Online Forms
National Ethics Application Form

Within which Jurisdictions will your research application be submitted to: *(tick all that apply)*

- [ ] New South Wales
- [x] Queensland
- [ ] South Australia
- [ ] Victoria

HREC Application Reference Number:

1. TITLE AND SUMMARY OF PROJECT

1. Title

What is the formal title of this research proposal?
Navigated medial opening wedge high tibial osteotomy versus navigated lateral closing wedge high tibial osteotomy: A randomised controlled trial

What is the short title / acronym of this research proposal (if applicable)?
Navigated HTO MO v LC

2. Description of the project in plain language

Give a concise and simple description (not more than 400 words), in plain language, of the aims of this project, the proposal research design and the methods to be used to achieve those aims.

In patients with symptomatic medial compartment (inner side) knee osteoarthritis (OA) and associated genu varum (bowing of the lower limb) performing a high tibial osteotomy (HTO) can provide pain relief by changing the shape of the limb. The shape changes the point at which compressive load crosses the knee. This unloads the painful arthritic side of the knee and transfer load to the undamaged lateral compartment (outside)of the knee. There are two widely used HTO techniques. These are the medial opening wedge (MO) and the lateral closing wedge (LC) HTO. Intra-operative computer navigation can increase the accuracy and precision of the intended correction but has not been used for the LC technique.

It is unclear in the literature, which approach yields the highest patient satisfaction as very few studies have been done that compare the two techniques. Additionally, there are even fewer studies that have examined the changes to gait mechanics that take effect as a result of the described procedures. To detect a difference between the two procedures, patients will undergo pre-operative and post-operative radiographic (x-ray) and functional joint assessments. In addition, investigators will assess changes to the patients' gait by performing analysis at a Gait Laboratory.

Aims and Outcomes:
1) The primary aim of this study is to analyse if the same correction made by the two above-mentioned techniques (MO wedge HTO and LC wedge HTO) produce the same change to gait mechanics.
2) The secondary aim will include comparisons between groups for time to union, time to weight bear, cosmesis (scar size), change to standing coronal hip knee angle, range of motion, change in patellar height and change in tibial slope. Investigators will record patient reported outcome measures (PROMs) to assess subjective functional outcome of the procedures.

Research Design:
The design of this project is a single centre, multi-surgeon, prospective, randomized controlled trial. (Evidence Level: II)

Materials and Methods:
Patients planned to undergo a HTO procedure at the investigators' clinic who fit study inclusion criteria, may be

approached to voluntarily participate in the study. Patients will be randomised to the MO wedge HTO group or LC wedge HTO group at time of consent. Alignment corrections associated with the procedure will be standardised to 3-5° of valgus. Patients will undergo assessments pre-operatively, and postoperatively for follow-up in clinic at six weeks, six months and yearly.

2. RESEARCHERS / INVESTIGATORS

1. Chief researcher(s)/investigator(s)

This question only applies to multi-centre research. If your research is not multi-centre, please leave this question blank. See Guidance Text (G) for the definition of a Chief Researcher

Chief researcher

Title: Forename/Initials: Surname:

Mailing Address:

Suburb/Town:
State:
Postcode:
Country:
Organisation:
Department*:
Position:
E-mail:
Phone (BH):
Phone (AH)*:
Mobile*:
Pager*:
Fax:

Is this person the contact person for this application?
◯ Yes ◯ No

Summary of qualifications and relevant expertise.

Please declare any general competing interests.

Name the site(s) for which this chief researcher / investigator is responsible.

Describe the role of the chief researcher / investigator in this project.

Is the chief researcher / investigator a student? ◯ Yes ◯ No

2. Principal researcher(s) / investigator(s)

Principal researcher / investigator 1

	Title:	Forename/Initials:	Surname:
	Dr	Peter	McEwen
Mailing Address:	Suite 3, Level 2, Mater Medical Centre 21-29 Fulham Rd Pimlico		
Suburb/Town:	Townsville		
State:	QLD		
Postcode:	4812		
Country:	Australia		
Organisation:	North Queensland Knee		
Department*:	Orthopaedics		
Position:	Orthopaedic Surgeon		

E-mail: peter@kneesurgeon.com.au
Phone (BH): 07 47794788
Phone (AH)*:
Mobile*:
Pager*:
Fax:

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
MBBS
Consultant Orthopaedic Surgeon
20 years clinical experience
Subspecialty interest in knee surgery

Please declare any general competing interests
Nil

Name the site(s) for which this principal researcher / investigator is responsible.
Mater Health Services North Queensland Ltd

Describe the role of the principal researcher / investigator in this project.
Recruitment of Patients according to study protocol,
Collation and analysis of data
Study and Manuscript Supervision
Execution of Surgery

Is the principal researcher a student? ○ Yes ◉ No

3. Associate Researcher(s) / investigator(s)

How many known associate researchers are there? (You will be asked to give contact details for these associate researchers / investigators) 4

Do you intend to employ other associate researchers / investigators? ○ Yes ◉ No

Associate Researcher / Investigator 1

Title:	Forename/Initials:	Surname:
Dr	Kaushik	Hazratwala

Mailing Address: Suite 101, Level 2 Mater Medical Centre, 21-37 Fulham Rd
Pimlico

Suburb/Town: Townsville
State: QLD
Postcode: 4812
Country: Australia
Organisation: Townsville Lower Limb Clinic
Department*: Orthopaedics
Position: Orthopaedic Surgeon
E-mail: drkosh@tsvllc.com.au
Phone (BH): 07 47274111
Phone (AH)*:
Mobile*:
Pager*:
Fax:

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise

Bsc Med, MBBS (UNSW) 1996
FRACS (Ortho) 2007
Consultant Orthopaedic Surgeon at Mater Hospital Townsville and The Townsville Hospital
Special interest in the surgery of the Lower Limb and Trauma

Please declare any general competing interests
Nil

Description of the role of the associate researcher / investigator in this project.
Recruitment of patients according to protocol
Collation and analysis of data
Execution of surgery

Name the site at which the associate researcher / investigator has responsibility.
Mater Health Services North Queensland Ltd

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 2

Title:	Forename/Initials:	Surname:
Dr	Matthew	Wilkinson

Mailing Address:	Dr Matthew Wilkinson Orthopaedic Surgeon
	1/34 Fulham Rd
Suburb/Town:	Pimlico
State:	QLD
Postcode:	4812
Country:	Australia
Organisation:	Dr Matthew Wilkinson Orthopaedic Surgeon
Department*:	Orthopaedics
Position:	Orthopaedic Surgeon
E-mail:	mprwilkinson@hotmail.com
Phone (BH):	0747799902
Phone (AH)*:	
Mobile*:	
Pager*:	
Fax:	

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
MBBS
FRACS Ortho
Consultant Orthopaedic Surgeon at Mater Hospital Townsville and the Townsville Hospital

Please declare any general competing interests
Nil

Description of the role of the associate researcher / investigator in this project.
Recruitment of patients according to protocol
Collation and analysis of data
Execution of Surgey

Name the site at which the associate researcher / investigator has responsibility.
Mater Health Services North Queensland LTD

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 3

Title:	Forename/Initials:	Surname:
Mrs	Andrea	Grant

Mailing Address:	7 Turner Street

Suburb/Town:	Pimlico
State:	QLD
Postcode:	4812
Country:	Australia
Organisation:	Orthopaedic Research Institute of Queensland (ORIQL)
Department*:	Orthopaedics
Position:	Clinical Research Coordinator
E-mail:	research_coordinator@oriql.com.au
Phone (BH):	0747550564
Phone (AH)*:	
Mobile*:	0413685331
Pager*:	
Fax:	

Is this person the contact person for this application?
(•) Yes ( ) No

Summary of qualifications and relevant expertise
BSp ExSc.

