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20 February 2018

Dr Anna Rosamilia
Head of Pelvic Floor Unit
Pelvic Floor Unit
Obstetrics and Gynaecology
Monash Medical Centre Moorabbin
Bentleigh East Vic 3165

Dear Researcher,

Research Project Application No. 16048A: Mini or Retropubic Sling in Women with Intrinsic Sphincter Deficiency - A RCT (mini RISD)

Research Project Application No. RES-17-0000-069A: Mini sling or retropubic sling in women with Stress Urinary Incontinence - a RCT study (Mini Retro)

We refer to the following documents which were considered by the Human Research Ethics Committee at its meeting on 01 February 2018.

a. Memo dated 18 December 2017 from Ms Deborah Dell;
b. Therapeutic Goods Administration Actions After Review Into Urogynaecological Surgical Mesh Implants dated 18 December 2017;
c. Email Correspondence dated 15 December 2017 from Dr Anna Rosamilia, Principal Investigator of the studies;
d. Email correspondence dated 15 December 2017, Professor Peter Dwyer, Head of Urogynaecology at Mercy Hospital for Women;
e. Miniarc Monarc suburethral sling in women with stress urinary incontinence - An RCT - 60m follow up published in the International Urogynecology Journal 201, 28 (Suppl): S1-282;
f. Randomized trial of a single incision versus an outside-in transobturator midurethral sling in women with stress urinary incontinence: 12 month results published in the American Journal of Obstetrics & Gynaecology 35 e7;

in respect of this study have been noted.

The Therapeutic Goods Administration have removed from the Therapeutic Goods Register, the approval for the Mini Slings (effective 04 January 2018). When these studies were approved by Monash Health as clinical trials, the trials did not need to be registered under the Clinical Trials Notification Scheme as the devices were approved. Now that the devices are no longer approved, if the studies are to continue at Monash Health they would need to be registered under the Clinical Trial Notification Scheme.

Dr Rosamilia attended the meeting to advise that upon there being a great deal of media attention, a Senate enquiry and a class action, due to complications associated with the slings, the Therapeutic Goods Administration have removed the Mini Slings as from the Therapeutic Goods Register. Although, the Therapeutic Goods Administration have advised Dr Rosamilia both verbally and in email communication that they have no objection to devices being used

under the Clinical Trials Notification Scheme and this is a decision for the Human Research Ethics and the Institutions conducting the research.

Dr Rosamilia explained that the majority of slings are used for urinary incontinence rather than prolapse and the complication rate is about 1% when used for urinary incontinence.

Whilst both studies are investigator-initiated studies, Coloplast were providing support for the Mini Retro study and have advised Dr Rosamilia that they are withdrawing their support for this study to continue.

For the mini RISD trial, Dr Rosamilia advises that the Retropubic Slings and the Solix Slings can be provided for the study free of charge. Boston Scientific has a comparable Retropubic Sling that may be used.

The mini RISD trial is a quarter of the way through and the interim analysis will be completed in the next month as the first 60 participants are due for their 6 month follow up.

The Human Research Ethics Committee approved the mini RISD study continuing at Monash Health on the provision that an updated Participant Information and Consent Form is provided for all prospective participants clearly explaining that the Mini Slings were on the Australian Therapeutic Goods Register but have now been removed and that the slings are not approved by the Therapeutic Goods Administration. They are considered experimental and the study is being done under the Clinical Trial Notification Scheme. The Participant Information and Consent Form is to be reviewed and approved by a representative of the Human Research Ethics Committee, prior to being provided to participants.

Further, a letter to the participants who have been in both studies is to be provided to the Human Research Ethics Committee for review and approval out of session. The letter is to explain that at the time the participants enrolled in the studies the Mini Slings were on the Australian Therapeutic Goods Register but have now been removed and that the slings are not approved by the Therapeutic Goods Administration. They are considered experimental. The mini RISD study is still being conducted but it is under the Clinical Trial Notification Scheme and the Mini Retro study is ceasing as the company that was providing financial support for the study has advised that they are no longer providing support. The participants are to be advised that they will be followed up and if they have any questions or concerns, to please contact the study team in the first instance. If they have any concerns or wish to lodge a complaint, they may do so in writing to the Manager of the Human Research Ethics Committee.

Yours sincerely

DEBORAH DELL
Manager, Human Research Ethics Committee

Cc: Dr Lin Li

Please Note: It is requested that correspondence be forwarded electronically to research@monashhealth.org with the local Monash Health reference number inserted.