevant, state the specific hypothesis to be tested. Also please provide a brief description of the relevance of your proposed study to current research, a justification as to why your research should proceed and an explanation of any expected benefits

to the community. Comment on it's potential to contribute to existing knowledge, treatment, disease prevention, health promotion or social improvement. (600 words max.)

Key Research question(s)

Does Snare-within-the-scope-channel technique reduce total polypectomy time compared to conventional polypectomy technique for diminutive and small colorectal polyps?

Aims / Objectives

Primary outcome measurement: Mean polypectomy time per patient.

Secondary outcome measurement: Mean polypectomy time per polyp and mean procedure time per patient.

Hypothesis

Snare-within-the-scope-channel technique (SWITCH) reduces total polypectomy time per patient by 30% compared with conventional cold polypectomy technique.

Significance of study

Assessing the efficiency two polypectomy techniques (both considered to be standard of care and routinely practised by endoscopists) and identify the which is superior.

Relevance to current research

Polypectomy is an important part of screening and surveillance colonoscopy to prevent bowel cancer. Small and diminutive polyps constitute 80-90% of colorectal polyps encountered during colonoscopy. Improving polypectomy efficiency can improve the efficiency of colonoscopy, specially in patients with multiple polyps, who we anticipate will benefit most.

Justification

This research will contribute to the current clinical practice of diminutive and small colorectal polypectomy. It can improve colonoscopy quality by improving time efficiency and utilisation of resources.

Expected benefits to the community

Potentially by reducing polypectomy time and colonoscopy time, more procedures can be performed more efficiently. This can have positive impact on patient's waiting time, reduced polypectomy time, reduced patient sedation time.

Potential contribution to knowledge, treatment, disease prevention, health promotion or social improvement

This study may demonstrate that using snare-within-the-scope-channel (SWITCH) technique is more efficient than conventional cold snare polypectomy technique for diminutive and small colorectal polypectomy.

Other comments

3.5. Provide the anticipated start and finish dates for the research study

Start date*:	14/06/2016 *(dd/mm/yyyy)*
Finish date#:	13/06/2017 *(dd/mm/yyyy)*
Duration (months):	12

** Start date refers to the first point of recruitment i.e. the date when the advertising or screening for participants begins. # Finish date refers to when no further contact with participants/data source is foreseen including the data analysis and reporting period.*

4. Other Approvals

(NHMRC "National Statement on Ethical Conduct in Human Research", Chapter 5.3)

The Principal Researcher is responsible for informing each ethical review body of all other Australian sites at which the research is being proposed or conducted, at the time of submission of the research study; of any previous decisions regarding the research made by another ethical review body; and informing each ethical review body of whether the protocol is presently before another ethical review body.

4.1. Is this study being submitted or has it been previously submitted to other ethical review bodies?

○ Yes ◉ No

Other External Approvals / Reviews?
If your research has undergone peer review, review from a funding body or involves participants from other organisations, copies of letters of approval or reviews must be attached to this application (if pending at the time the application is submitted, forward to HREC/Low Risk Review Committee when available). In some cases, institutions/authorities may decline to provide approval letters until ethics approval has been granted. In such cases, you should submit your application to the HREC for provisional approval pending receipt of the documentation.

4.2. Has the research undergone peer review, review from a funding body or does it involve participants from other organisations?

○ Yes ◉ No

5. Recruitment of Participants

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", Chapter 2.2)

5.1. Participant Details

Provide number, age range and source of participants.
370 patients, aged 18 or older undergoing elective colonoscopy at Endoscopy unit, QEII hospital.

5.2. What is the proposed method of recruitment of participants?

This explanation should include how potential participants will be identified and how initial contact will be made.
All patients aged 18 or older undergoing elective colonoscopy will be eligible for recruitment. Those who are found to have one or more polyps will be randomised in the study.

6. Consent

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", Chapter 2.2, 2.3)

Informing Participants: Participant Information Sheet and Consent Form
The potential participant must be provided with information at their level of comprehension about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the likelihood and form of publication of research results).

6.1. Will the research involve informed consent of participants?

◉ Yes ○ No

If yes, how will informed consent be obtained / recorded?
The research assistant at the clinic or on the day of colonoscopy will assess whether a patient fully understands the study before they sign the consent form.

7. Information Protection (Confidentiality, Data Storage and Security)

(NHMRC "National Statement on Ethical Conduct in Human Research 2007", section 1 and NHMRC, Universities Australia "Australian Code for the Responsible Conduct of Research 2007", Section 2)

7.1. Confidentiality

Explain what methods will be used to guarantee confidentiality/anonymity of participant data
De-identifiable data will be collected and stored in a secured cabinet, in a locked office that is security-code protected at the Department of Gastroenterology.

7.2. Data Storage and Security

Explain how and where data will be held, including any arrangements for data security during the course of the study
Written data will be collected and stored in a secured cabinet, in a locked office that is security-code protected at the Department of Gastroenterology.