Please declare any general competing interests
Nil

Description of the role of the associate researcher / investigator in this project.
Research Design,
Project management
Collation and analysis of data
Assist in manuscript preparation.

Name the site at which the associate researcher / investigator has responsibility.
Mater Health Services North Queensland Ltd

Is this associate researcher / investigator a student? ( ) Yes (•) No

Associate Researcher / Investigator 4

Title:	Forename/Initials:	Surname:
Dr	Ryan Bishal	Faruque

Mailing Address:	7 Turner St
Suburb/Town:	Pimlico
State:	QLD
Postcode:	4812
Country:	Australia
Organisation:	Orthopaedic Research Institute of Queensland (ORIQL
Department*:	Orthopaedic Surgery
Position:	Orthopaedic PHO
E-mail:	rbfaruque@gmail.com
Phone (BH):	
Phone (AH)*:	
Mobile*:	0434410242
Pager*:	
Fax:	

Is this person the contact person for this application?
( ) Yes (•) No

Summary of qualifications and relevant expertise
MBBS

Please declare any general competing interests
Nil

Description of the role of the associate researcher / investigator in this project.
Literature review and research design,
Patient recruitment and assessment,
Data collection,
Manuscript preparation.

Name the site at which the associate researcher / investigator has responsibility.
Mater Health Services North Queensland Ltd

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 5

Title:	Forename/Initials:	Surname:
Dr	Kenji	Doma

Mailing Address:	Sport and Exercise Science, College of Healthcare Sciences
	James Cook University
	Angus Smith Drive
Suburb/Town:	Douglas
State:	QLD
Postcode:	4814
Country:	Australia
Organisation:	James Cook University
Department*:	College of Healthcare Sciences
Position:	Lecturer
E-mail:	kenji.doma@jcu.edu.au
Phone (BH):	
Phone (AH)*:	47814952
Mobile*:	47814952
Pager*:	47814952
Fax:	

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
PhD, BSpExSci(Hons), CSCS, NSCAM, ESSAM

Please declare any general competing interests
Nil declared

Description of the role of the associate researcher / investigator in this project.
Statistician- Assist in formulating statistical methods for study protocol and analyze de-identified data after data collection.
Conducts gait laboratory assessments and analysis of data

Name the site at which the associate researcher / investigator has responsibility.
James Cook University

Is this associate researcher / investigator a student? ○ Yes ◉ No

5. Other personnel relevant to the research project

5a. How many known other people will play a specified role in the conduct of this research project?

5

5b. Describe the role, and expertise where relevant (e.g. counsellor), of these other personnel.

Please refer to Delegation Responsibilities Log in attachments.

Other roles include practice Research Coordinators for examination of potential recruits for study eligibility, patient recruitment, obtain medical history, patient randomisation, adverse events reporting, source documentation completion, safety monitoring, discharge instructions, follow-up phone calls and completion of case report forms electronically and paper-based.

5c. Is it intended that other people, not yet known, will play a specified role in the conduct of this research project?

◯ Yes ◉ No

6. Certification of researchers / investigators

6a. Are there any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research?

◯ Yes ◉ No

7. Training of researchers

7a. Do the researchers / investigators or others involved in any aspect of this research project require any additional training in order to undertake this research?

◯ Yes ◉ No

3. RESOURCES

Project Funding / Support

1. Indicate how the project will be funded?

Type of funding.

[Please note that all fields in any selected funding detail column (with the exception of the code) will need to be completed.]

Funding	Confirmed or Sought?			
External Competitive Grant	◯ Confirmed	◯ Sought	◉ Not Sought	
Internal Competitive Grant	◯ Confirmed	◯ Sought	◉ Not Sought	
Sponsor	◯ Confirmed	◯ Sought	◉ Not Sought	
By Researchers Department or Organisation	◯ Confirmed	◉ Sought	◯ Not Sought	*Amount of funding* $22 000

1d. By Researchers Department or Organisation

Name of Grant / Sponsor	Townsville Hospital Health Services Private Practice Research Fund.
Code (optional)	
Detail in kind support	Prinicipal Investigator's time plus administration staff time.
Indicate the extent to which the scope of the grant and the scope of this HREC application	Ethics approval is a requirement of Private Practice Trust to award funds. An application will be submitted to the Trust pending

are aligned: Ethics approval.

2. How will you manage a funding shortfall (if any)?

ORIQL has means to fund this project failing 'Trust' support

3. Will the project be supported in other ways eg. in-kind support/equipment by an external party eg. sponsor?

○ Yes ◉ No

4. Is this a study where capitation payments are to be made, and will participants be made aware of these payments to clinicians or researchers / investigators?

NA

Duality of Interest

5. Describe any commercialisation or intellectual property implications of the funding/support arrangement.

Nil

6. Does the funding/support provider(s) have a financial interest in the outcome of the research?

○ Yes ◉ No

7. Does any member of the research team have any affiliation with the provider(s) of funding/support, or a financial interest in the outcome of the research?

◉ Yes ○ No

Describe affiliation(s) and/or interest(s):
The ORIQL is a nonprofit organisation, the Principal Investigators are Senior Consultant Orthopaedic Surgeons and are founding Directors of ORIQL.
Do you consider the relationship between the research team and the funding/support provider constitutes:

☐ a potential conflict of interest

☐ a potential duality of interest

☑ no ethical issue

Provide an explanation:
No financial interest is gained for the ORIQL or by its members by supporting this project.

8. Does any other individual or organisation have an interest in the outcome of this research?

○ Yes ◉ No

9. Are there any restrictions on the publication of results from this research?

○ Yes ◉ No

4. PRIOR REVIEWS

Ethical Review

Some HRECs may require researchers to provide information additional to that contained in a NEAF proposal. For this reason, it is prudent to check whether the HRECs to whom you propose to submit this proposal require additional information.

