Sterling IRB
Achieve More.

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NOTICE OF APPROVAL OF WAIVER OF AUTHORIZATION

Approval Date: February 3, 2014

Study Expiration Date: February 2, 2015

Principal Investigator: John Miklos, MD

Protocol: Surgical Outcomes and Characteristics of Patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery

IRB ID: 4619

Description of the PHI: See Attachment A

ACTION: Approval for Waiver of Authorization

Sterling IRB has reviewed your request for waiver of authorization for your above captioned research project via **Expedited review** and has found that your requested waiver of authorization, in the context submitted, meets the following criteria for approval:

1. The use or disclosure of protected health information involves no more than minimal risk to the individuals.
2. The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals.
3. The research could not practicably be conducted without the waiver of authorization.
4. The research could not practicably be conducted without access to and use of the protected health information.
5. The privacy risks to the individuals whose protected health information is to be used or disclosed is reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research.
6. There is an adequate plan to protect the identifiers from improper use and disclosure.
7. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
8. There are adequate written assurances that the protected health information will not be reused or redisclosed to any other person or entity, except as required by law, for the authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by regulation.

No alteration to the procedures described in the study protocol as reviewed on February 3, 2014 may be instituted unless this Board has reviewed and approved the continuation of the waiver of authorization.

Accounting rules apply to this waiver.

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Sterling IRB reserves the right to report any violation of this approval to the Office for Civil Rights of the U.S. Department of Health and Human Services.

Signature Chairman or designee

Attachments: Attachment A: Description of PHI

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ATTACHMENT A: DESCRIPTION OF PHI

- Date of surgery
- MRN number
- Date of birth
- Age at the time of operation
- Gravity
- Parity
- Number of vaginal delivery
- Postmenopausal status
- Hormonal replacement therapy or local estrogen (current)
- Weight (at the first visit or early post op visit)
- Height
- Sexually active
- Race
- Insurance
- Smoker
- Diabetes
- Type of previous hysterectomy
- How many doctors has the patient seen for complaints related to the mesh
- Previous surgical mesh removal
- Classification
- Time (clinically diagnosed)
- Site
- Number of transvaginal mesh inserted
- Which compartment that the mesh was inserted
- Kit type for any kinds of pelvic floor reconstructive surgery
- Year the transvaginal mesh for POP inserted
- Number of previous slings inserted
- Number of previous retropubic sling inserted
- Number of previous transobturator sling inserted
- Number of previous minisling sling inserted
- Name the sling brand
- Year the sling for SUI inserted
- Number of previous intraperitoneal mesh inserted
- Route of sacrocolpopexy
- Year of sacrocolpopexy
- Chief complaint
- Pain location
- Additional complaints
- Additional pain locations
- Additional information of chief complaint
- Visual analog scale (scale 0-10) at right paraurethral area
- Visual analog scale (scale 0-10) at left paraurethral area
- Visual analog scale (scale 0-10) at suburethral area
- Visual analog scale (scale 0-10) at anterior vaginal wall area (proximal to bladder area)
- Visual analog scale (scale 0-10) at proximal posterior vaginal wall area
- Visual analog scale (scale 0-10) at distal posterior vaginal wall area
- Visual analog scale (scale 0-10) at right proximal levator ani area
- Visual analog scale (scale 0-10) at left proximal levator ani area
- Visual analog scale (scale 0-10) at right distal levator ani area
- Visual analog scale (scale 0-10) at left distal levator ani area
- Visual analog scale (scale 0-10) at vaginal apex area
- Urinary incontinence
- Number of incontinence events per day
- Empty supine stress test
- Number of pads per day
- Urinary retention
- Recurrent UTI, dyspareunia
- POP-Q pre op, -3 to +3
- -3 to tvl
- -tvl to tvl
- Genital hiatus
- Perineal body
- Total vaginal length
- -3 to +3
- -3 to tvl
- -tvl to tvl
- Vaginal atrophy
- Vaginal removal Mesh removed via vagina
- lap remove Mesh removed via laparoscopic
- groin remove Mesh removed via laparoscopic
- Mesh removed from urethra
- Mesh removed from bladder
- Number of mesh excised
- Concomitant procedures
- Anterior repair at time of surgery

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- Posterior repair at time of surgery
- Burch colposuspension
- Sling inserted at time of surgery
- Name of sling inserted at the time of surgery
- Estimated blood loss
- How long mesh excised
- Intraoperative complications
- Last follow-up date
- Length of hospital stay (days)
- Postoperative complications
- Postoperative fever
- Postoperative blood transfusion
- Postoperative UTI
- Postoperative infection
- Improvement scale
- Postoperative persistent pain symptoms
- Visual analog scale (scale 0-10) at right paraurethral area postoperatively
- Visual analog scale (scale 0-10) at left paraurethral area postoperatively
- Visual analog scale (scale 0-10) at suburethral area postoperatively
- Visual analog scale (scale 0-10) at anterior vaginal wall area (proximal to bladder area) postoperatively
- Visual analog scale (scale 0-10) at proximal posterior vaginal wall area postoperatively
- Visual analog scale (scale 0-10) at distal posterior vaginal wall area postoperatively
- Visual analog scale (scale 0-10) at right proximal levator ani area postoperatively
- Visual analog scale (scale 0-10) at left proximal levator ani area postoperatively
- Visual analog scale (scale 0-10) at right distal levator ani area postoperatively
- Visual analog scale (scale 0-10) at left distal levator ani area postoperatively
- Urinary incontinence postoperatively
- Number of incontinence events per day postoperatively
- Empty supine stress test postoperatively
- Number of pads per day postoperatively
- Urinary retention postoperatively, PVR>100cc
- Recurrent UTI postoperatively
- dyspareunia postoperatively
- POP-Q pre op, -3 to +3
- -3 to tvl
- -tvl to tvl
- Genital hiatus
- Perineal body
- Total vaginal length
- -3 to +3
- -3 to tvl
- -tvl to tvl
- Vaginal atrophy postoperatively
- Postoperative sexually active
- Pre operative Verbal Numerical Rating Scale (VNRS) scale 0-10
- Post operative Verbal Numerical Rating Scale (VNRS) scale 0-10
- Current pain medication
- Pain medication name
- Additional surgical treatment for mesh complications
- Surgical procedures
- ISS compared to before surgery for incontinence/pelvic organ prolapse
- PGI-I post-operative condition compared with before surgery
- Preoperative PISQ-IR score from the questionnaire scoring system
- Preoperative PFDI score
- Postoperative PISQ-IR score from the questionnaire scoring system
- Postoperative PFDI score
- Preoperative UDI6 total score
- Postoperative UDI6 total score
- Preoperative IIQ7 total score
- Postoperative IIQ7 total score