

AO CMF: Guidelines for research grant applications.

1st Consortium call on the topic:

'Translational approaches for bone constructs: their impact on facial bone reconstruction'

Applications failing to conform to the website application format or ignore or fail to comply with any part of the guidelines will be considered administratively unresponsive to grant guidelines and may be returned to the applicant. They will not be considered unless resubmitted by the deadline.

General information The AO CMF Research and Development (AO CMF R&D) Commission is pleased to announce a first call for consortia in the field of 'Translational approaches for bone constructs: their impact on facial bone reconstruction'. The application is a two-step process.

Background

This call is to solicit applications to develop constructs for translational bone repair approaches. Short-term preclinical research should focus on cell growth, cell carriers, scaffolds and other biomaterials, growth factors that enhance bone growth in experimental settings, development of 3D printable osteogenic or osteoconductive constructs, or assessing relevant bio-physiological aspects for cell maintenance in biomaterial, e.g. vascular components, stem cell properties, mechanics, magnets/ easy electricity, and bioreactors. The results should be applicable for future clinical studies.

The mid-term aim is to start bone defect repair studies using bone substitute biomaterials. Targets are maxillofacial defect repair using bone regeneration technology with scaffolds and/ or CAD – CAM reconstruction (plates and scaffolds). The research topic needs to be translational.

The long-term goal is the intraoperative reconstruction of facial bone defects using 3D printable bone substitute material. Relevant applications will identify research areas such as cell preparation techniques (including regulatory aspects), intraoperative reconstruction methods, TERM (Including ATMP aspects), custom-made scaffold printing and customized (tissue engineered) free flaps.

A further important program goal is to promote collaboration among basic scientists, clinical scientists, and clinicians. Interdisciplinary teams will be viewed favorably. The aim is not to fund several individual projects with little relevance to one another, but rather to support a program consisting of numerous projects where the whole is greater than the sum of the parts.

Interested scientists are invited to submit a pre-proposal outlining the proposed program (stage 1). These proposals will be reviewed, and

successful applicants will be asked to submit a full and detailed proposal (stage 2).

Research questions The use of bone tissue engineering for facial bone defect repair to enhance the clinical outcomes of orthopedic, oral and maxillofacial procedures is not well established. Despite clear development of CAD-CAM technology in medicine and regenerative medicine in surgery, modern facial reconstructive surgery will not be possible without focused high quality, multispecialty research on translational and clinical levels.

For example:

- What are optimal materials and/or bone substitute materials for additive manufacturing (CAD—CAM) for scaffolds, matrices and implants?
- What are the critical stages in CAD-CAM process in medicine?
- Are cells necessary in implantable bone substitute material?
- What are the relevant stages in bone defect repair and direct (digital) manufacturing technologies in clinical settings?

Focus The focus of the research projects includes repairing bone defects using bone substitutes, digital design technology, and additive manufacturing processes.

The proposed projects:

- Should focus on translational research
- Can be related to bone tissue biology/tissue engineering, implant development, documentation, diagnosis and treatment
- Should improve educational content for courses that address reconstructive surgery and tissue engineering
- The final aim of a project should be to have a bone product that is tested in an animal model

Type of research This open call is suitable for translational research.

Consortium-based project The aim of the consortium approach is to maximize the output of the AO CMF research funds, while aligning all AO CMF projects with the AO Foundations strategic goals. Consortia that emphasize interaction and knowledge exchange will be looked upon favorably. To better align with AO Foundation goals, consortia that include the AO Research Institute Davos (ARI) as a partner are encouraged.

Peer review All applications will be independently peer reviewed. Reviewers will score the consortium summary, plus individual projects based on expertise. consortia will be selected based on the novelty, feasibility, significance of the proposal, attributes of the candidates, evidence of institutional commitment, and the research environment.

Details of grants We invite grant applications for this call to be funded in 2021.
The purpose of these grants is to encourage investigators by providing funding of up to CHF 1.8 million. (CHF 360K per annum for 5 years) All applications will be evaluated for their financial aspects as well their scientific merit.

The research is expected to start 1st July 2021

ARI Research Fellowship The successful consortium may nominate one trainee CMF surgeon for a 6-12-month research fellowship in the ARI in Davos, Switzerland focusing on Bone regeneration. This fellowship is granted by AO CMF (CHF 3,500 per month) for the duration of the consortium. The purpose of that ARI fellowship is to provide a motivated clinician with on-site research training to gain experience in R&D projects and to foster the collaboration between the consortium and the AO Research Institute.

Application form The application is a two-stage proposal.
Stage one:
A stage one application form signed by all parties should be submitted detailing consortium goal(s), partners, aim, title and abstract of each partner project, collaborative aspects and budget.
The stage one application form will be evaluated by the AO CMF research commission to assess scientific rigor and collaborative elements. Successful applicants will be invited to submit full proposals, and instructions will be provided.

Stage two:
After the stage one review, applicants whose proposals have positive reviews will be invited to submit a full application.

Individual project applications must be submitted in English using the AO CMF application form "Translational approaches for bone constructs: Their impact on facial bone reconstruction": Do not exceed the indicated number of characters and pages. This allows adequate evaluation regarding relevance, quality and cost of the projects. ***In addition, a consortium summary must be submitted using the provided template "AO CMF Summary of the consortium".***

Time Line:
The call for stage one applications is open between 1st August – 24th September 2020.

