

Osteology Foundation

Application Guidelines Large Clinical Grants

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1 General Information

The Osteology Foundation aims to support clinical research to bridge the gap between scientific progress and clinical practice for the benefit of the patient. In order to actively promote clinical research, the Osteology Foundation awards grants to selected researchers once a year:

Deadline for submission of Abstract Applications - **15 November (biannually)**, please check our webpage as the submission deadline may have been prolonged).

The Osteology Foundation offers this clinical research grant programme to well-established research groups that demonstrated clinical research expertise. The Large Clinical Grant programme addresses hypothesis-driven clinical research questions in the field of oral and maxillofacial tissue regeneration.

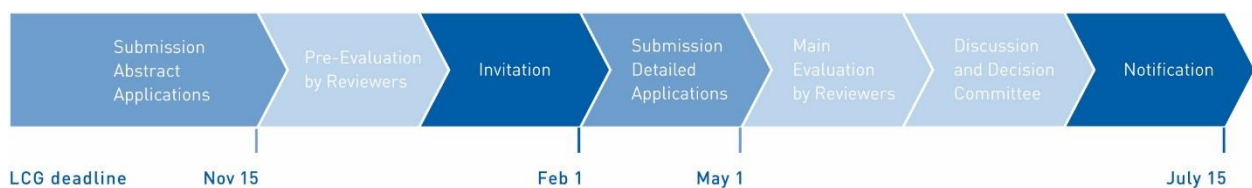
The Osteology Foundation ensures strict confidentiality of all applications and applying research teams, as well as of the results of the review process among the reviewers and the Osteology Foundation.

Study types

Research types falling within the scope of the Large Clinical Grant programme are for example:

- RCT (also small multi centres) and quasi RCT
- Case controlled studies
- Prospective cohort studies
- Surgical techniques (also in combination with biologics, drugs and devices)
- Biologics, devices and drugs (also e.g. phase I / phase II - pilot studies, proof of principle)
- Combination products

Timeline



All application documents must be submitted electronically via the online application system.

Therefore, the applicant has to create an account on The Box:

<http://box.osteology.org/>

Questions regarding the online application and information concerning the application process can be obtained from Dr. Benjamin Müller:

Phone: +41 41 368 44 49

E-mail: benjamin.mueller@osteology.org

2 Funding Policy

Maximum Funding Osteology Large Clinical Grant:

- Funding will be limited to CHF 350'000 with a maximum project duration of three years.

Reports

- Annual reports must be produced and are a prerequisite for continuing payments in case of studies exceeding the duration of one year. The deadline for submission of the annual report is 15 November. Starting with the year of grant notification and ending with publication of the study.
- Status report must be prepared according the time line given in the accepted Main Application study protocol. The report is an update of the time line for the remaining term of the project.
- The research group (principle investigator or coordinating investigator) will receive an Osteology Progress Report Form that is based on the time line of the Main Application. According to the time line given in the Main Application that was sent to the Osteology Foundation the report should provide a brief summary of the funded project.

Salaries

Salaries to be used in the grant application are limited to support of technical and research personnel directly related to the proposed project. The amount of effort on the specific Osteology Foundation grant must be clearly described as it relates to the research project.

All personnel and their amount of effort on the specific Osteology Foundation granted project must be listed in the budget plan (requested in the next step, upon invitation to the Main Application phase) with base salary and role within the project.

Institutional Overhead Costs

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 principle investigator or coordinating investigator must submit a copy of the official overhead regulations with the main application.

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.

Financial Transparency - other Funding Resources

It is understood that the Osteology Foundation 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 Osteology Foundation may not be submitted in parallel to another funding organisation or research grant provider (e.g. company). If so, the Osteology Scientific Committee may exclude the application from the granting process.
- Clearly product based research will be rejected at pre-proposal stage.

