Osteology Foundation

Geistlich-Stucki STIFTUNG

Peter and Annemarie Geistlich-Stucki Grant by Osteology Foundation

Application Guidelines

Content

General Information

The **Osteology Foundation** aims to support clinical research in the field of oral tissue regeneration, to bridge the gap between scientific progress and clinical practice for the benefit of the patient.

The purpose of the **Geistlich-Stucki Foundation** is to promote medical research and teaching on a nonprofit basis. The focus of their activities is on tissue regeneration with biological materials, especially in oral and maxillofacial surgery, and in the field of cancer treatment.

The two foundations have now joint forces and developed a joint grant programme to address sound **clinical research questions in the field of oral and maxillofacial tissue regeneration**.

Before applying – Good to know

To improve the efficacy of handling applications and to facilitate objective project comparison, please note that **incomplete applications as well as those that deviate from the given guidelines** (e.g. exceed the permitted length and/or deviate from formatting guidelines) **will be rejected.**

2.1 Application process

There are two stages in the application process:

Stage 1: Abstract Application
Applicants submit an abstract of their proposed project. The Science Committee of the Osteology Foundation, as well as members of the Geistlich-Stucki Foundation, review the Abstract applications and selects the projects which progress to the second stage. The successful applicants will be then invited to submit a Main Application.

Stage 2: Main Application
Applicants are invited to submit their full application. Members of the scientific committee, as well as external reviewers and members of the Geistlich-Stucki Foundation, will thoroughly review these detailed study proposals, discuss the evaluation results, decide about the final grant recipients, and confirm the amount of funds to be awarded.

2.2 Financial Transparency – Funding Details

- The funding is exclusively provided by the Geistlich-Stucki Foundation.
- It is understood that the grant may not provide the total amount of funding required to perform the planned study.
- Please provide details of any leveraging funds that may be included in support of the application and highlight budget impacts (contract with provider of leveraging funds needs to be submitted in the Main Application phase).
- A grant application submitted to the Peter and Annemarie Geistlich-Stucki Grant programme may not be submitted in parallel to another funding organisation or research

grant provider (e.g. company). If so, the application may be excluded from the granting process.
- Clearly product-based research will be rejected at pre-proposal stage.

2.3 Ethical guidelines for Clinical Research

For all clinical studies, the submission of full approval of the institutional human subjects review board of the respective official (national) body is demanded.

All clinical trials need to be registered through an international clinical trials registry before the trial is started. The registry that is recommended is: http://www.clinicaltrials.gov/

The trial registry number (ClinicalTrials.gov Identifier) as well as the approval of the institutional human subjects review board needs to be submitted to the Osteology Foundation before the start of the trial and before the granted amount can be transferred.

All clinical studies submitted through the Osteology Foundation need to be compliant with the current version of the Declaration of Helsinki (https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2013-JAMA.pdf), the ICH-GCP or the ISO EN 14155 (as far as applicable). In addition, all national legal and regulatory requirements need to be fulfilled by the applicants.

Moreover, we request to follow the CONSORT statement for setting up a study protocol for a randomized controlled clinical trial (see - http://www.consort-statement.org/). CONSORT checklist:

- http://www.consort-statement.org/download/Media/Default/Downloads/CONSORT%202010%20Checklist.doc

To strengthen the reporting of observational studies, we request to follow the Strobe Statement:

- http://www.strobe-statement.org/

Checklists for e.g. cohort, case-control, and cross-sectional studies are available here:
- http://www.strobe-statement.org/index.php?id=available-checklists

2.4 Submitting person

Please note that it is not accepted to apply in the name of a third person. Principal Investigators should use their own account to submit and electronically sign their Abstract and Main Applications.

2.5 Data sharing

The information provided upon application through The BOX, the online submission system hosted by the Osteology Foundation, will be shared between the Osteology Foundation and the Geistlich-Stucki Foundation for administrative and reviewing purposes. The Osteology Foundation, the Geistlich-Stucki Foundation and Review Committee will treat all application materials submitted for consideration for funding, as well as after the funding decision, in a

confidential manner. They shall not use, disclose, or transfer for any purpose other than the grant programmes any information or intellectual property disclosed in the course or as part of such programmes.

Abstract Application

All Abstract Application documents must be submitted electronically via the online application system of the Osteology Foundation (The BOX).

To ensure a comparable format for all applications, the space for entering the project information is limited. All information must be provided in English.

To avoid formatting errors when copying text from e.g. MS Word into the online application tool, please paste plain text only. Afterwards you can use the basic rich text formatting of the online application tool.

