PROTOCOL TEMPLATE

(Items to be considered when preparing a surgical research protocol to be read in conjunction with Notes regarding AGES funded Research Studies)

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

*Exclusive of your title page, contents page, references and appendices.
Inclusive of your executive summary and budget

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1.0 EXECUTIVE SUMMARY

This section should be no more than a page and outline the following:

- Type of research proposed (clinical study, device or medication study, basic science research) outlining the importance of this work for gynaecological surgery.
- Methodology (RCT, observational study, laboratory-based translational study).
- The anticipated duration of the study (from commencement of data to completion of analyses).
- The number of participants or experiments (if not in human research) expected for completion of the study.
- Inclusion of a statement that all devices or medications being used are either TGA approved or that application has been made for CTN or CTX approval through an appropriate HREC.
- A statement regarding HREC approval (preferably an attachment of HREC submission – approval is not necessary at the time of application, although it is essential to follow the Ethics in Research Statement in this information package).

Complete evaluation schedule table and time line (example only).

	Pre-op	Intra-op	Post-op 1	Post-op 2	Post-op 3	Final visit
History	X					
Operative Details		X				
Complications		X	X	X	X	X
Clinical outcome			X	X	X	X
Quality of life	X			X		X

Track Record

- This is a statement regarding your track record with regard to research and in particular AGES Research grants.
- A brief account of your research output in relation to opportunity is important.
- If you are a first time researcher, you may not have a significant track record, so it is important to state how you will complete the research study and whether you have a mentor or guidance in this task.

- For researchers who have previously held AGES Research Grants, or have current grants, a list or table of these and their status or outcome (such as publication) is appropriate.
- Researchers should note that AGES grants are for seed funding and unlikely to be awarded where the aim is to obtain small additional funds for a research project already funded by NHMRC or a similar large granting body.

PROTOCOL

2.0 INTRODUCTION

- The introduction should briefly (suggest 1-2 paragraphs) state the relevance of this research to gynaecological surgery.
- It should briefly describe the intervention and provide a précis of the most recent evidence in this area.
- For devices and drugs it is necessary to note that they are/not TGA approved and therefore the type of study that is recommended.

3.0 OBJECTIVES

- State the hypothesis of the research
- State the one primary outcome of this study
- State any secondary outcomes from this study
- Outcomes may include efficacy, complications, comparative data, observational data, superiority, non-inferiority, pilot data amongst others
- Note that safety is often stated as an outcome, however this is frequently not possible to assess in small studies, since it may require many hundreds to many thousands to assess safety (consider for example the safety issue of COX -2 inhibitors that was only discovers with thousands of patients post-market release).

4.0 SAMPLE SIZE

- State the expected sample size of the study.
- Note whether a sample size calculation was performed and how this was undertaken.
- If no sample size calculation is required (e.g. for an observational study) will the number be sufficient to arrive at the objective?).
- For comparative studies, a sample size calculation is appropriate.

5.0 STUDY DURATION

- This section should include the anticipated duration of the study.
- It should continue until the final patient has had her final follow-up.
- It should consider the enrolment duration based on actual date from your unit (the number of procedures that are undertaken in your unit).

6.0 PARTICIPANT SELECTION CRITERIA

The application should state:

- That participants will meet all the requirements to be enrolled in the proposed research study. Including all of the inclusion criteria and none of the exclusion criteria.
- Informed Consent of eligible participants will be obtained.
- The Patient Information and consent statement (PCIS) should be provided as an appendix to this application (see Research Notes).
- In this section and the PCIS, it must be stated that participants will be advised that they may voluntarily withdraw from the study at any time, for any reason and they are not obligated to reveal the reason to the Investigator and it will not affect their medical care.
- Participants will be allocated a unique participant identification number (PIN) for the study.
- Participants will be considered for enrolment based on the clinical findings and subject to gaining informed consent from the participant.

6.1 Inclusion Criteria (example only)

1. Women requiring a **[indicate procedure]** as determined and agreed to by both the surgeon and the participant.
2. Over 18 years of age at time of surgery.
3. Participants who understand the conditions of the study and are willing to participate for the duration of study including all follow-up.
4. Participants who are capable of, and have given, informed consent to their participation in the study.
5. Participants must have sufficient English reading and writing comprehension to complete the validated quality of life instruments

6.2 Exclusion Criteria (example only)

1. Pregnancy.
2. Known or suspected malignancy.

7.0 STUDY DESIGN

- This section should describe the primary study design such as an RCT, prospective, retrospective etc.
- If a RCT is performed, whether this is blinded and if so, single or double blinded.