Ethical Board Approval

For all clinical studies the Osteology Foundation requests the submission of full approval of the institutional human subjects review board of the respective official (national) body. Any clinical trials need to be registered through an international clinical trials registry before the trial is started. The registry that is recommended by the Osteology Foundation 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 to the Osteology Foundation need to be in compliance with the current version of the Declaration of Helsinki (2013):

- <http://www.wma.net/en/30publications/10policies/b3/>), the ICH-GCP or ISO EN 14155 (as far as applicable)

In addition, all national legal and regulatory requirements need to be fulfilled by the applicants. Moreover, the Osteology Foundation requests 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 the Osteology Foundation requests 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>

IMPORTANT NOTE:

Please calculate enough time to obtain approval from your national institutional human subjects review board (IRB). The **IRB approval is prerequisite for payment of any funds**.

This IRB approval as well as the trial registry number need to be submitted to the Osteology Foundation six months after receiving the grant notification.

Deadline: **31 December** (of the year of grant approval).

Non-compliance with this deadline can result in a withdrawal of the grants decision. Therefore, the Science Committee of the Osteology Foundation requests a written status report regarding the IRB approval process and the trial registration.

Declaration

The lead applicant must sign and submit the main application document electronically. He/she accepts the regulations stated within this document including the evaluation and funding procedure.

Budget Justification

The Osteology Foundation reviewers, Science Committee members, Expert Council members and in addition one external reviewer per application, must understand the budget. Hence, a detailed justification needs to be provided for each budget category. The budget justification is an explanation of the factors used to determine the costs of each budgeted item and budgeted salaries for personnel.

Acknowledgments

Financial support provided by the Osteology Foundation should be acknowledged in the publication(s) resulting from this support in the following way:

The project (Osteology project number) was supported by the Large Clinical Grant programme from the Osteology Foundation, Switzerland.

3 Application and Review Process

The application process is divided into two steps:

Abstract Application

In this phase the Osteology Foundation Science Committee does a pre-evaluation of the clinical research question, the general methodology and the facilities and expertise of the research team aiming to conduct the proposed clinical research project.

First, an abstract application has to be submitted by the principle investigator or coordinating investigator by **15 November** using the online abstract application system - <http://box.osteology.org/>

The abstract applications will be reviewed by the members of the Osteology Science Committee.

Based on the pre-evaluation results, the best project proposals will be **selected and invited before 1 February** (of the following year). The respective researchers will be invited to submit a complete main application (see also timeline on page one).

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.

The application guidelines for the abstract application phase are explained in detail in section 4 of this document.

Main Evaluation

Following a written invitation, the Osteology Foundation Science Committee does in this phase an in-depth evaluation of the clinical study protocol.

All invited research groups (principle investigator or coordinating investigator) must file the complete main application documents and **submit** them to the Osteology Foundation **by 1 May** (of the following year) in order to be reviewed before July.

The Science Committee members, Expert Council members and in addition one external reviewer per application will thoroughly review the study proposals. At the June Board meeting, the evaluation results will be discussed and a decision about the acceptance/rejection and the funding amount will be made.

The application guidelines for the main application phase are explained in detail in section 5 in this document.

The respective applicants will be informed by **15 July** about the decision of the Science Committee.

Review Criteria

The abstract and main applications (will be reviewed based on the following awarding criteria:

- Hypothesis answering a clinical research question relevant to the field of oral and maxillofacial regeneration
- Methodology
- Facilities and expertise to conduct a GCP study
- Sound and transparent budget

As a matter of policy the Osteology Foundation does only give comments on positive or negative decisions after the abstract evaluation cycle. The names of the members of the Scientific Committee and Expert Council are published on the Osteology Foundation website.

4 Instructions for Completing the online Abstract Application Form

Please fill in the online abstract application accurately and completely. Note that to ensure a comparable format for all applications, the space for entering the project information is limited. All information must be provided in English.

When copying text from a MS Word document into our online application tool directly it may cause formatting errors (due to the background formatting information saved).

We recommend to first erase the background formatting of MS Word (e.g. with an additional coping step into a text editor).

When copying the text from the editor into the Osteology online application tool only the plain text is copied. Afterwards you can use the basic rich text formatting of the online application tool.