Duration and location

1. In how many Australian sites, or site types, will the research be conducted?

1

2. In how many overseas sites, or site types, will the research be conducted?

0

3. Provide the following information for each site or site type (Australian and overseas, if applicable) at which the research is to be conducted

4. Provide the start and finish dates for the whole of the study including data analysis

Anticipated start date: 01/09/2016 *(dd/mm/yyyy)*
Anticipated finish date: 31/12/2018 *(dd/mm/yyyy)*

5. Are there any time-critical aspects of the research project of which an HREC should be aware?

○ Yes ◉ No

6. To how many Australian HRECs (representing site organisations or the researcher's / investigator's organisation) is it intended that this research proposal be submitted?

1
A list of NHMRC registered Human Research Ethics Committees (HRECs), along with their institutional affiliations and contact details is available on the NHMRC website at the following web address: http://www.nhmrc.gov.au/health_ethics/hrecs/overview.htm#d.

7. HRECs

HREC 1

Name of HREC:
Mater Health Services HREC (EC00332)

Provide the start and finish dates for the research for which this HREC is providing ethical review:
Anticipated start date or date range: 01/09/2016 *(dd/mm/yyyy)*
Anticipated finish date or date range: 31/12/2018 *(dd/mm/yyyy)*

For how many sites at which the research is to be conducted will this HREC provide ethical review?
1

Site 1

Name of Site:

Principal Researcher 1

Principal Researcher Name:
Dr Peter McEwen

Associate Researcher 1

Associate Researcher Name:
Dr Kaushik Hazratwala

Associate Researcher 2

Associate Researcher Name:
Dr Matthew Wilkinson

Associate Researcher 3

Associate Researcher Name:
Mrs Andrea Grant

Associate Researcher 4

Associate Researcher Name:
Dr Ryan Bishal Faruque

8. Have you previously submitted an application, whether in NEAF of otherwise, for ethical review of this research project to any other HRECs?

○ Yes ◉ No

9. HRECs

Research conducted overseas

Peer review

11. Has the research proposal, including design, methodology and evaluation undergone, or will it undergo, a peer review process?

◉ Yes ○ No

Provide details of the review and the outcome. A copy of the letter / notification, where available, should be attached

to this application.
This project was developed using the AO Surgical Foundation "Conducting Clinic Research Guidelines". The study design has undergone review and approval by the Orthopaedic Consultant Directors from ORIQL.

5. PROJECT

1. Type of Research

Tick as many of the following 'types of research' as apply to this project. Your answers will assist HRECs in considering your proposal. A tick in some of these boxes will generate additional questions relevant to your proposal (mainly because the National Statement requires additional ethical matters to be considered), which will appear in Section 9 of NEAF.

The project involves:

- [ ] Research using qualitative methods
- [ ] Research using quantitative methods, population level data or databanks, e.g survey research, epidemiological research
- [x] Clinical research
- [ ] Research involving the collection and / or use of human biospecimens
- [ ] Genetic testing/research
- [ ] A cellular therapy
- [ ] Research on workplace practices or possibly impacting on workplace relationships
- [ ] Research conducted overseas involving participants
- [ ] Research involving ionising radiation
- [ ] Research involving gametes or use or creation of embryos
- [ ] None of the above

Does the research involve limited disclosure to participants?

- ○ Yes
- ◉ No

Does the research involve:

- [ ] Opt out approach
- [ ] Waiver
- [x] None of the above

Research plan

2. Describe the theoretical, empirical and/or conceptual basis, and background evidence, for the research proposal, eg. previous studies, anecdotal evidence, review of literature, prior observation, laboratory or animal studies.

Medial compartment OA and associated genu varum deformity can be managed with HTO by either a MO wedge or a

LC wedge approach. MO wedge HTO changes the limb angle by lengthening the medial column of the tibia by creating a triangular defect (open wedge). A LC wedge HTO changes the limb angle by shortening the lateral column of the tibia by removing a wedge of bone (closed wedge). Both methods can adequately correct the limb shape but are different in some respects (4). The use of computer navigation can also be applied to HTO procedures to increase accuracy and precision (2). A database search of previous studies revealed four prospective clinical trials that compare traditional MO wedge HTO vs LC wedge HTO(1) and navigated MO wedge HTO vs traditional MO wedge HTO(3). Computer navigated MO HTO has not previously been compared with computer navigated LC HTO.

Nerhus et al performed a prospective randomized clinical trial comparing traditional MO Wedge HTO vs LC Wedge HTO where investigators compared final corrections to planned corrections. Radiological measurements were taken pre-operatively and at six months post-operatively. Leg length significantly increased by a mean 3.1 mm after MO HTOs and a decrease by mean 5.7 mm after LC. Amzallag et al, conducted a study investigating patellar height modification after HTO surgery. Both studies showed no significant difference in patellar height. For post-operative leg length changes, both studies demonstrated a significant decrease for the LC HTO group. Nerhus et al also found there was a significant reduction in tibial slope with the LC (6.5 ±2.3mm to 3.9 ± 4.4mm) where no change was measured with MO (7.0 ± 2.6mm to 8.0 ± 3.4mm).

In 2016, Na et al concluded from their retrospective investigation into the use of computer navigation in MO HTO compared to traditional MO wedge HTO, that navigation maintained tibial slope. According to investigators, the MO wedge HTO navigation group also had reduced radiation exposure. There were, however, no studies investigating the use of navigation for LC wedge HTO for comparison of these parameters.

The primary aim of an HTO is to correct coronal plane limb alignment. Both techniques have been shown to be effective in this regard. There is an assumption that the same intra-operative correction achieved using different techniques produces the same correction to gait mechanics post-operatively.

Ground reaction force analysis is one method that is used to measure the effect on gait pattern following HTO surgery. DeMeo and colleagues investigated adduction moment and vertical ground reaction force with gait analysis along with the clinical and radiographic results after a MO HTO in a case series of 20 consecutive patients with isolated medial compartment osteoarthritis and varus deformity. Gait analysis was performed pre-operatively and at 6 months post-operatively. Their pre-operative gait analysis showed abnormal weight bearing pattern. Post-operative analysis of vertical ground-reaction force revealed a return to normal double peak pattern. Pre-operative varus averaged 3.6° (range, 0°-6°) and was corrected to an average of 7.5° (range, 4°-9°) of valgus. There was a 29% reduction in the adduction moment post-operatively, indicating improved weight distribution when walking.

We are unaware of any literature comparing navigated medial opening (MO) wedge HTO versus navigated lateral closing (LC) wedge HTO.

REFERENCES:
See Study Protocol in supporting documents.

3. State the aims of the research and the research question and/or hypotheses, where appropriate.

Hypothesis:
(1) That the same correction achieved intra-operatively using two different osteotomy techniques will produce the same correction to standing limb shape and gait mechanics.
(2) Computer navigated LC wedge is as accurate as computer navigated MO wedge HTO.