Applicants with positive reviews will be invited in mid-October to submit a full proposal (stage two) The submission deadline for the complete proposals is **15 January 2021**.

Applications which are incomplete or do not comply with our guidelines will be considered administratively unresponsive and returned.

The following topics must be covered in the application under these headings:

- General Information: at least 3 keywords must be chosen from the provided pdf keyword list
- Abstract describing the consortium, clinical problem and aims
- Outline of the problem
- State of the art in this field
- Past research of the applicants in this field
- Hypothesis, open questions, aims of the project
- Detailed research plan:
 - Study subjects, study design, specimens or materials
 - Work Packages
 - Consortium management, required partner interactions & deliverables
 - Relevance of the project
- Time schedule
- Short table of: Technical deliverables & milestones anticipated
- Relevant literature by the applicant and by other authors

All stage two applications must contain a signed contract from each partner confirming they agree to the application terms and conditions outlined by the AO Foundation

The final proposals will undergo a peer-review scientific evaluation by invited external international experts, again with consideration of the collaborative nature of the consortium. Based on these reviews, the AO CMF Research Commission will select the successful application. The decisions of the Commission are final and binding. The peer-review critiques will be provided for consideration to the awardees of full proposal (all proposals reviewed by AORRC). No critiques will be provided for other applicants.

The application form must be e-mailed as an unprotected Word-document to mirjam.bucher@aocmf.org. Please do not edit any fonts and do not use full text capital letters

Funding policy

Duration

Up to 5 years provided successful progress/milestones are reached

Salaries

Salaries for the principal applicant and co-applicants will not normally be approved.

If the project is only possible with some funding for the applicants, it must be clearly shown that the funding requested is essential, project specific and well documented, and that the individual has no other source of grant or income.

Written and signed confirmation is required with the application from the PI and the head of his/her institution, indicating that no alternative source of income (including salary, stipend or grant) is available. This confirmation must indicate how this/those individual/s are currently employed and paid. Applications which fail to provide this information will be returned to the applicant.

Overhead / indirect costs

This grant will not cover any overhead contributions or indirect costs

Consortium meetings

Successful consortia will meet once a year to disseminate results and consolidate future plans. **Participation in this meeting is mandatory.** All travel-related expenses must be covered by this grant award.

Travel expenses

Only project specific travel expenses will be granted. A maximum amount of CHF 3,000 per year will be covered. This amount includes the yearly expenses for the consortium meeting and one conference. Expenses over CHF 3,000 should be covered separately.

Additional funding

Additional funding from any other source must be disclosed in detail. If other funding is available, it must be made clear how this will affect the overall budget of the project if the AO grant application is successful.

⇒ Use the Excel budget template to calculate your budget and transfer all numbers into the application form. The filled in excel budget template must be submitted with your application.

Conditions of Contract

Prior to applying for stage two of this grant, please ensure with your legal department that the contract provided is acceptable to your institution. The contract template is embedded in this call on our website.

Please note that the contract is not negotiable and a signed letter indicating the agreement with the contract template for each partner must be included at the time of Stage 2 form grant submission.

ARI (AO Research Institute Davos)

ARI will assist the AO CMF R&D Commission by acting as an interface between the consortia and the commission.

Applications that involve the AO Research Institute Davos (ARI) are highly encouraged. Where collaboration is foreseen, **ARI must be contacted at least 4 weeks prior to the stage one submission.**

Animal Model

If an in vivo animal model is used in the planned research work, please describe the model in detail. The description should include: anesthesia protocols, treatment protocols, pain management, surgical techniques, post-operative care, criteria for removal from the study if necessary, and euthanasia protocols.

The AO Foundation is committed to animal welfare and requires AAALAC standards in AO Foundation sponsored external research:

At application, AAALAC Accreditation has to be provided if AAALAC accredited by either providing a copy of the AAALAC accreditation certificate or the certificate from your Federal or local authority, confirming that you meet the standards. If the applicant's animal research unit is not AAALAC accredited, the national accreditation has to be approved by AO VET. In case the applicant's animal research units is not national accredited, the form 'Animal Care Program Description for Non-AAALAC Facilities' has to be submitted. Please note that the above-mentioned documents are requested in English.

Please see:

- a) [AO Foundation Guiding Principles on Human Care and Use of Animals in Research and Education](#)
- b) [Institutional Research Animal Program Review Policy](#)
- c) [Animal Care Program Description for Non-AAALAC Approved Facilities](#)

Publication of outcomes

The investigators may decide on their choice of journal for publication from a funded project. However, all funded researchers are required to submit a publication (e.g. a review paper) to the journal of Craniomaxillofacial Trauma & Reconstruction (CMTR) on the funded project

Medical Devices

The current CPP (Clinical Priority Program) call is not focused on medical device development. The AO Innovation Translation Center (AO ITC) is the product development resource for these types of requests.

https://www.aofoundation.org/what-we-do/innovation-translation#newssearch_o=News%20Date%20Facet,Descending



- Notification** The applicants will receive a confirmation e-mail from AO CMF within a week regarding receipt of the application.
- Decision** Decisions on stage one will be communicated mid October 2020
Funding decisions (stage two) will be communicated latest in May 2021