Investigator Initiated Study

Proposal Form

**HOW TO APPLY**

To submit your Study Proposal, email the Proposal Form in English, along with your CV, to research-screening@straumann.com

Only **completed** forms will be considered.

**REVIEW PROCESS**

Straumann is committed to Investigator Initiated Studies and evaluates each Proposal Form for, among other factors, scientific merit, strategic interest, and degree of new scientific and clinical evidence.

The Research Screening Committee is composed of Straumann experts pursuing responsibilities within various departments of the company. The Research Screening Committee meets on a regular basis to review all incoming applications. A decision on your proposal will be communicated within **three months** after submission. The application process is by nature competitive and due to the high volume of applications, we are not able to support all projects.

|  |  |
| --- | --- |
| **Application Date :** |       |

|  |
| --- |
| **Study Team:** |
| Primary Investigator (PI):       Co-Investigators:      Email:       Study nurse/ Coordinator:       (if applicable)Institution and Department:       |
| Contact details primary investigator (lead study center):Street:       Postal Code:      City:       Country:      State (for US addresses):      Email:       Phone:      |
| Additional study centers:      |

|  |
| --- |
| **Study Overview:** |
| Study Title:       |
| Rationale of study:(what is the reason for performing this study?) |       |
| Study hypothesis:(Formulate only **one** hypothesis) |       |
| Type of study: | [ ]  In vitro study[ ]  Animal study  | [ ]  Clinical study |
| Study design:(in case of a clinical study) | [ ]  Prospective [ ]  Controlled [ ]  Randomized [ ]  Observational  | [ ]  Retrospective [ ]  Single-arm (single cohort) [ ]  Non-randomized  |
| Field: | [ ]  Implants [ ]  Prosthetics Other:       | [ ]  Regenerative [ ]  Digital workflow  |
| Number of patients /animals/samples | Total:       Per group (if applicable):       |
| Sample size calculation (if applicable): | Calculated number (without drop-outs):      Rationale:       |
| Study Device (Product Name):{needs to be Straumann product(s)} |       |
| Control Device (Product Name): |       |

|  |
| --- |
| **Study Budget** |
| **Expected patient care costs for clinical studies, if applicable:** ***Please state your currency:*** [ ]  *USD* [ ]  *CAD* [ ]  *GBP* [ ]  *CHF* [ ]  *EUR* [ ]  *Other:*       |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Clinic / Hospital  | Cost type/item (i.e. CBCT, patient stipend) | Cost per patient  | Type of patient (inpatient/outpatient) | No. Of patients  | Total costs | % contribution by Straumann |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
| **Expected costs for pre-clinical studies, if applicable:**       |
| Laboratory/Facility | Cost type/item (e.g. animal purchase, ELISA kit, histology) | Total costs | % contribution by Straumann |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
| **Any additional cost:**       |
| Type of cost | Total cost  | % contribution from Straumann |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
| **Overhead costs:**  |
| % of required overhead / administrative costs of University / institution |      % |  |
| Total amount applied towards total study budget:       |
| **Total study budget:** |       |
| **Expected overall financial contribution from Straumann:**  |       |

|  |
| --- |
| **Project timetable:**  |
| No. Of milestone | Milestone(Ex. IRB submission/ approval, End of enrollment, manuscript submission) | Start date(mm/yyyy) | End date(mm/yyyy) | Installment from Straumann, if applicable | Comments  |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |

|  |
| --- |
| **Requested material support** (***Straumann products only***): |
| Article description | Article number | Quantity |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
| Discs for in vitro studies: | Type:       ∅ 15 mm:       ∅ 5 mm:       |

|  |
| --- |
| **Study Details:** |
| Primary endpoint:      |
| Secondary endpoints:      |
| Indication:      |
| Materials and Methods:      |
| Statistical methods:      |
| Publications & Presentation Plan (describe number, content and target journals of planned publications and congress contributions):      |

|  |
| --- |
| **Experience of primary investigator:** |
| Number of published articles in international peer-reviewed journals **(as PI)**: |       |
| Specify three most relevant currently ongoing studies you are running **(as PI or co-investigator)**:  |
| Nr.  | Type | Title | Industry partner |
| 1) |       |       |       |
| 2) |       |       |       |
| 3) |       |       |       |
| ISO 14155 or GCP training performed (certificate available)?If yes, please include certificate with the application.*For clinical studies: GCP and/or ISO 14155 training is expected*  | [ ] Yes [ ] No [ ] NA |
| CV included? *mandatory* | [ ] Yes [ ] No |

|  |
| --- |
| **Monitoring, data management and analysis:** |
| Who performs monitoring (only applicable for clinical studies)? |       |
| Who manages the data (e.g. creates and maintains the database)? |       |
| Who performs the statistical analysis? |       |
| Who writes the publication(s)? |       |