Primary Aim: Investigate what effect on gait pattern, if any, MO HTO versus LC HTO based on the changes in:
- Ground reaction force
- Adductor moment
- Abductor moment

Secondary Aims: What are the comparisons between LC and MW HTO in regards to the radiographic parameters
- Time to union
- Time to weight bear
- Scar size
- Change in leg length
- Change to coronal hip knee angle angle (HKA) (Measured radiographically)
- Change to ROM (Measured by digital inclinometer)
- Change in patellar height (Lateral radiographs assessed using 'Blackburn Peele' methodology)
- Change in tibial slope (Assessment from lateral radiograph)
- PROM (patient reported outcome measures) to assess patient subjective functional outcome

4. Has this project been undertaken previously?

○ Yes ◉ No

Benefits/Risks

In answering the following questions (Q 5 – 11) please ensure that you address all issues relevant to the type of participants that will be involved in your research project. Refer for guidance to relevant chapters of the National Statement.

5. Does the research involve a practice or intervention which is an alternative to a standard practice or intervention?

○ Yes ◉ No

7. What expected benefits (if any) will this research have for the wider community?

Medial compartment OA is a common problem, in particular for the younger active people, who often find the condition debilitating affecting their recreational and professional life. Better understanding of effects of current management will enable surgeons to progress patients towards a pain free and productive life; for younger individuals to remain in the workforce, live a more constructive life and remain an active part of the community.

8. What expected benefits (if any) will this research have for participants?

There are no specific benefits to the participants to be part of this study.

9. Are there any risks to participants as a result of participation in this research project?

◉ Yes ○ No

10. Explain how the likely benefit of the research justifies the risks of harm or discomfort to participants.

Participation in this trial poses no additional risk to the patients outside of the risks associated with surgery and anaesthetic risk inherent to the procedure.

11. Are there any other risks involved in this research? eg. to the research team, the organisation, others

○ Yes ◉ No

12. Is it anticipated that the research will lead to commercial benefit for the investigator(s) and or the research sponsor (s)?

○ Yes ◉ No

16. Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?

○ Yes ◉ No

Monitoring

17. What mechanisms do the researchers / investigators intend to implement to monitor the conduct and progress of the research project?

The study will be conducted according to the Research Protocol, whereby patients will be assessed and monitored at clinically relevant time points:

1. Pre-operative clinical review: Knee function assessment, medical assessment by an anaesthetist.

2. On Ward (Peri-operative): Patients will undergo a clinical assessment on a daily basis during inpatient post-operative periods until discharge. This will include pain and wound management.

3. Clinician review and assessment: Patients will be reviewed at six weeks, six months and 12 months post-operatively. At all time points (including pre-operative) patients will be requested to complete Patient Reported Outcome Measure Scores as part of their participation in the trial. Interpretation of these scores enables the Investigating surgeon to assess patient pain, function, satisfaction in conjunction with physical assessments.

18. Please detail your Data and Safety Monitoring Board (DSMB) and its nominee for this trial.

Data monitoring and safety will be done externally by a fellow colleague, Senior Consultant Orthopaedic Surgeon Dr David Ness.

6. PARTICIPANTS

1. Research participants

The National Statement identifies the need to pay additional attention to ethical issues associated with research involving certain specific populations.

This question aims to assist you and the HREC to identify and address ethical issues that are likely to arise in your research, if its design will include one or more of these populations. Further, the National Statement recognizes the cultural diversity of Australia's population and the importance of respect for that diversity in the recruitment and involvement of participants. Your answer to this question will guide you to additional questions (if any) relevant to the participants in your study.

Tick as many of the following 'types of research participants' who will be included because of the project design, or their inclusion is possible, given the diversity of Australia's population. If none apply, please indicate this below.

If you select column (a) or (b), column (c) will not apply.

The participants who may be involved in this research are: ***If you select column (a) or (b), column (c) will not apply.***	**a) Primary intent of research**	**b) Probable coincidental recruitment**	**c) Design specifically excludes**
People whose primary language is other than English (LOTE)	☐	☑	☐
Women who are pregnant and the human fetus	☐	☐	☑
Children and/or young people (ie. <18 years)	☐	☐	☑
People in existing dependent or unequal relationships	☑	☐	
People highly dependent on medical care	☐	☐	☑
People with a cognitive impairment, an intellectual disability or a mental illness	☐	☐	☑

Aboriginal and/or Torres Strait Islander peoples	☐	☑	☐
People who may be involved in illegal activity	☐	☑	☐
None apply	☐		

You have indicated that it is probable that
- People whose primary language is other than English (LOTE)
- Aboriginal and/or Torres Strait Islander peoples
- People who may be involved in illegal activity

may be coincidentally recruited into this project. The National Statement identifies specific ethical considerations for these groups(s).

Please explain how you will address these considerations in your proposed research.
1)Regarding participants whose primary language is other than English (LOTE), a translator will be utilized to gain informed consent. If there is a question regarding the patients understanding or ability to consent, we will not seek consent, and patients will not be enrolled into the study.

2) The doctor-patient relationship is inevitably a dependent/unequal relationship in that the patient is dependent on the doctor for advice regarding their illness and surgery. Although paternalistic in nature, the surgeon will always act in the best interest of the patient and for their best outcome. The best course of action will be taken in consultation with the patient, patient carers, and family where feasible. This includes the decision for the patient not to have surgery or be part of the study if the parties involved feel this is in the patient's best interest.

3)Regarding Aboriginal and/or Torres Strait Islander peoples, the racial/religious/social backgrounds have no bearing on recruitment or management in this project.

4)Regarding people who may be involved in illegal activity, such activity is not identified and will not be sought to be identified

Participant description

2. How many participant groups are involved in this research project?

2

3. What is the expected total number of participants in this project at all sites?

20

4. Groups

Group 1

Group name for participants in this group: Medial Opening Wedge Group (MO HTO)
Expected number of participants in this group: 10
Age range: 30–60 years

Other relevant characteristics of this participant group:
BMI<35
Medial compartment OA with medial knee pain
Intact ACL
Varus malalignment of <10°
Clinically silent patellofemoral compartment
Normal lateral compartment
Fixed flexion deformity <10°

Exclusion criteria:
Symptomatic OA of the lateral compartment

Rheumatoid arthritis
Previous infection in the knee
History of an angulated fracture of the lower extremity
Flexion contracture of >10°
Why are these characteristics relevant to the aims of the project?
These patients are amenable to undergo a HTO procedure. They will undergo a MO HTO specifically. The results of which will be used for comparison to outcome of LC HTO group.

