



AGES CLINICAL RESEARCH FUND

GRANTS TO AGES MEMBERS –
TRAINEES & YOUNG FELLOWS

CALL FOR SUBMISSIONS: 2011 GRANTS

Information Pack:

Call for submissions

Ethical Principles

Interim Reports 2011 Grants

Application Template



Australasian Gynaecological Endoscopy & Surgery Society Limited

AGES CLINICAL RESEARCH FUND

GRANTS TO AGES MEMBERS – FELLOWS

CALL FOR SUBMISSIONS: 2011 GRANTS

AGES has established a Clinical Research Fund with major contribution from Stryker Australia, Platinum Sponsor of AGES. The Society has undertaken to make available a total of up to \$300,000 over the next three years for research into gynaecological surgery and its impact on improvements in women's health.

An AGES Subcommittee, chaired by Professor David Healy, will assess applications and allocate grants.

Preference will be given to projects primarily involving research into endoscopic surgery. Applicants should bear in mind when budgetting that more than \$30,000 is unlikely to be awarded for any one application in any one year. Both short and medium-term projects will be considered.

Applications are invited from AGES members and should include:

1. A clear and comprehensive project outline, supplemented by a detailed protocol
2. Clear indications of how the project will improve women's health
3. A specific time-line for progress of the project
4. Information about the process for obtaining Ethics Committee approval
5. Comprehensive costings and a detailed project budget: the grant is expected to be supplemented by other sources of research funding, eg NHMRC, and these should be stated.
6. A current curriculum vitae from all applicants

Successful applicants will be required to submit an interim report, and may be required to present during a Clinical Research Grant Session at the AGES Annual Scientific Meeting. Failure to fulfil these conditions may result in cancellation of further funding.

A comprehensive package with advice on preparation of applications can be obtained from the AGES Secretariat. The closing date for submissions is Friday 10 September 2010.

All submissions (*by electronic submission only*) & enquiries:

Ms Michele Bender
AGES Executive Director
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Castlecrag NSW 2068
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Australasian Gynaecological Endoscopy & Surgery Society Limited

AGES CLINICAL RESEARCH GRANTS

THE PRINCIPLES OF ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

All applicants should read the National Statement for the Ethical Conduct of Research Involving Humans (1999) at: <http://www.nhmrc.gov.au>
Do you need to submit your project for ethical review?

The first step in deciding whether it is necessary to complete an HREC Application is for you to determine whether your project is research. The National Statement provides a broad definition of "research", which you may find helpful.

If you decide that your project is not research but is, instead, an audit or quality assurance activity, you may not need to submit it for ethical review by an HREC. However, if the proposed activity involves any potential breach of confidentiality or privacy, or raises ethical issues, then review by an HREC may be necessary.

For example, if the project involves identified (or potentially identifiable) information about an individual that is being collected, used or disclosed without that person's consent, then the activities must be approved by an HREC, whether they are for the purposes of research, compilation or analysis of statistics.

In summary, the following types of projects must be submitted to an HREC for ethical review:

- All research projects;
- All projects involving the collection, use or disclosure of information for the purposes of compilation or analysis of statistics, where the information is identified (or potentially identifiable) and consent will not be obtained;
- All projects involving the collection of health information for the purposes of management, funding or monitoring of a health service, where the information is identified (or potentially identifiable) and consent will not be obtained, where the Privacy Principles set out in Section 95A of the Commonwealth Privacy Act 1988 apply.

Other projects involving the collection, use or disclosure of information for the purposes of funding, management, planning, monitoring, improvement or evaluation may benefit from ethical review by an HREC, particularly if the activity raises any ethical issues.

All projects requiring submission to an HREC will need to provide evidence of Ethics Committee approval before funding will be released by AGES.



Australasian Gynaecological Endoscopy & Surgery Society Limited

AGES CLINICAL RESEARCH GRANTS

INTERIM REPORTS – 2011 GRANTS

Each successful applicant for AGES Research Grant funding in 2011 will be required to submit a detailed interim report by Friday 9 September 2011, addressing the following headings:

1. Date funding received
2. Date when project started (eg first advertising for subjects or first recruitment)
3. Number of subjects recruited
4. Total of subjects required overall
5. Report on progress of the project
6. Any interesting interim findings
7. Any adverse events or outcomes
8. Any difficulties encountered or protocol changes
9. Any publications, abstracts or presentations of interim findings
10. Grant expenditure for 2011
11. Budget and budget justification for 2012 (if requested)
12. Additional comment

This interim report should be marked 'Confidential' and details of its content will not be released publicly, unless the authors agree.

