

Topics of Interest

Investigator Sponsored Research (ISR) Grants – UroPH

The BSC ISR Program provides support for research that advances medical and scientific knowledge related to our products and relevant disease states. This global program is open to all researchers who are interested in conducting their own research in the field. Areas of particular interest for the Boston Scientific Urology and Pelvic Health Division include, but are not limited to:

Upper Tract Stone Disease

- Optimal laser settings for dusting vs. fragmentation and associated stone free rates
- Endoscope – flexible ureteroscope - economics – single use versus reusable (repair costs, deterioration of performance, safety, etc.)
- Stent encrustation (causes, effects on patients, economic impact, patient and economic costs of forgotten indwelling stents)
- Ureteral stent pain

BPH

- Use of GreenLight XPST™ PVP Laser System in men with prostate volume > 80 grams
- Use of GreenLight XPS PVP Laser System in men that are high risk surgical candidates i.e. anticoagulated
- Comparison of GreenLight XPS PVP Laser System with other surgical modalities for BPH (Plasma Button, HoLep, Thulium)
- Economic data regarding the health system costs of Green Light XPS Laser System compared to other treatments for BPH

Female Stress Urinary Incontinence

- The case for minislings as standard of care therapy for stress urinary incontinence: Solyx™ SIS System versus TVT™ Retropubic System
- White paper on requirements for moving minislings into the office: clinical and re-imburement perspectives

Pelvic Floor Reconstruction

- Randomized study on distal support of the anterior vaginal compartment utilizing the Uphold™ LITE Vaginal Support System with and without concomitant anterior wall plication
- Safety and efficacy outcomes following treatment of apical and anterior vaginal compartment with the Uphold LITE transvaginal mesh system and with abdominal sacrocolpopexy
- Predictors of repair durability in treatment of anterior vaginal compartments with the Xenform™ extra cellular matrix

Abnormal Uterine Bleeding

- Comparisons of different treatment modalities on patient outcomes and post-procedural complications (i.e. pain)
- Assess impact of vasopressin and mean arterial pressure on fluid management

Removal of Uterine Tissue (Fibroids, Polyps)

- Data on efficacy and safety
- Comparative studies with currently available technologies
- Data on the cost effectiveness of Symphon™ Tissue Removal System for polyps and fibroids

Male Stress Urinary Incontinence

- Predictors of urethral atrophy after AUS placement
- Long-term outcomes for AUS placement after pelvic XRT
- Validation of a questionnaire to assess the severity of male SUI to show correlation to treatment options

Male Erectile Dysfunction

- Patient satisfaction in men receiving an IPP for ED (flaccid state, rigidity, penile girth)
- Cost effectiveness of IPP as first line therapy in men with ED and a poor prognosis for the success of conservative therapies

Investigator Sponsored Research (ISR) Grant Submission Process

Thank you for your interest in applying for a research grant from Boston Scientific. Boston Scientific has an on-line formal submission process. Please follow the guidelines below to help ensure a smooth grant submission.

1. Where can I access the on-line application?

- Please use the online application process. Click on the link to learn more and apply. <http://www.bostonscientific.com/en-US/investigator-sponsored-research.html>

2. What are my options for submitting an ISR request?

- Either a full or concept proposal can be submitted.
 - Full proposal: Includes details on project objectives, study hypothesis, methods, statistical analysis plan, itemized budget, Investigator's CV, and the institution's W-9. If the full proposal is approved, BSC will move forward with contract execution.
 - Concept proposal: Includes scientific question and budget. If the concept proposal is approved, it is an invitation to then submit a full proposal for review.

3. How do I submit a proposal?

- Log into the online application process to request a username/password (first time user's only)
- Submit the proposal
- Boston Scientific's Research & Education (R&E) Committee meets once per month to review proposal and will notify you of the decision
- If the R&E Committee approves the proposal, a contract is signed by both parties and the project is executed by the Investigator

4. Can Boston Scientific be involved in the ISR project?

- Sales and Marketing can have no involvement in the grant submission or review process
- The Investigator is considered the study sponsor and is responsible for all activities related to the project

5. Who do I call if I have questions?

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For FEMALE Mid-Urethral Slings: **Caution:** Federal (US) law restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence.

For Xenform Soft Tissue Repair Matrix: **Caution:** Federal (US) law restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of pelvic organ prolapse.

For Uphold LITE Vaginal Support System: **Caution:** Federal (US) law restricts this device to sale by or on the order of a physician trained in use of surgical mesh for transvaginal repair of pelvic organ prolapse.

For Symphion- **Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician trained in diagnostic hysteroscopy.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician. Refer to package insert provided with this product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using these products.

Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

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