Group 2

Group name for participants in this group: Lateral Closing Wedge Group (LC HTO)
Expected number of participants in this group: 20
Age range: 30–60 years

Other relevant characteristics of this participant group:
BMI<35
Medial compartment OA with medial knee pain
Intact ACL
Varus malalignment of <10°
Clinically silent patellofemoral compartment
Normal lateral compartment
Fixed flexion deformity <10°

Exclusion criteria:
Symptomatic OA of the lateral compartment
Rheumatoid arthritis
Previous infection in the knee
History of an angulated fracture of the lower extremity
Flexion contracture of >10°
Why are these characteristics relevant to the aims of the project?
These patients are amenable to undergo a HTO procedure. They will undergo a LC HTO specifically. The results of which will be used for comparison to outcome of MO HTO group.

Your response to question 1 at Section 6 - "Research Participants" indicates that the following participant groups are excluded from your research. If this is not correct please return to question 1 at Section 6 to amend your answer.

- Women who are pregnant and the human fetus
- Children and/or young people (ie. <18 years)
- People with an intellectual or mental impairment
- People highly dependent on medical care

5. Have any particular potential participants or groups of participants been excluded from this research? In answering this question you need to consider if it would be unjust to exclude these potential participants.

1)Surgery of this nature is unnecessary to perform on women who are pregnant as well as their unborn fetus and will not be required to undergo this surgical procedure.

2)Children and/or young people (i.e. <18 years)do not generally suffer isolated medial compartment OA, and are not treated with such procedures.

3)People with an intellectual or mental impairment are not able to provide informed consent for the procedure, and therefore it is unethical to include those patients in the study.

4)People highly dependent on medical care may have very poor outcomes given tehir medical conditions and required care thus causing bias to the data. Furthermore, they would not be amenable to the surgery and thus it would be malicious and unethical to include them in the study.

Participant experience

6. Provide a concise detailed description, in not more than 200 words, in terms which are easily understood by the lay reader of what the participation will involve.

Patients will be assessed for eligibility according to the selection criteria and recruited for the study in clinic during

their initial consultation. Participants will be randomized to one of the two study groups. Participants will complete pre-operative PROMs (questionnaires), undergo functional assessments in clinic as well as diagnostic x-rays. Pre-operative x-rays are part of initial assessment irrespective of patient study recruitment. Patients will remain under hospital care after surgery until pain is managed adequately by oral medication and meet mobilization milestones under observation of ward physiotherapists. Post-operative management in clinic will include review at two weeks, six weeks, three months, six months and 12 months. The purpose of a review is to assess patient progress. Post-operative gait analysis will be organised for around 6-8 months. Repeat x-ray will be performed at six weeks to check for bony union; repeated at three, six and 12 months to check for maintenance of surgical correction. Repeat functional assessment and PROMs will be performed at three, six and 12 months.

Relationship of researchers / investigators to participants

7. Specify the nature of any existing relationship or one likely to rise during the research, between the potential participants and any member of the research team or an organisation involved in the research.

The participants involved in the study will be patients of the three principal researchers from the ORIQL Dr. McEwen, Dr. Hazratwala or Dr. Wilkinson. There will be no other predictable or potential relationships.

9. Describe what steps, if any, will be taken to ensure that the relationship does not impair participants' free and voluntary consent and participation in the project.

Being part of the trial will be completely voluntary. If the patient wishes to follow a certain management path, then there will be no prejudice or affect to their current or future treatment otherwise.

10. Describe what steps, if any, will be taken to ensure that decisions about participation in the research do not impair any existing or foreseeable future relationship between participants and researcher / investigator or organisations.

Being part of the trial is completely voluntary. If the patient wishes to follow a certain management path, then there will be no prejudice or affect to their current or future treatment otherwise.

11. Will the research impact upon, or change, an existing relationship between participants and researcher / investigator or organisations?

○ Yes ◉ No

Recruitment

13. What processes will be used to identify potential participants?

Potential participants will be identified at initial or subsequent consultation in clinics by the respective surgeons participating, Dr's McEwen, Hazratwala and Wilkinson.

14. Is it proposed to 'screen' or assess the suitability of the potential participants for the study?

◉ Yes ○ No

How will this be done?
If patients are scheduled to undergo a HTO procedure and meet the following inclusion and exclusion criteria they will be asked to participate.

Inclusion criteria:
Age 30–60 years
BMI<35
Medial compartment OA with medial knee pain
Intact ACL
Varus malalignment of <10°
Clinically silent patellofemoral compartment
Normal lateral compartment

Fixed flexion deformity <10°

Exclusion criteria:
Symptomatic OA of the lateral compartment
Rheumatoid arthritis
Previous infection in the knee
History of an angulated fracture of the lower extremity
Flexion contracture of >10°

15. Describe how initial contact will be made with potential participants.

Patients are referred to the consulting orthopaedic surgeon and attend a face-to-face consultation with the respective surgeon and practice nurses.

16. Do you intend to include both males and females in this study?

◉ Yes ○ No

What is the expected ratio of males to females that will be recruited into this study and does this ratio accurately reflect the distribution of the disease, issue or condition within the general community?
We expect to have equal numbers of male and female patients to exclude any gender associated bias to our data and ultimate conclusions.

17. Is an advertisement, e-mail, website, letter or telephone call proposed as the form of initial contact with potential participants?

○ Yes ◉ No

18. If it became known that a person was recruited to, participated in, or was excluded from the research, would that knowledge expose the person to any disadvantage or risk?

○ Yes ◉ No

Consent process

19. Will consent for participation in this research be sought from all participants?

◉ Yes ○ No

Will there be participants who have capacity to give consent for themselves?
◉ Yes ○ No

What mechanisms/assessments/tools are to be used, if any, to determine each of these participant's capacity to decide whether or not to participate?
Potential particpants will be assessed by the surgeon during the initial consultation. The consent process for the surgery is much more complicated and extensive than the ensuing recruitment process for this trial. Therefore, it is acceptable to consider that patients with capacity to provide consent for their surgery are cognizant to do so for participation in this trial.

Are any of the participants children or young people?
○ Yes ◉ No

Will there be participants who do not have capacity to give consent for themselves?
○ Yes ◉ No

The following questions relate to participants who are able to provide consent and also to participants for whom consent may be provided by a person with legal authority to do so. When answering these questions you need to describe any differences in the processes followed, or the documentation used, for different groups of participants in

your proposal, e.g. processes and documentation for users of facilities/services will differ from those for providers of those facilities/services. Where your proposal involves participants with an intellectual or mental impairment, or people in dependent relationships, additional questions about their consent appear at section 7 questions 19-20 and questions 15-18 respectively.