The submission of this interim report is a condition of the grant.

PROTOCOL TEMPLATE

(items to be considered when preparing a surgical research protocol)

TITLE

Principal Investigator: Insert name, address and contact details

I have read and agree to follow the NHMRC National Statement on Ethical
Conduct in Research Involving Humans.

Signature _____ Date _____

**APPLICATIONS FOR AGES CLINICAL RESEARCH GRANTS ARE TO
BE A MAXIMUM OF 8 PAGES
ADDITIONAL PAGES WILL NOT BE CONSIDERED**

TABLE OF CONTENTS

Section	Title	Page No.
1.0	Summary	
2.0	Introduction	
3.0	Objectives	
4.0	Number of Patients	
5.0	Length of Study	
6.0	Patient Selection Criteria	
6.1	Inclusion	
6.2	Exclusion	
7.0	Study Design	
8.0	Device Description	
8.1	Device Trade Name	
8.2	Device Supply	
9.0	Surgical Procedures	
10.0	Informed Consent	
11.0	Evaluations	
12	Statistical Methods	
12.1	Enrolment and Randomisation	
12.2	Sample Size Justification	
12.3	Data Analysis	
13.0	Selection Criteria for Investigators and Clinical Monitors	
14.0	Admittance of Patient	
15.0	Patient Accounting	
16.0	Duration of the Study and Patient Participation	
17.0	Quality Assurance of the Data	
18.0	Management of Intercurrent Events	
19.0	Failure to Obtain Informed Patient Consent	
20.0	Modification of The Protocol	
21.0	Postoperative Complications/Current Medical	
22.0	Unanticipated Adverse Device Effects	
23.0	Institutional Review Board Interactions	
23.1	Approval	

23.2	Prior to Initiation of the Study	
23.3	Progress Reports	
23.4	Withdrawal of Ethics Committee Approval	
23.5	Final Reports	
24.0	Use of Information and Publications	
25.0	Analysis/Conclusions	
26.0	Bibliography	
27.0	Appendices	
27.1	Appendix I:	

1.0 SUMMARY

A prospective, randomised, ? blind, ? centre, ? series with a minimum ? **years/month/weeks** patient evaluation period to evaluate the **name of experimental** system.

As all components used in this study are FDA (TGA? - **check**) approved, this will be a phase **I/II/III** study.

The **name of experimental** system will be used in **what procedure** for **what indications**.

A cohort of a minimum of ? patients will be enrolled into the study.

Describe what evaluations will be carried out and when

Complete evaluation schedule table and time line

	Pre-op	Intra-op				
History	X					
Operative Details		X				
Complications		X	X	X	X	X

2.0 INTRODUCTION

Introduce procedure, state aims and include latest literature survey

Describe system

Briefly introduce aims and evaluations

As all components used in this study are FDA (TGA? - **check**) approved, this will be a phase **I/II/III** study.

3.0 OBJECTIVES

The primary objective of this Phase ? clinical investigation is to **state primary objective**

The secondary objectives are to evaluate the:

1. **Efficacy parameters**
2. Complication rate
3. **Other safety parameters**

4.0 NUMBER OF PATIENTS

[State the following if appropriate: No formal sample size calculation is necessary, as there are no comparators in the primary variable.]

This a ? centre study and ? investigators will be used. A total of ? cases will be enrolled in the study, utilising the ? System. Additional patients will be recruited (approximately ? per group) to compensate for early withdrawals (e.g. death, lost to follow up)

Include sentence on how different treatments will be randomly allocated.

If sample size calculated describe how based on primary variable. Include all references and assumptions.

5.0 LENGTH OF STUDY

Individual study patients will be seen for at least ? **years/month/weeks** after surgery. However, all patients will be continued to be followed until every patient has the required ? **years/month/weeks** follow up. The enrolment period is expected to be ? **years/month/weeks** or until the required sample size is reached; it is therefore anticipated that the entire study will take ? **years/month/weeks** to complete.

6.0 PATIENT SELECTION CRITERIA

The Investigator is responsible for evaluating each patient against the following criteria and assuring that the patient meets the requirements to be enrolled in this clinical investigation. Each patient enrolled in this investigation must meet each of the following inclusion criteria and have none of the exclusion criteria. The Investigator must notify the Ethics Committee of any patient enrolled in this study who does not meet the inclusion and exclusion criteria.