The following sections describe the information that is requested for the abstract application phase and needs to be filled in the online application tool (in total nine steps).

1. General Information

LARGE CLINICAL ABSTRACT APPLICATION

Please complete the following steps in order to submit your application.

1. GENERAL INFORMATION

Study Type: Randomized Controlled Trial
 Controlled Clinical trial
 Multi Centre Single Centre
 Cohort study
 Case-control study
 Case series (large)

Title of Study: *

Study Focus: Hard Tissue Soft Tissue Tissue Engineering
 Growth Factor Implants Biomaterials

Intended Start: * (mm-dd-yy)

Duration: * months

Total project costs: * CHF

Requested funding: * CHF

Other sources of financial support: * CHF

Keywords: *

Please give at least three Keywords that characterize your Abstract Application - e.g. Bone Formation, Soft Tissue Management, Cell Therapy, Surgical Procedure

How did you get the information about the Osteology Foundation Grant?

Poster 'Call of Grants' Advertising in a dental Journal
 Online Advertising World-of-Mouth, Colleagues, Friends
 E-mail Advertising

- Study Type: Indicate here the type of your trial or study
- Title: Please limit the title of your study to fewer than 300 characters.
- Start: Estimated start of practical work (select in the calendar)
- Duration: Expected duration of complete project (maximum 36)
- Requested Funding: Estimated total amount of funding needed to conduct the project. Please also indicate the funds requested from the Osteology Foundation as well as other sources of financial support (e.g. institutional funds, industry funds, etc.). Please note that this funding programme does not cover salaries or travel expenses which are not directly related to the conducting of the proposed research project.
- Keywords: Please enter up to 5 most relevant keywords describing the research topic of your project, e.g. tooth extraction, ridge preservation, GTR, cell signalling, TGF

2. Applicant Information

- GCP-training: GCP training (basic or advanced) is mandatory for the Principal Investigator/ Coordinating Investigator.
- Principal Investigator/ Coordinating Investigator: Please indicate the name, academic degree, institutional position and full address and contact details of the main applicant and up to two co-applicants, if involved.
- Sponsor: Indicate the sponsor of the clinical study (Principal Investigator/ Coordinating Investigator)
- Co-Investigators or Local Investigators: Please indicate the name, academic degree, institutional position and e-mail address

3. Study Background/Introduction

- Maximum 1500 characters including spaces
- E.g. what has been done in this field so far? Does this proposal address an important problem? Explain why this study has to be done.

4. Research Question or Hypothesis and Aims of the Project

- Maximum 1500 characters including spaces
- Please include a description of primary and secondary outcomes.

5. Relevance for Clinical Practice

- Maximum 1500 characters including spaces

6. Materials and Methods

- Maximum 2500 characters including spaces
- Including details of the study design, e.g. interventional/observational study, justification of power, inclusion/exclusion criteria, randomisation, data management, etc.

7. Facilities and Expertise:

- Box 1 – Study team
 - Maximum 1000 characters including spaces
 - Describe the expertise and the role of each investigator participating in the clinical study
- Box 2 – Organisation

- Maximum 1000 characters including spaces
- Describe which departments and corresponding clinics involved
- **Box 3 – Infrastructure**
 - Maximum 1000 characters including spaces
 - Describe the resources and facilities that allow to conduct a clinical study at the involved departments and clinics
- **Box 4 – Research expertise**
 - Maximum 1000 characters including spaces
 - Bibliography in the field of the proposed project, published and/or ongoing studies

8. Necessary files (upload only PDF documents)

- GCP training certificate of Principal Investigator/ Coordinating Investigator
- CV of Principal Investigator/ Coordinating Investigator

9. Statement

9. STATEMENT

Please carefully read your given information and double-check it for content, Osteology Foundation purposes and ethical principles.
 This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP or ISO EN 14155 (as far as applicable) as well as all national legal and regulatory requirements.
 Please note that it is not accepted to apply in the name of a third person and that subsequent complete applications have to be signed by the author of the abstract application. By adding your name you accept the Osteology regulations (see application guidelines) regarding the abstract evaluation and funding of research.
 Following data will also be saved:
Tuesday, July 24, 2018 4:28:18 PM

