| **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 (see Section II)  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**](mailto:IISP@coloplast.com) |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION I. INVESTIGATOR/SITE/STUDY INFORMATION** | | | | | | | | | |
| **Investigator Name(s)** | |  | | | | | | | |
| **Institution or Practice Name** | |  | | | | | | | |
| **Institution Profile** | | Private Practice | | | Academic Center | | | | Hospital System |
| Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| **Address** | |  | | | | | | | |
| **Phone** | |  | | | | | | | |
| **Email** | |  | | | | | | | |
| **Study or Project Title** | |  | | | | | | | |
| **Section II. STUDY DESCRIPTION** | | | | | | | | | |
| Please include a study protocol or protocol synopsis with submission. 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 * Study follow-up schedule * Enough detail to support/explain budget (see also Section V) | | | | | | | | | |
| **Coloplast Product(s), check all that apply** | | | | | | | | | |
| Genesis Malleable | | | Altis | | | Axis | | Restorelle M/L/XL | |
| Titan/Titan Touch IPP | | | Aris | | | Suspend | | Restorelle Y/Restorelle Y Contour | |
| Torosa | | | Supris | | | Tutoplast | | Other, specify: | |
| Virtue | | | | | | | | | |
| **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: | | |
| **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.**  Technical support directly related to study activities (e.g. statistician support, writing support)  **Include type of technical support, estimated hours, and hourly rate.**  Free 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: | | | | | | | | | | |
| **SECTION VI. RESEARCH AGREEMENT INFORMATION** | | | | | | | | | | |
| **Each Coloplast research grant is documented in an Investigator Initiated Research Agreement** | | | | | | | | | | |
| **All parties 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** | |