Written data will be entered onto a database in a deidentified form and stored on a password-protected computer within the Department of Gastroenterology.

7.3. Please indicate how long the data will be kept?

24 months or less. Data will be destroyed after submission for publication.

7.4. How will data be disposed of?

Written data will be disposed of in a confidential manner via shredding (using departmental confidential information shredding equipment) and data files will be erased.

8. Dissemination of Results

(NHMRC 'National Statement on Ethical Conduct in Human Research 2007', section 1 and NHMRC, Universities Australia 'Australian Code for the Responsible Conduct of Research 2007', Section 4)

8.1. Explain when, how, where and to whom results will be disseminated, including whether participants will be provided with information on the findings or outcomes of the study.

The results of this study are for understanding more about the efficiency of "Snare-within-the-scope channel technique". The results will be analysed at the end of the study and reported as a group in gastroenterology conferences/journals. Individual results will not be meaningful to the participant and will not be disseminated.

9. Conflict of Interest

(NHMRC 'National Statement on Ethical Conduct in Human Research 2007', Chapter 5.4)

9.1. Are there any 'conflict of interest' issues likely to arise in relation to this research?

○ Yes ◉ No

Section 10 Declarations

Signatures and undertakings

Applicant/Principal Researchers (including Students and Supervisors where permitted)

Study Title (in full):	Efficiency of Snare-WithIn-The-scope-CHannel Technique (SWITCH trial) During Cold-Snare Polypectomy: A randomised controlled trial

I/we certify that:

- All information is correct and complete as far as I am / we are aware;
- I/we have had access to and read the NHMRC *"National Statement on Ethical Conduct in Human Research"* (2007)
  - The research will be conducted in accordance with the National Statement;
- I/we have consulted all relevant legislation and regulations and the research will be conducted in accordance with these;
- I/we will immediately report to the HREC/Non-HREC review body any issue which might warrant review of the research, including:
  - Serious or unexpected adverse effects on participants;
  - Complaints;
  - Proposed changes in the protocol; and
  - Unforseen events that might affect continued ethical acceptability of the study;
- I/we have attempted to identify all the risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of participants;
- I/we will not continue the research if ethical approval or site authorisation is withdrawn and will comply with any special conditions required by the HREC/Non-HREC review body, including;
  - Conditions of approval stipulated by the HREC/Non-HREC review body;
  - Cooperate with monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC/Non-HREC review body;
- I/we have the appropriate qualifications, training, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise;
- This study complies with the Queensland Health guidelines for submission for Low Risk Research review.

Researcher name	Designation	Signature	Date
Dr Ammar Kheir	Coordinating Investigator		
A/Prof David Hewett	Principal Investigator		
Dr Nicholas Tutticci	Principal Investigator		
	Student Supervisor		
Dr Shinichro Sakata	Associate Investigator		
Dr Antonio Lee	Associate Investigator		
Dr Ammar Kheir	Contact Person		

Designation means designated title related to the study eg coordinating principal investigator, principal investigator, co investigator, student, study coordinator, site sponsor if principal researcher not a Qld Health employee etc

Please note: Any changes to the signed application form prior to the submission code being generated will invalidate any electronic signatures and as such they will need to be sought again.

Section 11 Attachment

Please attach the following documents as appropriate to your study via the 'Documents' tab.

Core Attachments	Attachments which may be required/appropriate
Recruitment/invitation	Copy of advertisement, letter of invitation etc.
Protocol	Copy of the study protocol with a footer containing version number and date
Participant Information	Copy or script for participant Copy or script for parent, legal guardian or person responsible as appropriate
Consent Form	Copy for participant For parent, legal guardian or person responsible as appropriate For, optional components of the study eg. genetic sub study
Peer review	Copy of peer review report or grant submission outcome
Letters of support	Copies of letters from relevant persons in support of the research application.
Study materials	Copies of questionnaires, data collection tools, patient cards, case report forms etc.
HREC approvals	Copy of outcome of other HREC reviews

Section 12 Ethical Review Processing

HREC Reference Number	HREC/16/QPAH/395
Study Title (in full)	Efficiency of Snare-WithIn-The-scope-CHannel Technique (SWITCH trial) During Cold-Snare Polypectomy: A randomised controlled trial
Principal Investigator(s)	A/Prof David Hewett Dr Nicholas Tutticci
Coordinating Investigator	Dr Ammar Kheir

Accepted for Low Risk Review	◯ Yes ◯ No	
Low risk review AU RED Number		
Allocated to:		
Low Risk Review panel	◯ Yes ◯ No	
Designated HREC members:	1.	
	2.	
	3.	
	4.	
Date Sent to review body:	/ /	
Response Required by:	/ /	
Signed:	Designation:	Date: / /