Name (digital Signature):

I have read the Guidelines carefully and accept the regulations of the Osteology Foundation.
 I agree that my personal data entered above and provided with the uploaded files will be saved and used for statistical analyses by the Osteology Foundation

- Please carefully read your given information and double-check it for content, Osteology Foundation purposes and ethical principles.
- Please note that it is not accepted to apply in the name of a third person and that subsequent complete applications have to be signed electronically by the author of the abstract application.
- By adding your name, you accept the Osteology regulations (see application guideline above) regarding the abstract evaluation and funding of Osteology Foundation Large Clinical Grants.

5 Instructions for Completing the online Main Application Form

Please fill in the online main application accurately and completely. Note that to ensure a comparable format for all applications, the space for entering the project information is limited. All information must be provided in English.

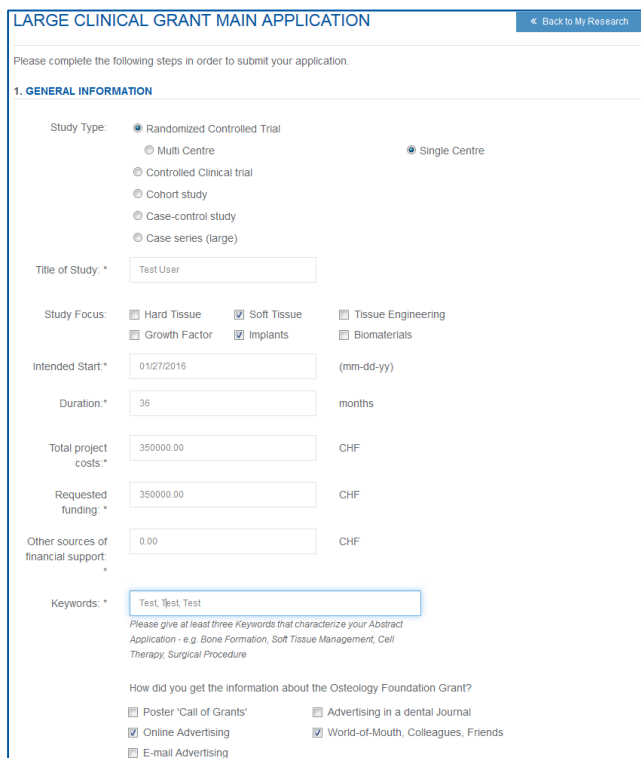
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We recommend to first erase the background formatting of MS Word (e.g. with an additional coping step into a text editor).

When coping the text from the editor into the Osteology online application tool only the plain text is copied. Afterwards you can use the basic rich text formatting of the online application tool.

The following sections describe the information that is requested for the main application phase and needs to be filled in the online application tool or uploaded as additional files (in total - eleven steps).

1. General Information



LARGE CLINICAL GRANT MAIN APPLICATION [← Back to My Research](#)

Please complete the following steps in order to submit your application.

1. GENERAL INFORMATION

Study Type: Randomized Controlled Trial
 Multi Centre Single Centre
 Controlled Clinical trial
 Cohort study
 Case-control study
 Case series (large)

Title of Study: *

Study Focus: Hard Tissue Soft Tissue Tissue Engineering
 Growth Factor Implants Biomaterials

Intended Start: * (mm-dd-yy)

Duration: * months

Total project costs: * CHF

Requested funding: * CHF

Other sources of financial support: * CHF

Keywords: *

Please give at least three Keywords that characterize your Abstract Application - e.g. Bone Formation, Soft Tissue Management, Cell Therapy, Surgical Procedure

How did you get the information about the Osteology Foundation Grant?

