Coloplast
Ostomy Care
Continence Care
Wound & Skin Care
Interventional Urology

Investigator Initiated Study Program (IISP)

STUDY PROPOSAL AND RESEARCH GRANT REQUEST FORM

Mission

The mission of the Coloplast Investigator Initiated Study Program (IISP) is to provide support for research that advances medical and scientific knowledge. Through the support of ethical and scientifically sound research we hope to improve the overall quality of patient care. This program is open to all qualified researchers who are interested in designing, conducting, and analyzing their own research projects, and who desire funding and/or other assistance from Coloplast.

Process

This form serves as a request for assistance and collects information to assess the scientific merit of the proposed study.

Complete and qualified submissions will be reviewed by the Coloplast IISP Review Committee to determine alignment with Coloplast areas of clinical interest, budget, and compliance with applicable laws/regulations and Coloplast policies. The submission of a study proposal does not imply approval, and any support is contingent upon obtaining a fully-signed research agreement.

For human subject studies, Coloplast device use must align with current approved labeling for the geographical location in which the study will be conducted, unless an Investigational Device Exemption (IDE) has been approved by the U.S. Food and Drug Administration. Ethics approval (e.g., Institutional Review Board, Ethics Committee, Institutional Animal Care and Use Committee), where relevant, is required.

Financial and product/materials/services support are subject to Fair Market Value assessment. Coloplast will report the value of all funds, products, data, materials and services provided under any grant as may be required by state and federal disclosure laws, including the Federal Physician Payment "Sunshine Act".

The following documents *must* accompany this study proposal and research grant request form. Incomplete submissions will be returned to requestor.

☐ Complete, signed/dated Study Proposal and Research Grant Request Form

☐ Study protocol or synopsis, where relevant. Include, as applicable, at a minimum:

- Primary research objective
- Patient population, inclusion/exclusion criteria
- Primary/secondary study endpoints (include how endpoints will be defined and measured)
- Comparison or control group
- Subject follow-up schedule
- Sufficient detail to support/explain budget (see also Section V)

☐ Current CV, signed/dated

☐ Proposed budget (see Section V for requirements)

Complete all sections relevant to your request.

Indicate N/A for questions not applicable to your request.

Return the completed form and supporting documentation to IISP@coloplast.com

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SECTION I. INVESTIGATOR/SITE/STUDY INFORMATION	
Investigator Name(s)	
Institution/Practice Name	
Institution Profile	☐ Private Practice ☐ Academic Center ☐ Hospital System ☐ Other (specify):_____
Address	
City/State/Country/Postal	
Phone	
Email	
Study or Project Title	

SECTION II. STUDY DESCRIPTION		
Coloplast Product(s), check all that apply		
Men's Health Products	**Women's Health Products**	
☐ Genesis® Malleable Penile Implants	☐ Altis® Single Incision Sling System	☐ Restorelle® Flat Mesh
☐ Titan® Penile Implants	☐ Aris® Transobturator Sling System	☐ Restorelle® Y-Mesh
☐ Torosa® Testicular Implants	☐ Supris® Retropubic Sling System	☐ Restorelle® Y-Contour Mesh
☐ Virtue® Urinary Incontinence Sling	☐ Durasphere® EXP Injectable Bulking Agent	☐ Meridian® VPS
☐ Tutoplast® Processed Pericardium	☐ Suspend® Fascia Lata	☐ Axis™ Dermis Allograft
☐ Other _____	☐ BoNee® Bladder Injection Needle	☐ Other _____
Endourology Products		
☐ Biosoft® Duo Ureteral Stents	☐ ISIRIS® Stent Removal System	☐ SabreGuard™ Holmium Laser Fibers
☐ Dormia® N. Stone Retrievel Devices	☐ Orchestra™ Hydrophilic Nitinol Guidewires	☐ SabreLine™ Holmium Laser Fibers
☐ Dormia® No-Tip Stone Retrieval Devices	☐ Percutaneous Nephrostomy Dilators	☐ Stenostent® Ureteral Stents
☐ EasiVac® Bladder Evacuator	☐ PTFE-Coated Seldinger Guidewires	☐ Ureteral Catheters
☐ Folysil® Silicone Catheters	☐ Pyelostent® Ureteral Stent	☐ Ureteral Dilators
☐ Imajin® Hydro Ureteral Stent Kits	☐ Retrace® Access Sheath	☐ Vortek® Ureteral Stents
☐ In-Ka® Ureteral Balloon Dilatation Catheters	☐ In-Ka® Percutaneous Access Needles	☐ X-Flow® Silicone Prostatic Catheters
		☐ Other _____
Study Type, check all that apply		
☐ Case Series	☐ Multicenter	☐ Record-based analysis
☐ Cohort	☐ Observational	☐ Retrospective
☐ Controlled	☐ Prospective	☐ Other, specify:
☐ Experimental Model	☐ Randomized	
Statistical Analysis (Indicate the test that will be applied for comparator group, if applicable)		
☐ Superiority ☐ Non-inferiority	☐ Descriptive	☐ Other, specify:_____

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SECTION III. KEY STUDY METRICS (PROVIDE BEST ESTIMATE)	
Anticipated Study Start Date	
Anticipated Study End Date	
Anticipated Enrollment Duration	
Anticipated Sample Size	

SECTION IV. PUBLICATION/PRESENTATION PLANS		
	Targeted Scientific Meeting(s)	**Submission Deadline(s)**
☐ Abstract(s)		
	Targeted Peer-Reviewed Journal(s)	**Anticipated Time Frame**
☐ Manuscript(s)		

Study Registration

Do you plan to register your study? ☐ Yes ☐ No

If Yes, specify all that apply: ☐ ClinicalTrials.gov ☐ EU Clinical Trials Register ☐ ISRCTN ☐ ANZCTR ☐ Other, specify: _____

SECTION V. FINANCIAL, TECHNICAL OR OTHER SUPPORT REQUESTED

Check all that apply:

☐ Funding to pay for expenses that are directly related to study activities

Include budget proposal (including total) with adequate detail for calculation of Fair Market Value. Costs to include, as applicable, start-up costs, title/hourly personnel rate, cost of non-Standard-of-Care follow-up visits, lab fees, data entry.

Note: ***Requests to add to budget after study approval must undergo additional review which may result in delays.***

☐ Technical support directly related to study activities (e.g. statistician support, writing support)

Include type of technical support, estimated hours, and hourly rate.

☐ No-cost product or other clinical trial materials to support study activities

Include adequate detail to permit calculation of Fair Market Value. To include, as applicable, devices, components, materials, size(s), quantities requested.

☐ Other, specify: _____

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SECTION VI. RESEARCH AGREEMENT INFORMATION		
Each Coloplast research grant is documented in an Investigator Initiated Research Agreement		
Please list names and titles of all parties who will be named to the research agreement:		
Investigator(s)	Name	Title
	Name	Title
Institution	Name	Title
Other, specify:	Name	Title

SECTION VII. SIGNATURE		
	Investigator Name (print or type)	
	Signature	**Date**