6.1 Inclusion Criteria

1. Patients requiring a **indicate procedure** as determined jointly by the surgeon and the patient.

2. Non-pregnant female patients.
3. Over 18 years of age at time of surgery.
4. Patients with the following (but not limited to) diagnoses:
 - ?
5. Patients who understand the conditions of the study and are willing to participate for the length of the prescribed term of follow-up.
6. Patients who are capable of, and have given, informed consent to their participation in the study.

6.2 Exclusion Criteria

1. ??

7.0 STUDY DESIGN

This is a prospective, ? series, randomised, ? blind, ? centre clinical study; a minimum of ? patients will be enrolled over a ? **years/month/weeks** recruitment period. All cases must satisfy the inclusion/exclusion criteria and will be followed for a minimum of ? **years/month/weeks**.

Patients will be randomised to one of two equally sized groups between **the describe treatment group**. All cases will undergo **describe evaluations**.

Patients will be considered for enrolment according to the clinical findings and subject to gaining suitable informed consent from the patient.

Patients will follow the individual postoperative rehabilitation program established at the study site.

Prior to enrolment each patient will be screened for eligibility according to the inclusion and exclusion criteria. Upon consent, each patient will understand their right is waived to know which group they have been randomised to, unless their doctor deems it medically necessary to inform them. All patients eligible for the study who give their informed consent and are randomised will be enrolled.

A randomisation schedule will be kept and controlled by the Investigator. When the next eligible patient signs the consent form, and meets the inclusion/exclusion criteria the patient will be randomised according the method described in section 12.1. Each of the

Investigators will be randomised independently to ensure balance across treatments.
Any deviation from the assigned treatment will be reported as a deviation from Protocol.

8.0 DEVICE DESCRIPTION

The **experimental device name** is a commercially available, TGA (Therapeutic Goods Administration) listed device.

All components of the system have been approved for sale and use throughout Australia **(check)**.

8.1 Device Trade Name

The **experimental device name** System.

8.2 Device Supply

The **experimental device name** components will be obtained through the manufacturer's local distributor.

9.0 SURGICAL PROCEDURES

All devices will be implanted using the **experimental device name** Instrumentation System as described in the surgical technique provided by the manufacturer.

Appropriate post-operative care will be given and is at the discretion of the physician. Rehabilitation time frame and regimen will be patient specific and also at the discretion of the physician.

10.0 INFORMED CONSENT

The Investigator will inform the patient of the purpose of the study, proposed duration of the study, follow-up schedule, method of application and randomisation of study groups. The Investigator will discuss foreseeable risks involved, as well as potential benefits that result from the use of the device. The Investigator will also inform all patients that, should an unanticipated adverse device-related effect occur during the study which, in their opinion presents unreasonable risks to the patients, all patients will be notified and patient enrolment will be terminated. Patient information will be used during the analysis of the results of the clinical study but the confidentiality of the patient will be maintained at all times.

The patients will be informed by the Investigator that they are free to refuse participation in this Investigation; and if they should participate, that they may withdraw from the study at any time without compromising further medical care.

A signed and dated Informed Consent must be obtained by the Investigator or his/her designee from the patient prior to enrolment into this study. The original signed and dated information sheet and patient consent will be kept by the Investigator. A copy will be provided to the patient.

11.0 EVALUATIONS

All data will be recorded on the Case Report Forms. The surgeon will complete and sign forms at the time of each protocol required visit.

Describe all evaluations in detail and the use of any independent evaluators.

All information on general medical, operative and device related complications will be documented and tabulated.

All information on complications (date of occurrence, description, severity, related to study device, treatment and resolution) will be recorded at the time of occurrence.

12.0 STATISTICAL METHODS

12.1 Enrolment and Randomisation

At least ? patients per study group will be enrolled. The randomisation will be stratified according to investigator. Enrolment is defined as completion of informed consent and randomisation.

The randomisation procedure by which the **describe treatment** type for the individual operation will be chosen (? versus ?) will be centrally organised for all investigators. The treatment type, will be selected according to randomisation schedule. At the time when a patient is enrolled into the study, the surgeon will open the next envelope in sequence to determine which of the two treatment types will be used in the **describe procedure**. The randomisation scheme, in a blocking size of ? (? of each treatment), will be used to generate the randomisation list. The randomisation scheme will insure that during the enrolment period the ratio of the number of cases in the two groups remain approximately constant.