**Please check that these documents are included with the submission:**

[ ]  Signed CV

[ ]  GCP and/or ISO certificate, if applicable

[ ]  Draft protocol, if available

**Clinical Research Agreement**

1. **Introduction**
	1. The ideas, information, concepts, protocols, technical drawings, and other information related to a proposed research study concept (collectively, the “Submitting Party Information”) by the individual or entity submitting the Proposal Form (“Submitting Party”) to Institut Straumann AG, a Swiss stock company with a principal place of business at Peter Merian-Weg 12, CH-4002 Basel, Switzerland (“Straumann”) are regulated according to the following terms and conditions (“T&Cs”).
	2. Straumann or its affiliates (collectively, with Straumann, the “Straumann Entities”) will evaluate the Submitting Party Information to assess the possibility of entering a study agreement between the Submitting Party and Straumann. Straumann does not commit to entering into any study agreement with Submitting Party. Submitting Party expressly acknowledges that any study that may arise out of the Submitting Party Information shall be subject to the terms of a separate, written study agreement to be negotiated between the parties.
	3. Submitting Party acknowledges and agrees that the Straumann Entities are receiving and reviewing Submitting Party Information at Submitting Party’s request, and Submitting Party hereby grants to the Straumann Entities any and all rights, licenses, and privileges that may be necessary or appropriate to permit the Straumann Entities to evaluate the Submitting Party Information to assess potential research study opportunities between the Submitting Party and Straumann.
2. **Submitting Party Information**
	1. Submitting Party expressly acknowledges and agrees that the term “Submitting Party Information,” as it is used in this T&Cs, does not include ideas, information, concepts, protocols, technical drawings, or other information that: (i) is or are generally known outside of Submitting Party, (ii) Straumann can demonstrate was or were already known to the Straumann Entities immediately prior to the delivery of the Submitting Party Information to Straumann, (iii) is not or are not owned exclusively by Submitting Party, and (iv) is or are obvious to someone knowledgeable in the field of implant dentistry or dental tissue regeneration.
	2. Submitting Party agrees that the Straumann Entities shall have no obligation to Submitting Party, whether contractual or otherwise, with respect to information that is not Submitting Party Information, and Submitting Party hereby releases the Straumann Entities, individually and jointly, from any and all claims, whether in law or equity or otherwise, related to any such information.
	3. Submitting Party understands and agrees that the Submitting Party Information may be similar or identical to existing information that the Straumann Entities possess or have independently developed (the “Straumann Information”), and that the Straumann Entities shall have no liability to Submitting Party with respect to any such Straumann Information. Straumann’s acceptance of information from Submitting Party does not constitute an admission or acknowledgment by the Straumann Entities that such information constitutes Submitting Party Information under this T&Cs.
3. **Other Acknowledgments and Agreements**
	1. Submitting Party represents and warrants that it has the right to provide the Submitting Party Information to the Straumann Entities, and it is the owner of all right title and interest in and to the Submitting Party Information. Submitting Party acknowledges that submitting the Proposal Form to Straumann does not grant or convey to Submitting Party any right, title, or interest in any intellectual property of the Straumann Entities.
	2. The submission of the Proposal Form and any dispute including those concerning any statue of limitations, set-off claims, tort claims and interest claims, shall be governed by the laws of Switzerland, excluding its conflict of laws rules, and shall be exclusively resolved by the ordinary courts at Basel-Stadt.

By submitting the attached Proposal Form to Straumann, the Submitting Party acknowledges and agrees to the present T&Cs.

|  |
| --- |
| **Submitting Party**       |
| Signature       |  |
| Name       |  |
| Title       |  |
| Institution name       |  |
| Address      |  |
| Date |  |