Describe the consent process, ie how participants or those deciding for them will be informed about, and choose whether or not to participate in, the project. 1) Only patients with capacity will be considered.
2) Participants will have been assessed for capacity prior and provided consent for the surgery proposed.
3) The surgeon will explain the aims of the trial and the participant's involvement in order to obtain consent. The patient will be given information regarding the trial as well as a copy of their consent detailing their involvement.
4) If the patient wishes to be part of the trial they will provide consent as witnessed by the practice nurse. Information on who to contact for further information on the trial, potential adverse events and or other research related queries will be provided to the patient.
If a participant or person on behalf of a participant chooses not to participate, are there specific consequences of which they should be made aware, prior to making this decision? No
Might individual participants be identifiable by other members of their group, and if so could this identification could expose them to risks? No
If a participant or person on behalf of a participant chooses to withdraw from the research, are there specific consequences of which they should be made aware, prior to giving consent? No
Specify the nature and value of any proposed incentive/payment (eg. movie tickets, food vouchers) or reimbursement (eg travel expenses) to participants. Nil
Explain why this offer will not impair the voluntary nature of the consent, whether by participants' or persons deciding for their behalf. There is no incentive for the patient to participate other than the patient's willingness to be involved in the trial.

Are the participants from which you are recruiting attending for therapeutic care? If yes please provide the details of this care Participants will have been referred to a participating consultant orthopaedic surgeon for treatment of medial knee osteoarthritis unresponsive to simple measures. HTO is one treatment option with indications and exclusion recored above.

Do you propose to obtain consent from individual participants for your use of their stored data/samples for this research project?
(●) Yes ( ) No

7. Participants Specific

People in dependent or unequal relationships

You have indicated that the project involves persons in dependent relationships. You may need to reconsider your answers to Section 6 Questions 7-11 to ensure that the information provided is accurate and consistent.

15. Describe the dependent relationship between the participants and the researcher, members of the research team, and/or any person involved in the recruitment/consent process.

The principal researcher and two associate researchers are the treating surgeons of the study participants. The surgeon / patient relationship is inherently unequal and dependent with the patient relying completely on their treating surgeon to be highly competent and acting in their best interests at all times.

16. How will the process of obtaining consent enable persons in dependent relationships to give voluntary consent?

It will be made clear at the point of recruitment that participation is voluntary and can be refused without prejudice.

17. Will there be any specific risks to participants in this research project as a result of the dependent relationship?

( ) Yes (●) No

18. If a participant chooses to withdraw from the research, how will the ongoing dependant relationship with the participant be maintained?

The treating surgeons' primary responsibility is to the patient not the research. Withdrawal from the study does not alter this and the treating surgeon is morally and ethically compelled to complete the episode of care.

8. CONFIDENTIALITY/PRIVACY

Answers to the questions in section 8.1 will establish whether an HREC will need to apply guidelines under federal or State/territory privacy legislation in reviewing your application. Answers to questions in the remaining parts of section 8 will show how confidentiality of participants is to be protected in your research.

1. Do privacy guidelines need to be applied in the ethical review of this proposal?

Indicate whether the source of the information about participants which will be used in this research project will involve:

- [x] collection directly from the participant
- [ ] collection from another person about the participant
- [ ] use or disclosure of information by an agency, authority or organisation other than your organisation
- [ ] use of information which you or your organisation collected previously for a purpose other than this research project

Information which will be collected for this research project directly from the participant

Describe the information that will be collected directly from participants. Be specific where appropriate.
Patient Demographic data:
-Age
-Gender
-Body mass index (BMI)
-Co-morbidities: Diabetes, smoking, bleeding diathesis, clotting disorder

Functional Outcomes:
-Type of osteotomy
-Pre-operative and post-operative mobility
-ROM (measures by inclinometer)
-Time to weight bear (defined as time, in days post-operatively, that the patient is able to bear weight on the operated limb)
-Time to weight bear without crutches (defined as time, in days post-operatively, the patient is comfortable to walk and gait pattern normalised, not requiring crutches as indicated by physiotherapist)
-Scar size (length measured in centimetres)
-Reduced symptoms related to the internal fixation device

Radiological Outcomes (measured from patient's x-rays)
- Hip knee ankle angle (HKA) from weight bearing long leg x-rays.
- Posterior tibial slope
- Patellar height
- Time to union

PROM's:
-Knee injury and Osteoarthritis Outcome score (KOOS)
-Oxford Knee score (OKS)
-VAS Pain Score(Visual-analogue-scale)

The information collected by the research team about participants will be in the following form(s). Tick more than one box if applicable.

- [ ] individually identifiable
- [x] re-identifiable
- [ ] non-identifiable

Give reasons why it is necessary to collect information in individually identifiable or re-identifiable form
Patients' details will be stored on an orthopaedic specific research registry/database at ORIQL. Primary data collection will include name and date of birth as mandatory identifiers. Recording of such information will allow easy identification of patients by the Research Coordinator to review data collected during recruitment phase. The database is password protected with limited access only to the named investigators and Research Coordinator. Raw data will be de-identified (re-identifiable) and given to an independent statistician to perform the appropriate statistical analysis.

1c. Will the information to be used in medical research?

◉ Yes ○ No

1d. Does this application include an attachment relevant to state/territory privacy legislation?

○ Yes ◉ No

1e. Is the information health information?

◉ Yes ○ No

Using information from participants

2. Describe how information collected about participants will be used in this project.

Information will be used to define research groups, and to establish clinical, outcome and baselines endpoints. Data collection will be de-identified, analysed by statistical software (SPSS)and collated with the intent for presentation and publication.

3. Will any of the information be used by the research team be in identified or re-identifiable (coded) form?

◉ Yes ○ No

Indicate whichever of the following applies to this project:

☐ Information collected for, used in, or generated by, this project will not be used for any other purpose.

☐ Information collected for, used in, or generated by, this project will/may be used for another purpose by the researcher for which ethical approval will be sought.

☑ Information collected for, used in, or generated by, this project is intended to be used for establishing a database/data collection/register for future use by the researcher for which ethical approval will be sought.

☐ Information collected for, used in, or generated by, this project will/may be made available to a third party for a subsequent use for which ethical approval will be sought.

4. List ALL research personnel and others who, for the purposes of this research, will have authority to use or have access to the information and describe the nature of the use or access. Examples of others are: student supervisors, research monitors, pharmaceutical company monitors.

Dr Peter McEwen (Clinical data collection and supervision of manuscript)
Dr Matthew Wilkinson(Clinical data collection)
Dr Kaushik Kazratwala (Clinical data collection)
Mrs Andrea Grant (Research Coordinator)
Dr Ryan Bishal Faruque (Clinical research assistant, data analysis and publication)

Storage of information about participants during and after completion of the project

5. In what formats will the information be stored during and after the research project? (eg. paper copy, computer file on floppy disk or CD, audio tape, videotape, film)

Information will be stored on a computer hard drive located at ORIQL and in a password protected secure cloud based server. Source data and collection via study case report forms may be obtained directly from patients electronically or through a paper-based medium. Electronic data and paper-based copies will be stored securely for at least five years.

6. Specify the measures to be taken to ensure the security of information from misuse, loss, or unauthorised access while stored during and after the research project? (eg. will identifiers be removed and at what stage? Will the information be physically stored in a locked cabinet?)