3.1 Summary of Abstract Application requirements for submission

- A clear overview of the study background, research question, aims of the project, proposed methodology, clinical relevance and available expertise and facilities (1500 characters for each section)
- Additional documents to upload upon application:
  - Proof of GCP training certificate of principal investigator (PI)
  - CV of PI (max. 2 pages)
  - Font: Times New Roman, font size 12, line spacing 1.2
  - Page margins: 2.5 cm (left, right, top), 2 cm (bottom)
- Respect the character and page limits
- Upload PDF files only

Review Process

Each Abstract submission is evaluated by six members of the Review Board, one Osteology Foundation Science Committee member, as well as one member of the scientific advisory board of the Geistlich-Stucki Foundation. The final decision on Abstract submissions to be invited for the Main Application round involves members of the Osteology Foundation Science Committee, as well as of the scientific advisory board of the Geistlich-Stucki Foundation.

All submitted Main Applications are thoroughly evaluated by 5 independent, external reviewers. The Osteology Foundation's Scientific Committee members together with two representatives of the scientific advisory board of the Geistlich-Stucki Foundation, further discuss the applications in light of the external reviewer comments and take a final decision on the grant recipients.

The maximum available funding can be assigned to one or more projects, depending on the budgeted amounts and the adherence to the above-mentioned awarding criteria.

Please note that during the Abstract Application phase the reviewers do only provide a quantitative evaluation (grades for each application). No written or qualitative evaluation is provided by the reviewers. As a matter of policy, the Foundation does only give comments on positive or negative decisions after the Main evaluation cycle, upon request.

Main Application

All Main Application documents must be submitted electronically via the online application system of the Osteology Foundation (The BOX). For this, the applicant must use the same account created when submitting the Abstract Application. Hand-written signatures are not necessary.

5.1 Summary of Main Application requirements for submission

- Specify the study design in detail and specify the most important study parameters, e.g. study hypothesis, control and test groups, primary outcome
- Include a detailed Budget overview (template provided) and provide a narrative justification of all items and expenses within the detailed study proposal. This may include other sources of financial support, a justification of particularly expensive items, etc. Do budget material costs (e.g. biomaterials) and open-access publication fees.
  - Provide corporate support letters or sponsorship agreements for materials
  - Consider the following budget limitations:
    - Publication fees – max. 7500 Swiss francs of total requested amount
    - Overhead – max. 10% of total requested funding
- Respect the page limits and formatting guidelines. Use the document templates on The BOX whenever available.
- Necessary documents:
  - Detailed study proposal – max. 15 pages
  - Overhead policy – max. 2 pages
  - CVs of PI and co-investigators (template) – max. 2 pages
  - CRF
  - Budget overview (template)
  - Graphical Abstract – max. 1 page
  - Other sources of financial support (if applicable)
  - Font: Times New Roman, font size 12, line spacing 1.2
  - Page margins: 2.5 cm (left, right, top), 2 cm (bottom)
- Upload PDF files only

5.2 Study Proposal – Further Details

A detailed study proposal must be submitted with the Main Application. The proposal should include the following information:

- Background and Rationale
  - Investigational Product (treatment, device) and Indication
  - Preclinical Evidence and Clinical Evidence to Date
  - Risks / Benefits
  - Justification of choice of study population
- Study registration
  - Provide a statement of study registration, where it is, or is intended to be, registered, include the number and date; include further registrations if registered in other registries.
  - The study should be registered in a registry listed in the WHO International Clinical Trials Registry Platform – the registry that is recommended is: http://www.clinicaltrials.gov/
- Study Objectives and Outcomes
  - Overall objective
  - Primary outcome
  - Secondary outcome
  - Other Outcomes of Interest
- Study Design
  - General study design and justification of design
  - Methods of minimising bias
  - Randomisation
- Study Population
  - Eligibility criteria
  - Recruitment and assignment to study groups
- Study Intervention
  - Identity of Investigational Products (treatment / medical device)
    - Experimental Intervention (treatment / medical device)
    - Control Intervention (standard/routine/comparator treatment / medical device)
- Study Assessment
  - Study flow chart(s) / table of study procedures and assessments
  - Assessments of outcomes
    - Assessment of primary outcome
    - Assessment of seconday outcome
- Statistical Methods
  - Hypothesis
  - Determination of Sample Size
  - Planned Analyses
  - Handling of missing data and drop-outs
- Quality Assurance and Control
  - Data handling and record keeping / archiving

