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| **Study Proposal and Research Grant Request Form** |
| **The purpose of this form is to collect information in order to assess scientific attributes of your proposed study.**   * **Submissions considered complete and qualified will be reviewed by the Coloplast IISP Review Committee.** * **For human subject studies, Coloplast device use must align with current approved labeling for the geographical location in which the study will be conducted to be eligible for consideration.** * **Ethics approval (e.g., Ethics Committee, Institutional Review Board, Institutional Animal Care and Use Committee), where relevant, will be required.** * **Financial and product/materials/services support granted 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”.** |

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| **Requestor *must* submit the following documents or supporting information.**  **Requests submitted without these items *will not* be considered and will be returned to the requestor:**  **Signed and dated Study Proposal and Research Grant Request Form with all sections completed**  **Study protocol or synopsis, where relevant (see Section II)**  **Current CV, signed and dated**  **Proposed budget (see Section V for requirements)**  **Complete all sections relevant to your request.**  **Mark as N/A anything that is not applicable to your request.**  **Return the completed form and supporting documentation to** [IISP@coloplast.com](mailto:IISP@coloplast.com) |

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| **Section I. SITE INFORMATION** | |
| Investigator Name(s) |  |
| Institution or Practice Name |  |
| Institution Profile | Private Practice  Academic Center  Hospital System  Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Address |  |
| Phone |  |
| Email |  |

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| Section II. STUDY DESCRIPTION  **Please include a study protocol or protocol synopsis with this submission.**  **Include, as applicable, at a minimum:**   * **Study name** * **Primary research objective** * **Patient population, inclusion/exclusion criteria** * **Primary/secondary study endpoints (include information on 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 | Restorelle DirectFix | | Titan/Titan Touch IPP | Aris | Restorelle M/L/XL | | Torosa | Supris | Restorelle Y/Restorelle Y-Contour | | Tutoplast | Suspend | Axis | | Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| Type of Study (Check all that apply)   |  |  |  | | --- | --- | --- | | Prospective | Multicenter | Experimental Model | | Retrospective | Cohort | Record-based analysis | | Randomized | Observational | Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Controlled | Case Series | Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **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. PUBLICATION/PRESENTATION PLANS** | | |
|  | **Targeted Scientific Meeting(s)** | **Submission Deadline(s)** |
| Abstract(s) |  |  |
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|  |  |
|  | **Targeted Peer-reviewed Journal(s)** | **Anticipated Time Frame** |
| Manuscript(s) |  |  |
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| Do you plan to register your study?    Yes      No  If Yes, please specify all that apply:     ClinicalTrials.gov           EU register           ISRCTN           ANZCTR  Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

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| **SECTION IV. KEY STUDY METRICS (Provide your best estimate)** | |
| Anticipated Study Start Date |  |
| Anticipated Study End Date |  |
| Anticipated Enrollment Duration |  |
| Anticipated Sample Size |  |

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| **SECTION V. FINANCIAL, TECHNICAL OR OTHER SUPPORT REQUESTED** |
| Please check all that apply:  Funding to pay for expenses that are directly related to study activities  **Include your proposed budget with enough detail to allow calculation of Fair Market Value, e.g., specific study start-up costs, title/hourly rate of personnel, cost of follow-up outside of Standard of Care. See example below.**  Technical support that is directly related to study activities (e.g. statistician)  **Include type of technical support, estimated hours, and hourly rate. See example below.**  Free product or other clinical trial materials to support study activities  **Include enough detail to allow calculation of Fair Market Value, e.g., devices, components, materials, size(s), quantities requested. See example below.**  Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Example of detail needed for Fair Market Value evaluation of your proposed budget (submit your budget separately):**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Line Item | Quantity | Rate  **EXAMPLE** | Total | Job Title (if relevant) | | Lab expenses | Describe | $/each | $ | N/A | | Lab personnel | x hours | $/hour | $ | Laboratory technician | | Product | Specific devices, components or materials requested, including sizes/quantities | N/A | FMV of product (Coloplast will determine this amount) | N/A | | Patient follow-up | x hours | $/hour | $ | Research Nurse | | Patient visits | x visits | SOC | $0 | N/A | | Patient visits outside SOC | x visits/x patients | $/visit | $ |  | | Data entry | x hours | $/hour | $ | Research Coordinator | | Statistical support | x hours | $/hour | $ | Senior Statistician | | Writing support | X hours | $/hour | $ | Medical Technical Writer | | **Total** | | | **$** |  | |

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| **SECTION VI. RESEARCH AGREEMENT INFORMATION** |
| **Each Coloplast research grant is documented by an Investigator Initiated Research Agreement, which is typically milestone-based (e.g., compensation is tied to completion of one or more milestones).** |
| **List all parties who, pending approval of this proposal, would be named to the research agreement:** |
| Investigator(s) Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Institution Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Other Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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