All data will be recorded on a password secure hard drive and cloud based server. Secure system with both server and database password protected. Data cannot be de-identified initially as routine clinical practice requires indefinite surveillance
of patients progress and reviews. A study number will be allocated to patients on recruitment. Data analysis will utilize a randomized study number to maintain confidentiality in the re-identifiable format.

9. The information which will be stored at the completion of this project is of the following type(s). Tick more than one box if applicable.

- [x] individually identifiable
- [ ] re-identifiable
- [ ] non-identifiable

Give reasons why it is necessary to store information in individually identifiable or re-identifiable form.
Data will not be de-identified as the routine clinical practice requires indefinite surveillance of post-operative patient progress and reviews. All data is securely stored, and cannot be accessed by the general public. Any data to be analysed will be de-identified and send to a statistician.

10. For how long will the information be stored after the completion of the project and why has this period been chosen?

Success in HTO surgery is measured in terms of decades. In line with best practice the intention is to monitor the patients until failure of the procedure which may exceed 20 years. NHMRC regulations suggest at least five year maintenance of trial data. Thus, ORIQ will store data for at least five years.

11. What arrangements are in place with regard to the storage of the information collected for, used in, or generated by this project in the event that the principal researcher / investigator ceases to be engaged at the current organisation?

The ORIQL will employ a new research fellow at completion of the current research fellow's 12-month tenure; the change over will occur during the current Governance period pending application is approved. The change-over will not affect the continuation of research nor the Associate's ability to fulfill their requirements to this project. The Principal Research group will remain Investigators of this project.
There will be consistency in the Research Coordinator (Research Associate for this trial) as their position is Permanent within ORIQL.
All information will remain property of ORIQL; external access to the ORIQL Server and Database is prohibited outside of an employment contract or prior approval by ORIQL Directors. Source Data by form of paper and or electronic, remains property of ORIQL and is required to be handed over to the Institute upon end of term.

Ownership of the information collected during the research project and resulting from the research project

13. Who is understood to own the information resulting from the research, eg. the final report or published form of the results?

The Orthopaedic Research Institute of Queensland (The ORIQL)

14. Does the owner of the information or any other party have any right to impose limitations or conditions on the

publication of the results of this project?

◯ Yes ◉ No

Disposal of the information

15. Will the information collected for, used in, or generated by this project be disposed of at some stage?

◉ Yes ◯ No

At what stage will the information be disposed?
Information may be securely destroyed once the lifespan of the HTO procedure or the patient is exceeded.
How will information, in all forms, be disposed?
Secure hard copies (i.e. paper form) will be disposed via mechanical shredding at the host institution in due course. Any secure digitized (i.e. computer files) will be erased using commercially available data disposable software (e.g.Think Vantage Secure Data Disposal) which removes data from hard drives and makes the erased data irretrievable. In addition to these measures, data will be stored on encrypted hard drives, ensuring that any 'data remanence' is diminished.

Reporting individual results to participants and others

16. Is it intended that results of the research that relate to a specific participant be reported to that participant?

◯ Yes ◉ No

Explain/justify why results will not be reported to participants:
The results following this study will have no bearing on the outcome of the patient post-operatively; it will not change their recovery, progress or prognosis in anyway thus will not greatly benefit from receiving a report of their individual research results.

17. Is the research likely to produce information of personal significance to individual participants?

◯ Yes ◉ No

18. Will individual participant's results be recorded with their personal records?

◉ Yes ◯ No

19. Is it intended that results that relate to a specific participant be reported to anyone other than that participant?

◯ Yes ◉ No

20. Is the research likely to reveal a significant risk to the health or well being of persons other than the participant, eg family members, colleagues

◯ Yes ◉ No

21. Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?

◯ Yes ◉ No

22. How is it intended to disseminate the results of the research? eg report, publication, thesis

Presentation at national and international meetings and publication in peer reviewed journals.

23. Will the confidentiality of participants and their data be protected in the dissemination of research results?

(•) Yes ( ) No

Explain how confidentiality of participants and their data will be protected in the dissemination of research results:
No individual identifiers of research results will be presented. All data will be expressed in terms of groups rather than individuals. Summary statistics will be used.

9. PROJECT SPECIFIC

Your responses to question 5.1 "Type of Research" and question 6.1 "Research participants" indicate that the HREC will require additional information which is specific to your research project. The following table indicates the question sets relating to the project that you will need to complete. If this is not correct please return to question 5.1 and 6.1 at to amend your answer.

- 9.1. Type of research/trial
- 9.2. Clinical research

9.1 Type of research/trial

1. The study involves:

- [ ] The administration of a drug / medicine (includes a complementary / alternative medicine)
- [ ] The use of a medical device
- [ ] The administration of human somatic cell gene therapy
- [ ] The use of a xenotransplant
- [ ] The use of stem cells (adult or embryonic) as therapy
- [x] Other

*Describe the type of study to be conducted:*The study involves the prospective comparison of two commonly employed surgical procedures coupled with computer navigation to increase surgical accuracy and precision. TGA approved devices will be used to maintain surgical correction of the bone.

2. The project will be conducted as follows:

Under the Clinical Trial Notification Scheme (CTN) ( ) Yes (•) No

Under the Clinical Trial Exemption Scheme (CTX) ( ) Yes (•) No

You have indicated that you are conducting a clinical trial under neither the CTN or CTX scheme. Please ensure that this is correct by referring back to your answer at Page 16, Section 5, Question 1 'Type of Research' If you are conducting a trial in clinical setting, which will not take place under CTN or CTX, please ensure that enough detail has been provided about the research to allow a HREC to adequately review it. This may require you to review your answers in Page 16, Section 5, Quest Type of Research and/or Page 20, Section 6, Question 1 Research participants

3. Provide the following details for the clinical trial protocol:

Protocol name: NA
Protocol version number:
Protocol version date: *(dd/mm/yyyy)*

*If you intend to/have registered this trial in a publicly accessible register, please provide the details of it here*This trial will be registered with ANZCTR (Australia New Zealand Clinical Trials Registry)

4. Provide the following details for the investigator's brochure/product information (as relevant):

Title of Investigator's Brochure: NA
Investigator's brochure version number:
Investigator's brochure version date: *(dd/mm/yyyy)*

9.2 Clinical research

1. The study examines:

- ☐ The administration of a drug / medicine (includes a complementary / alternative medicine)
- ☐ The use of a medical device
- ☑ Other

*Describe briefly the type of study to be conducted:*Single centre, multi-surgeon, prospective, observational, randomised controlled trial (level II evidence)

2. Provide the following details for the study protocol:

Protocol title: NA
Protocol version number:
Protocol version date: *(dd/mm/yyyy)*