12.2 Sample Size Justification

[State if there will be no formal sample size for this study.]

Sample sizes are determined based on the primary end point and as there are no comparators in the primary end point for this particular study (i.e. ? response of the ? System) no formal calculation is necessary. A minimum of ? patients will be recruited into the study. An additional ? patients per group will be recruited to account for early withdrawals.]

If formal sample size calculation, state primary endpoint (superiority or equivalence), measure of variability, clinically significant difference. Include all references and assumptions made.

12.3 Data Analysis

Data will be reviewed and entered onto **insert software used for database**. The data will be summarised and comparisons presented according to:

1. **Treatment type**
2. Adverse events:
 - General complications
 - Local complications
 - Device-related complications
 - Revisions/removals

Frequency and percent distributions will be presented in tabular form for categorical variables and the chi-square test for 2-way contingency tables will be used for comparison of the study groups. The mean, median, standard deviation, minimum and maximum will be presented by study group for quantitative variables and the appropriate parametric or non-parametric statistical test will be used, depending on the distribution of the data. Survival analysis (Kaplan Meier or life tables method) will be performed using ?? as the event definition.

In the event of errors in randomisation, the patient will be classified according to the treatment received. All randomisation inconsistencies will be listed.

For the above an intent to treat analysis will be performed using all patients enrolled. Patients missing the measure of the primary end point (i.e. **describe primary endpoint**) will be considered missing in the intent to treat analysis; no inputting of missing data will be conducted for any variables.

A secondary per protocol analysis of the primary end point involving only those patients satisfying certain important protocol requirements will be made. All randomisation errors will be deleted from this analysis.

13.0 SELECTION CRITERIA FOR INVESTIGATORS AND CLINICAL MONITORS

The Investigators selected to participate in this study are qualified ? surgeons Each Investigator will be required to adhere to this protocol completely and accurately.

Clinical monitors of the study will be representatives of the Institute under the direction of the Principal Investigator.

14.0 ADMITTANCE OF PATIENT

The Investigator must wait for written Ethics Committee approval prior to beginning the study or enrolling patients.

A review of the inclusion and exclusion criteria must be completed by the Investigator pre-operatively. A pre-operative physical examination will be conducted within ? months prior to the date of surgery.

A patient will be identified as a patient in this clinical trial upon signing a study Informed Patient Consent and upon being randomised into the study. The randomisation date will be used as the enrolment date for each patient. [Patients will be blinded as to which group he/she is assigned to, unless his/her doctor deems it medically necessary for the patient to be told. – **delete sentence if open-labelled, i.e. irrelevant**] Should a patient be randomised and withdraw from the study before receiving the study device, the reason for withdrawal will be documented and no further follow-up will be obtained.

15.0 PATIENT ACCOUNTING

Timely receipt of clinical trial data will be monitored. At each time interval, the actual compliance with follow-up will be assessed.

Rigorous monitoring procedures are intended to assure that each patient returns for their follow-up visit according to the Evaluation Schedule. Documentation of patients who voluntarily withdraw from the study or who are lost to follow-up will be obtained on a Study Completion Form.

16.0 DURATION OF THE STUDY AND PATIENT PARTICIPATION

The Investigation is scheduled for a minimum of approximately ? **years/month/weeks** per patient; for patient accrual and scheduled follow-up evaluation.

17.0 QUALITY ASSURANCE OF DATA

Case Report Forms will be routinely reviewed by the Principal Investigator for completeness and accuracy as well as any evidence which may be indicative of patient risk. When any discrepancies are noted, they will be resolved with the Investigator and/or individual designated by the Investigator. When the data are incomplete, attempts will be made to obtain the data whenever possible.

18.0 MANAGEMENT OF INTERCURRENT EVENTS**Withdrawal from Study**

Patients will be advised that they may voluntarily withdraw from the study at anytime, for any reason and they are not obligated to reveal the reason to the Investigator and it will not effect their medical care. However, in such cases, appropriate effort will be made to determine the reason for voluntary withdrawal form the study. Patients are not obligated to reveal their reasons for withdrawal, but the Investigator may request a letter from the patient noting his or her desire to withdraw from the study. The last known status of these patients will be reported with the study results and all attempts to locate patients lost to follow up will also be documented.

