Australasian Gynaecological Endoscopy & Surgery Society Limited

NOTES ON AGES FUNDED RESEARCH STUDIES

HUMAN RESEARCH ETHICS COMMITTEE INTERACTIONS

Approval

- The Investigator is responsible for obtaining the relevant HREC approval to conduct this study.
- The Investigator must wait for written approval from the relevant HREC prior to beginning the study.

Informed Consent

- Potential participants must be informed by the Investigator that they are free to refuse participation in this study; 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 their designee from the patient prior to enrolment into this study.
- The original signed and dated PICS will be kept secure at a different location to the Case Report Form (CRF = documentation of the PIN coded clinical data) collected by the Investigator.
- A copy of the PICS will be provided to the participant

Failure to Obtain Informed Consent for Research Participation

- The Investigator must wait for written HREC approval prior to beginning the study or enrolling participants.
- All participants 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.
- Participation in the study will only be considered after signing a PICS and receiving a PIN.
- Should a participant receive the investigational device within the study without signing the relevant and ethics approved Participant Informed Consent, the Investigator must notify the relevant HREC of the deviation.
- The Investigator must follow this notification with a formal written report, including a description of the circumstances that led to the failure to obtain Participant Informed Consent.

- The Investigator will then follow the HREC instructions regarding the breach in protocol.

MODIFICATION OF PROTOCOL

- No changes to this Protocol are permitted without the written approval of the HREC and subsequent notification of the AGES Research Sub-committee.
- If Protocol changes become necessary, written approval by the Investigator's HREC must be obtained before the changes are implemented.

POSTOPERATIVE COMPLICATIONS

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

UNANTICIPATED ADVERSE EVENTS (AE) and SERIOUS ADVERSE EVENTS (SAE)

- Should any unanticipated adverse events occur, these must be 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 AE or SAE. An evaluation of the safety of continuing the study must be undertaken by the investigator before further recruitment. If not deemed safe, the cessation of the study must be notified to the ethics committee and AGES.

WITHDRAWALS AND LOSS TO FOLLOWUP

- In the PCIS, participants must 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.
- However, in such cases, appropriate effort will be made to determine the reason for voluntary withdrawal from the study.
- Participants are not obligated to reveal their reasons for withdrawal, but the Investigator may request a letter from the participant noting her desire to withdraw from the study (this will be attached to the PICS).
- The last known status of these participants will be reported with the study results and all attempts to locate participants lost to follow up will also be documented.

- Participants 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 participant 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 participant may withdraw or be withdrawn from the clinical study for the following reasons:

- She may withdraw if she relocates to another geographic area that requires a change of physician.
- Reasonable attempts will be made to locate and request cooperation from a gynaecological surgeon in the new geographical area, but this may not be successful in all cases.
- The participant 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 participants who withdraw from the study.

RECORD KEEPING

- All data will be recorded on the Case Report Form (CRF).
- Each participant will have their own CRF with their unique PIN on each page of the CRF.
- The CRF should be included as an appendix to the protocol.
- The Investigator will complete and sign CRF at the time of each protocol required visit.

- All demographic information, information on general medical, operative and device related complications will be documented within the CRF and stored separately from the PCIS in a secure location.
- All information on complications (date of occurrence, description, severity, related to study device, treatment and resolution) will be recorded at the time of occurrence.
- For AEs and SAEs this will not only be recorded in the CRF, but appropriate notification of the local HREC is required by the AGES Research Sub-committee.

PROGRESS REPORTS

- As a condition, upon award of an AGES Research Grant, the Investigator agrees to submit an annual progress report regarding this research to be sent to AGES Research Sub-committee by email to ages@yrd.com.au by September 1st of the year following the grant approval. .

Withdrawal of Ethics Committee Approval

- Should the HREC withdraw its approval for the study for any reason, the Investigator must notify the AGES research sub-committee no later than five working days following such withdrawal.

Final Reports

- Upon completion of the research study, the Investigator must submit a Final Report as per HREC requirements.
- This report will be also be submitted to the AGES Research Sub-committee and (a completed manuscript that is in-press (accepted) or notification of publication in a peer-reviewed journal is deemed to be an adequate and indeed preferable final report).

USE OF INFORMATION AND PUBLICATIONS

- Investigators must respect the confidentiality of data, especially regarding its use by potential competitors.
- It should be noted that new regulations for some journals may require the production of original databases and documentation for proof of study