

# Competitive Grant Program in Bone Research

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An independently-reviewed competitive grant program supported by Amgen to fund innovative research improving quality of osteoporosis care and patient outcomes

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## Introduction

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Amgen is committed to serving the needs of patients facing serious illness and we work to advance this, in part, by supporting externally sponsored research.

Amgen is therefore delighted to announce the launch of the Competitive Grant Program in Bone Research, which will provide an opportunity for investigators from around the world to compete for individual Amgen-funded research grants of up to **150,000 USD** for novel research proposals that seek to **improve quality of osteoporosis care and patient outcomes**.

The selection of research proposals will be performed by an external, Independent Review Committee (IRC) comprising experts in the field. Grants will be awarded based on scientifically sound protocols that can advance science, clinical medicine, and ultimately, patient care.

The program is global in reach and is open to proposals from established and junior investigators.

The deadline for applications is **Friday, June 28th, 2019 (11:59 pm PT)**.

## Eligible Research Criteria

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Carefully review the eligible research criteria below to confirm that your proposal is within scope for the Competitive Grant Program in Bone Research. Proposals that are out of scope for the program will not be reviewed by the IRC or considered for a grant.

Proposals should highlight the novelty of your research idea; the Competitive Grant Program in Bone Research aims to encourage innovation.

### *In Scope Proposals*

The Competitive Grant Program in Bone Research aims to improve quality of osteoporosis care and patient outcomes, related to osteoporosis screening, diagnosis, and adherence to therapy.

Specific predefined areas of research eligible for a Competitive Grant Program in Bone Research award include:

- Longitudinal data describing long-term (5+ years) osteoporosis care relative to the diverse guidelines.
- Effectiveness of post-fracture care programs demonstrated at a regional or global level (e.g., successfully implemented approaches and techniques, cost savings realized).
- Delivery of optimal care for osteoporosis in the primary care setting (e.g., patient/physician dialogue, patient disease education, disease recognition).
- Impact of osteoporosis on patient quality of life, including loss of independence.
- Health system interventions to improve screening rates in high-risk osteoporosis patients.
- Novel tools and approaches beyond bone-density scanning (dual X-ray absorptiometry) to identify high-risk osteoporosis patients.
- Solutions to improve patient adherence to their osteoporosis care regimen (e.g., ways to recognize and correct non-compliance).

### *Out of Scope Proposals*

The following topics are considered out of scope and thus are **not** eligible for the Competitive Grant Program in Bone Research:

- All proposals **not related to osteoporosis and the eligible predefined areas of research** (see In Scope Proposals).
- Any research proposal involving use of **specific osteoporosis medications**.

### **Investigator Eligibility Criteria**

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- Proposals are welcomed from established investigators and junior investigators.
  - Junior investigators should be within 5 years of completion of training (instructors, assistant professors, interns, residents, fellows, healthcare professionals) and should provide a letter of recommendation from their department or laboratory head.

- There can be only one Principal Investigator per proposal. Additional co-investigators may be included.
  - The Principal Investigator will be the primary contact for all correspondence and contracting.
- The Principal Investigator should hold a doctoral degree (e.g., MD, PhD, or PharmD) and an academic or institutional appointment.
- The Principal Investigator must not receive funding from other pharmaceutical companies in respect of the research proposal submitted to the Competitive Grant Program in Bone Research. See Budget Information below for additional details.
- Proposals are welcomed from investigators and institutions from countries around the world.
  - Countries that are currently subject to sanctions by the United States are excluded.

## Proposal Eligibility Criteria

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- Proposals must be submitted in **English**.
- Budgets must be submitted in USD and should not exceed **150,000 USD**, including institutional overheads.
- Research must be conducted in accordance with local regulatory, legal, and ethical guidelines, including posting on a clinical trial registry, if appropriate. Amgen does not assume responsibility for the conduct of the selected research.
- Investigators must adhere to all applicable laws and Amgen [contracting terms](#).
- The proposed research study must begin within 2 months of contract execution.
- The study duration, including any follow-up, should not exceed 2 years.
- Funded research should merit submission as an abstract to a scientific meeting and subsequent publication in a peer-reviewed journal.