Poster 'Call of Grants' Advertising in a dental Journal
 Online Advertising World-of-Mouth, Colleagues, Friends
 E-mail Advertising

- The information from your abstract application will automatically be imported into this file – please check correctness of the information
- Study Type: Indicate here the type of your trial or study
- Title: Please limit the title of your study to fewer than 150 characters.
- Start: Estimated start of practical work (select in the calendar)

- Duration: Expected duration of complete project (maximum 36)
- Requested Funding: Estimated total amount of funding needed to conduct the project. Please also indicate the funds requested from the Osteology Foundation as well as other sources of financial support (e.g. institutional funds, industry funds, etc.). Please note that this funding programme does not cover salaries or travel expenses which are not directly related to the conducting of the proposed research project.
- Keywords: Please enter up to 5 most relevant keywords describing the research topic of your project, e.g. tooth extraction, ridge preservation, GTR, cell signalling, TGF

2. Project Summary / Abstract

- Maximum 1500 characters including spaces
- The summary should characterize the application.
- Describe in a few sentences the background, the clinical relevance, your hypothesis and aims, the questions asked and the methodology used to answer your questions in the proposed project.

3. Applicant Information

- Principal Investigator/ Coordinating Investigator: Please indicate the name, academic degree, institutional position, full address and further relevant contact details of the lead applicant
- Sponsor: Indicate the sponsor of the clinical study (Principal Investigator/ Coordinating Investigator)
- Co-Investigators or Local Investigators: Please indicate the name, academic degree, institutional position and e-mail address
- Principal Investigator's/ Coordinating Investigator's institution: Please indicate the full address and further relevant contact details

4. Literature

- List the 10 publications which are most relevant to the project and list the most important publications by the lead applicant and the co-applicants in the last 5 years (maximum 5 each)
- Format: authors, title, journal, publication date, issue, page

5. Study Administrative Structure

- Please enter all relevant names of the investigators and technicians who are involved in the project and responsible for the listed aspects of the study. If a position is not applicable enter n.a. instead of the name
- If work is not done in the primary institutions, please add the names and city of the external institution or company.

6. Time Line/Project Plan

- As far as the project can be foreseen a project plan should be indicated
- Please enter the proposed duration and time period (e.g. Sep 2020 – Aug 2023) of the complete project
- Note that the total duration of the project should not exceed 36 months

- Project plan: List the key activities of the research project (e.g. healing phase or histological analysis) and the realistically estimated time period needed for the completion of each activity (e.g. month 03 – 09)
- It is important to show clearly how the work is planned time-wise.
- The proposed timeline will be the basis for the annual report that has to be prepared until the Osteology Foundation receives a final report or the project was published in a peer reviewed journal.

7. Financial Aspects

- Total costs: Total amount needed for the completion of the study, including budget items which are not fundable by the Osteology Foundation or funds provided by other agencies or companies.
- Requested amount: Total amount requested from the Osteology Foundation. The requested amount should be in accordance with the budget plan (see also 8.) below
- Other sources of financial support: If any other funding has been granted for this study by any other funding agency or company, the source and amount must be declared to the Osteology Foundation. In addition, a contract with provider of leveraging funds needs to be submitted in the Main Application phase (see 10. Necessary Files).

8. Budget Plan Outline

- Provide within your detailed study protocol (needs to be uploaded in 10. Necessary Files) a detailed budget plan and budget justification to allow reviewers to estimate the realistic costs of the research project
- Provide a 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, ...)
- Only include items which are not already funded by other agencies and which are fundable by the Osteology Foundation
- Note that all amounts are in Swiss Francs (CHF)
- **Personnel:** Academic salaries of the investigators included in the project can be funded by the Osteology Foundation
- Technical staff can be funded when a clear budget justification is provided
- **Equipment:** New equipment or extensions to existing equipment which are necessary for the conduct of the project
- Basic laboratory equipment (e.g. microscope, cell culture incubator) is assumed to be available at the lab and is therefore excluded from funding
- **Supplies:** Itemize supplies in separate categories (e.g. cell culture material, antibodies, general laboratory supplies, histology material, augmentation materials, implants, radioisotopes ...)
- Categories in amounts less than CHF 1000 do not need to be listed
- **Travel expenses:** Only expenses directly related to the project are covered (e.g. investigator meeting, travelling to external research sites)
- **Clinical studies:** Recruitment costs, patient care costs, medication, fees for ethic committee or notified bodies, etc.
- **Institutional overhead costs:** Overhead contributions are only made up to a maximum of 10% of the total project costs. As a prerequisite for funding of overhead costs, the

investigator must submit a copy of the official overhead regulations with the main application.