Patients will be informed that should they withdraw from the study they should remain under the care of an appropriately experienced physician until the physician deems further follow-up unnecessary.

The following are circumstances for which a patient would be identified as not continuing her participation in the study:

- Study Completed / Terminated
- Death
- Voluntary Withdrawal
- Unable to Return

- Unwilling to Return
- Intercurrent Illness
- Lost to follow-up
- Other

Additionally, the patient may withdraw or be withdrawn from the clinical study for the following reasons:

- The patient may withdraw if he or she relocates to another geographic area which requires a change of physician. Reasonable attempts will be made to locate and request cooperation from an orthopaedic surgeon in the new geographical area, but this may not be successful in all cases.
- The patient may withdraw, or be withdrawn by the Investigator, if she is unable to continue participation in the study due to some condition unrelated to this study.

A Study Completion Form will be completed for all patients who withdraw from the study.

19.0 FAILURE TO OBTAIN INFORMED PATIENT CONSENT

All patients entered into this clinical research study should be fully informed verbally by the Investigator and then read, understand, and sign a consent form agreeing to study participation. Should a patient receive the investigational device within the study without signing a Patient Informed Consent, the Investigator must notify his/her Ethics Committee of the deviation. The Investigator must follow this notification with a formal written report, including a description of the circumstances which justify the failure to obtain Patient Informed Consent. The Investigator will then follow Ethics Committee instructions regarding how to handle patient/situation and obtaining Informed Consent.

20.0 MODIFICATION OF PROTOCOL

No changes to this Protocol will be permitted without the written approval of the AGES research sub-committee. If Protocol changes become necessary, written approval by the Investigator's Ethics Committee will be obtained before the changes are implemented.

21.0 POSTOPERATIVE COMPLICATIONS/CONCURRENT MEDICAL

Postoperative complications/concurrent medical events will be treated with appropriate medical care and are to be reported on the appropriate Case Report Form.

22.0 UNANTICIPATED ADVERSE DEVICE EFFECTS

Should any unanticipated adverse device effects occur, the Clinical Monitor will ensure that these are documented by the Investigator and reported to the reviewing Ethics Committee as soon as possible, but not later than ten working days after the Investigator first learns of the effect. The Clinical Monitor will conduct an evaluation of such effects. Following this evaluation, if the Investigator determines that an unanticipated adverse device effect presents an unreasonable risk to patients, the Investigation will be terminated as soon as possible. Termination shall occur no later than five working days after the Investigator makes this determination and no later than fifteen working days after the Investigator first receives notice of the unanticipated adverse effect. TGA and Ethics Committee approval will be obtained prior to resuming a terminated Investigation.

23.0 INSTITUTIONAL REVIEW BOARD (IRB)/ETHICS COMMITTEE INTERACTIONS**23.1 Approval**

The Investigator is responsible for obtaining Ethics Committee approval to conduct this study.

23.2 Prior to Initiation of the Study

The Investigator must wait for written approval by his/her Ethics Committee prior to beginning the study. The Investigator may discuss the study with prospective patients, however, he/she may not obtain written Patient Informed Consent, nor use the experimental device for surgery in prospective study patients until all required approvals are granted.

23.3 Progress Reports

The Investigator will also submit, at intervals requested by AGES research sub-committee, a Progress Report on this Investigation. These reports will be submitted both to AGES and to the Investigator's Ethics Committee.

23.4 Withdrawal of Ethics Committee Approval

Should the Ethics Committee withdraw its approval, the Investigator will notify the AGES research sub-committee no later than five working days following such withdrawal.

23.5 Final Reports

Upon completion of the Investigation, each Investigator will submit a Final Report on his/her part of the Investigation within three months of completion of the Investigation.

This report will be submitted both to the AGES research sub-committee and the Investigator's Ethics Committee.

24.0 USE OF INFORMATION AND PUBLICATIONS

Investigators must respect the confidentiality of data, especially regarding its use by potential competitors.

25.0 ANALYSIS/CONCLUSIONS

The data obtained in this Investigation will be maintained and periodically assessed throughout the study. The safety and efficacy of the ? System will be evaluated. Based on the above analysis, we believe this Protocol is scientifically sound and that the clinical evaluation of the knee navigation system is justified.

26.0 BIBLIOGRAPHY

27.0 APPENDIX

28.0 The applicant must attach a **DETAILED BUDGET** and **COMPREHENSIVE COSTINGS** with the application.