    - Data management
    - Data Management System
    - Data security, access and back-up
- Publication and Dissemination Policy
    - Plans to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements)
- Funding and Support
    - Detailed budget plan and budget justification to allow reviewers to estimate the realistic costs of the research project
    - Detailed description why a budget item is important for the project and how the budgeted amounts will be used (e.g. what are the duties of the technical staff or what kind of supplies or material is needed for histomorphometry, animal care costs, patient related costs within clinical studies, …).
    - Fees for open access publication must be included
- References
    - List all relevant literature related to project proposal (max. 30)
- Appendices (if space is an issue, they can also be uploaded as extra PDF documents)
    - CRF
    - Specific protocols (e.g. for radiology, MRI, etc.)
    - CE approval if a new product is part of the clinical trial

5.3 Overhead Regulations – Further Details

- Overhead contributions are only made up to a maximum of 10% of the total project costs. As a prerequisite for funding of any overhead costs, the principal investigator or coordinating investigator must submit a copy of the official overhead regulations (only an excerpt with the most relevant information, **maximum of 2 pages**) stating the amount of requested overhead fees.
- An acknowledging letter including a statement to honour the policy of 10% of total project cost, or a letter with an indirect cost waiver reduction (if your Institution's overhead costs are higher) from your grants office, can also be considered.

After acceptance

6.1 Progress Reports

- Biannual progress reports must be sent to the Osteology Office and are a prerequisite for continuing payments in case of studies exceeding the duration of one year, ending with the publication of the study.
- Status reports must be prepared according to the timeline given in the accepted Main Application study protocol. The report should provide a summary of the funded project and include an update of the timeline for the remaining term of the project.
- The research group (principle investigator or coordinating investigator) should fill out a Progress Report Form that is based on the timeline of the Main Application.

6.2 Open-access Publication

Manuscripts originating from the funded project must be published in peer-reviewed scientific journals **with open access**. Fees for open access publication must be included in the budget plan.

6.3 Acknowledgments

Financial support provided by the Peter and Annemarie Geistlich-Stucki Grant should be acknowledged in the publication(s) resulting from this support in the following way:

The project [project number] was supported by the Peter and Annemarie Geistlich-Stucki Grant by Osteology Foundation, Switzerland.

6.4 IRB approval

Please calculate enough time to obtain approval from your national institutional human subjects review board (IRB). The **IRB approval is prerequisite for the payment of any funds**.
This IRB approval as well as the trial registry number need to be submitted by **31 December** (of the year of grant approval notification). Non-compliance with this deadline, without any further communication by the applicant, can result in a withdrawal of the grant decision.

6.5 Grant database

When submitting a Main Application, the principal investigator and all co-applicants agree that the following information will be published with a delay of 12 months after a positive funding decision within the grant database of the Foundation's website (https://www.osteology.org/grants/project-database/):

Year of funding, Funding programme, Investigators, Project title, Academic affiliation, Country, Region, Amount of funding, Project status and Link to publications, Graphical abstract, Layman summary

6.6 Funding Policy

Upon the acceptance of the Main Application and submission of the IRB approval documentation, the **first instalment** (30% of the total funding) can be requested by the applicant. The **second and third instalment** (40% and 20% of the total funding amount, respectively) will be released at enrolment start and end, respectively. The **final instalment (10%)** will be released upon reception of a proof of submission of a manuscript to an **open-access, peer-reviewed journal** OR of a final report sent to the Osteology Office (in case of no publication). With that, the project is successfully completed.

6.7 Exclusion from further Research funding by the Osteology Foundation

Principal investigators who received funding from the Peter and Annemarie Geistlich-Stucki Grant will be excluded from funding for the next three application cycles, i.e. for the following three years after their funding notification.

6.8 Project extensions

Projects can be extended twice at no costs for a maximum of 1 year at a time. To request a no-cost extension, please contact the Osteology Office (grants@osteology.org).

6.9 Termination of projects

Projects that exceed the maximum project duration including the duration of the no-cost extensions will be terminated. The remaining funds will no longer be available. Moreover, the Osteology Foundation and the Peter and Annemarie Geistlich-Stucki Foundation reserve the right to terminate projects that do not regularly report on the status/progress of the funded study. If such progress reports are not submitted in due time to the Osteology Foundation, funds may be frozen, and the corresponding financial account eventually liquidated. The Osteology Foundation and the Peter and Annemarie Geistlich-Stucki Foundation reserve the right to decide on an individual project basis.