- If it is an intention to treat study or if randomisation is based on other criteria.
- The method of randomisation and concealment should be stated.
- If the randomisation schedule is blocked, this should be documented.
- For all studies, the number of centres should be stated and ethics approval for each centre is required.
- If the study is stratified for a particular aspect (age or size of pathology for example) this should be documented in the study design.

8.0 STUDY DESCRIPTION

- This section should describe any device, medicine or intervention that will be under investigation in the study.
- This must note approval of the device, medicine or intervention by the TGA or the appropriate certification approval (CTN or CTX) that the Investigator has applied for.
- A detailed description of exactly what will happen during the course of the study will be required in this section and this will be required in the Participant Information and Consent Statement (PICS).
- A flow chart describing the pathway that participants will follow during the study. In RCTs this will also indicate how they are allocated to control and treatment group.

9.0 RISKS OF THE STUDY

- In this section, the potential risks over and above what would be considered routine care should be described.
- How these risks will be minimised and managed should be stated.
- Any additional treatments or requirements (such as blood tests, the completion of questionnaires or surveys, additional attendances at clinics) must be clearly outlined and documented in this section.
- These additional risks requirements must be clearly stated in the attached PCIS.

10.0 EVALUATION AND RECORD KEEPING

- A case report form (CRF) that collects all demographic data, inclusion criteria and all clinical and research outcome information needs to be included as an appendix to the application.

- It must be stated that confidential clinical information will be anonymised and identified only by the patients unique Patient Identification Number (PIN) and stored in a secure (locked) location.
- All confidential clinical documentation for each participant including the CRF should be labelled only with this PIN.
- Any identifiable information (PCIS and code for the PIN) is stored securely (locked) at a different location to the CRF and any anonymised confidential clinical information in accordance with HREC requirements and for audit purposes.

11.0 STATISTICAL ANALYSIS PLAN

It is highly recommended that a specific database be created and utilised for storage of information obtained in the study.

- The type of software used should be stated and data must be stored in accordance with local HREC requirements.
- A statistical plan should be presented regarding the presentation of data from the study (e.g. simple descriptive data, inter and/or intra group comparisons and the types of statistical tests that will be required (for example the chi-square, t test, Wilcoxon-Sign rank test, Mann-Whitney U test or Kaplan Meier survival curve).
- How the data distribution will be assessed (is it normally distributed or not) and which statistical methods will be used (parametric or non-parametric) to ensure the appropriate description of central tendency (mean or median) and distribution (standard deviation and range) will be used for the dataset analysis.
- How will missing data will be described and sensitivity analysis performed if appropriate.

12.0 MONITORING

This application should state that:

- Timely receipt of clinical trial data will be monitored by the Investigating team and avoidance of missing information will be minimised as much as is possible.
- At each time interval noted in the study protocol for follow-up, the actual compliance with all study data requirements will be assessed.
- Rigorous monitoring procedures are intended to assure that each participant returns for their follow-up visit according to the Evaluation Schedule.

- Documentation of participants who voluntarily withdraw from the study or who are lost to follow-up will be obtained on a Study Completion Form which should be included in the appendix.

13.0 QUALITY ASSURANCE OF DATA

This application should state that:

- Case Report Forms will be routinely reviewed by the Principal Investigator for completeness and accuracy as well as any evidence that may be indicative of participant 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.
- Audit of data throughout recruitment and follow-up will be performed.

14.0 MANAGEMENT OF INTERCURRENT EVENTS

- In this section, a description of the management of patients lost to follow up should be described.
- It should be stated that every reasonable attempt will be made to determine the reason for a patient being lost to follow-up (see Research notes).
- A description of how this will be documented in the data analysis and published outcomes should be provided.

15.0 REFERENCES

- All references used in the study documentation and protocol should be listed according to Vancouver style with appropriate in-text citations.
- It is highly recommended that a reference managing system be used to note and store references for audit and manuscript writing and presentation.

16.0 BUDGET AND EXPENDITURE

- The applicant *must* attach a DETAILED BUDGET and COMPREHENSIVE COSTINGS as an appendix to the application.
- The limitations of grant funding should be noted and any comment regarding part funding and allocation of funds from other sources (particularly if there is a shortfall in funds) made in this statement.

17.0 APPENDICES

Applicants should submit the following documents with the application:

1. The study application and protocol as outlined in this document.
2. The PICS.
3. The CRF.
4. The Study Completion form.
5. A detailed Budget.
6. The NEAF or relevant ethics application or statement of submission to an appropriate HREC in order to release funding for the study.