3. Provide a statement addressing the following as may be applicable to the project.

a) Method of randomisation
b) Whether the hypothesis offers a realistic possibility that the intervention is at least as effective as standard treatment
c) The justification for the use of placebo or non-treatment control group, including alternative effective treatments and any risk of harm in the absence of treatment.
d) How variations in response will be treated
e) Endpoints
f) Details of contingencies and management of these
g) Explain the arrangements in place to ensure there is adequate compensation for participants.

a)Randomization will be performed at the time of patient consent during the initial consult at the clinic. Randomization at this time-point will enable the surgeon to plan his surgical approach and calculate the pre-operative corrections. Sequentially numbered sealed envelopes will be used to assign treatment according to the patients' study enrollment number, identified at recruitment.

b)The intervention is proven to be comparable in efficacy to the control. Our study is quantifying its effectiveness.

c)No placebo/control group as this is not ethical given that patients are symptomatic and not treating would be inappropriate.

d) Variations to response will be recorded and analysed. if any adverse event occurs the participant will be reviewed and medically managed as appropriate (i.e. if any complications arise). Their results will remain part of the study

e)The end point is 12 months after surgery

f)Contingencies in this study relate to either a variation in response, deviation from protocol or complication at any

time during the study duration. Each variation will be assessed on a case by case basis with management tailored to ensure patient well-fare is primary consideration.

g) Compensation for patients is not required as the treatment is already part of accepted current practice.

4. How many drugs will be used in this research project?

0

10. Declarations And Signatures

Applicant / Principal Researchers (including students where permitted)

Project Title (in full):	Navigated medial opening wedge high tibial osteotomy versus navigated lateral closing wedge high tibial osteotomy: A randomised controlled trial
HREC to which this application is made:	
HREC Reference number:	

I/we certify that:

- All information is truthful and as complete as possible.
- I/we have had access to and read the National Statement on Ethical Conduct in Research InvolvingHumans.
- The research will be conducted in accordance with the National Statement.
- The research will be conducted in accordance with the ethical and research arrangements of the organisations involved.
- The research will be conducted in accordance with the ethical and research arrangements of the organisations involved.
- I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
- I/we will immediately report to the HREC anything which might warrant review of the ethical approval of the proposal (NS 2.37), including:
- serious or unexpected adverse effects on participants;
- proposed changes in the protocol; and
- unforseen events that might affect continued ethical acceptability of the project.
- I/we will inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion (NS 2.38);
- I/we will not continue the research if ethical approval is withdrawn and will comply with any special conditions required by the HREC (NS. 2.45);
- I/we will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC.

Applicant / Chief Researcher(s) / Principal Researcher(s)

	..... Signature	...../ ...../ ..... Date
Dr Peter McEwen North Queensland Knee	..... Signature	...../ ...../ ..... Date

Associate Researchers

Dr Kaushik Hazratwala Townsville Lower Limb Clinic	..... Signature	...../ ...../ ..... Date
Dr Matthew Wilkinson Dr Matthew Wilkinson Orthopaedic Surgeon	..... Signature	...../ ...../ ..... Date
Mrs Andrea Grant Orthopaedic Research Institute of Queensland (ORIQL)	..... Signature	...../ ...../ ..... Date
Dr Ryan Bishal Faruque Orthopaedic Research Institute of Queensland (ORIQL	..... Signature	...../ ...../ ..... Date
Dr Kenji Doma James Cook University	..... Signature	...../ ...../ ..... Date

Supervisor(s) of student(s)

Project Title (in full):	Navigated medial opening wedge high tibial osteotomy versus navigated lateral closing wedge high tibial osteotomy: A randomised controlled trial
HREC to which this application is made:	
HREC Reference number:	

I/we certify that:

- I/we will provide appropriate supervision to the student to ensure that the project is undertaken in accordance with the undertakings above;
- I/we will ensure that training is provided necessary to enable the project to be undertaken skilfully and ethically.

Heads of departments/schools/research organisation

Project Title (in full):	Navigated medial opening wedge high tibial osteotomy versus navigated lateral closing wedge high tibial osteotomy: A randomised controlled trial
HREC to which this application is made:	
HREC Reference number:	

I/we certify that:

- I/we are familiar with this project and endorse its undertaking;
- the resources required to undertake this project are available;
- the researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

.....	.....	.....
Title	First Name	Surname

.....	.....
Position	Organisation Name

.....	...../ ...../ .....
Signature	Date

11. Attachments

List of Attachments

Core Attachments	Attachments which may be required/appropriate
Recruitment/invitation	Copy of advertisement, letter of invitation etc
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 project eg. genetic sub study
Peer review	Copy of peer review report or grant submission outcome
HREC approvals	Copy of outcome of other HREC reviews

Attachments specific to project or participant group	Attachments which may be required/appropriate
People whose primary language is other than English (LOTE)	English translation of participant information/consent forms
Aboriginal and/or Torres Strait Islander peoples	Evidence of support / permission of elders and/or other appropriate bodies

Participant information elements

Core Elements
Provision of information to participants about the following topics should be considered for all research projects.

Core Elements	Issues to consider in participant information
About the project	Full title and / or short title of the project Plain language description of the project

	Purpose / aim of the project and research methods as appropriate Demands, risks, inconveniences, discomforts of participation in the project Outcomes and benefits of the project Project start, finish, duration
About the investigators / organisation	Researchers conducting the project (including whether student researchers are involved) Organisations which are involved / responsible Organistions which have given approvals Relationship between researchers and particpants and organisations
Participant description	How and why participants are chosen How participants are recruited How many participants are to be recruited
Participant experience	What will happen to the particant, what will they have to do, what will they experience? Benefits to individual, community, and contribution to knowledge Risks to individual, community Consequences of participation
Participant options	Alternatives to participation Whether participation may be for part of project or only for whole of project Whether any of the following will be provided: counselling, post research follow-up, or post research access to services, equipment or goods
Participants rights and responsibilities	That participation is voluntary That participants can withdraw, how to withdraw and what consequences may follow Expectations on participants, consequences of non-compliance with the protocol How to seek more information How to raise a concern or make a complaint
Handling of information	How information will be accessed, collected, used, stored, and to whom data will be disclosed Can participants withdraw their information, how, when Confidentiality of information Ownership of information Subsequent use of information Storage and disposal of information
Unlawful conduct	Whether researcher has any obligations to report unlawful conduct of participant
Financial issues	How the project is funded Declaration of any duality of interests Compensation entitlements Costs to participants Payments, reimbursements to participants Commercial application of results
Results	What will particpants be told, when and by whom Will individual results be provided What are the consequences of being told or not being told the results of research How will results be reported / published Ownership of intellectual property and commercial benefits
Cessation	Circumstances under which the participation of an individual might cease Circumstances under which the project might be terminated

Research Specific Elements

Provision of information to participants about the following topics should be considered as may be relevant to the research project.

Specific to project or participant group	Additional issues to consider in participant information
Aboriginal and/or Torres Strait Islander peoples	Describe consultation process to date and involvement of leaderswhether ATSI status will be recorded