- **Publication costs:** Publication costs for open-access publication (mandatory)
- **Other expenses:** Any project-related costs which do not fall into any of the above categories.

9. Requirements for Osteology Research Grant Applications

- The research projects must serve the purpose of the Osteology Foundation and fulfil all of the requirements

10. Necessary Files

- All documents must be provided as PDF, see also screenshot of the upload page below.
- For the completion of the application following information and documents must be provided in electronic form at the end of the online application form:

1. **Study Protocol** - we suggest to include the following content and to keep the suggested sequence of the requested information:

Detailed study proposal (**max. 12 pages** including tables and figures, A4, with numbered pages, line spacing 1.2, Font: Times New Roman, Font Size: 12, Margins: 2.5 cm (left, right, top), 2 cm (bottom)). The project description has to **include a detailed budget and a budget justification of all items listed.**

- 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 by the Osteology Foundation 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 secondary 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
 - Describe 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
 - Funding
 - Other Support
- References
 - List all relevant literature related to project proposal (max. 30)
- Appendices (if applicable can also be uploaded as extra PDF)
 - CRF
 - Specific protocols (e.g. for radiology, MRI, etc.)
 - CE approval if a new product is part of the clinical trial

3. CVs of the project participants

- Lead applicant (Principle or Coordinating Investigator) and
- Co-Investigators (when these are already known) **max. 2 pages** per investigator
- More CVs can be added by clicking on the + sign

4. Ethics application or approval

- Copy of the IRB application or approval, if already available, and the trial registry number (ClinicalTrials.gov Identifier) needs to be submitted.

- This information is not mandatory when submitting the detailed main application (see also page 4) but needs to be submitted with six months after funding notification.

5. Overhead regulation

- If the budget includes overhead costs payable to the university, a copy of the official regulations (only an excerpt with the most relevant information, **maximum of 2 pages**) stating the amount of requested overhead fees.

6. CRF

- A copy of the case report form used for this study

7. Other sources of financial support

- A copy of contract with provider of leveraging funds

8. Other

- Here the applicant can upload all other documents supporting this project
- More documents can be added by clicking on the + sign

11. Declaration

11. DECLARATION

I certify that the information provided herein is complete and accurate. I will inform the Osteology Foundation if I request support from any other organisation, or if additional support is granted. I declare that the research project proposed will be conducted with the consent of the head of the research institution and that he / she agrees that the entire infrastructure of the institution shall be made available to all project participants. The research institution fulfills every prerequisite (infrastructure, know-how, staff) for the successful conducting of the proposed research project.

Please carefully read your given information and double-check it for content. Note that it is not accepted to apply in the name of a third person and that subsequent complete applications have to be signed by the author of the abstract application. By adding the date and name you accept the Osteology regulations regarding the abstract evaluation and funding of research. The following data will also be saved: **4:45 PM, Tuesday, July 24, 2018**

Name (digital Signature)

I have read the Guidelines carefully and accept the regulations of the Osteology Foundation.

I agree that my personal data entered above and provided with the uploaded files will be saved and used for statistical analyses by the Osteology Foundation

- Please carefully read your given information and double-check it for content, Osteology Foundation purposes and ethical principles.
- Please note that it is not accepted to apply in the name of a third person and that subsequent complete applications have to be signed electronically by the lead applicant
- By adding your name, you accept the Osteology regulations (see application guideline above) regarding the main evaluation and funding of Osteology Foundation Large Clinical Grants.