## Eligibility Exclusions

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To ensure fairness, proposals must meet all eligibility criteria (i.e., research, investigator, and proposal eligibility criteria, as indicated above) to be considered for a Competitive Grant in Bone Research. Proposals outside these parameters will not be considered.

## Budget Information

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- Budgets must be submitted in USD.
  - Budgets submitted in other currencies will be rejected.
- Total budgets should not exceed **150,000 USD**, including direct costs (e.g., labor and study costs), institutional overhead costs, and any other costs (e.g., additional expenses, such as software fees and travel costs).
- This is a competitive grant program. Each grant is non-renewable and paid as described below. A competitive grant awarded by the IRC cannot later be amended upwards with additional funding.
- Grants will be paid in USD at these milestones:
  - Initial payment will be up to 50% of the total grant.
  - Final payment, upon receipt of study results, will be 50%.
- Grants can be used to pay for direct expenses incurred during the study and for the study, such as laboratory supplies, diagnostic test fees, salary for technical staff, data management, etc. However, grants may not be used to purchase equipment.
- To encourage novelty and to avoid direct overlap, no other government, non-government, or industry-sponsored projects can cover the proposed research submitted to the Competitive Grant Program in Bone Research. Funding from foundations or government agencies is permitted for related research if there is no direct overlap with the submitted proposal.

## Contract Information

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Prior to applying to the Competitive Grant Program in Bone Research, review Amgen's contract requirements, summarized below and more fully described via this [link](#) with your institution's legal group. If awarded a grant, the Principal Investigator/institution will be required to execute a contract consistent with Amgen's key contractual positions. These terms are non-negotiable.

- Amgen confidential information will be held in confidence.

- Principal Investigator is able to receive grant funding in compliance with all applicable laws, including applicable export control and economic sanctions regulations.
- Principal Investigator is not debarred, disqualified, or excluded from any federal reimbursement program in the United States or in other countries.
- Ownership of data arising from the research will be owned by Principal Investigator/institution and Amgen will have right to use such data for any purpose (after first publication by the Principal Investigator).
- Ownership of proprietary rights arising from the research will be owned by Principal Investigator/institution.
- Principal Investigator/institution presently grants Amgen a royalty free, non-exclusive license with a right to sublicense any inventions and discoveries resulting from the research for all purposes, as well as an option for an exclusive license to any such inventions.
- Publication of the research is encouraged, and all publications (manuscript or otherwise) will be submitted to Amgen for review with at least 45 days for manuscript review, and 15 days for other oral or written materials.
- Amgen's support of the research will be acknowledged in all publications.
- Where required based on the research, Principal Investigator will obtain valid informed consent.
- For human studies, Amgen provides no compensation or support for subject injury.
- Principal Investigator/institution indemnifies Amgen for claims arising from the conduct of the research.

## How to Apply

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Applications must be submitted through Amgen's submission portal, which can be accessed from the Competitive Grant Program in Bone Research home page at [AmgenScientificGrants.com/Bone](https://AmgenScientificGrants.com/Bone). Scroll to the 'time to apply' section and click 'submission portal.'

If this is your first time visiting the submission portal, please register. You will receive an email to confirm your registration.

To begin your submission, click on 'start new application.' Choose 'Bone' from the drop down menu and then complete all requested fields with your contact details and proposal information

and upload all required documents (e.g., curriculum vitae [CV] and research protocol) to create your submission. You may save your submission in draft form by clicking on 'save as draft.' You can return to your application by clicking on the application from the user dashboard when you log back into the submission portal.

Once you have finished your application, you **must** click 'submit' in order to submit your application. You will see confirmation of submission on the user dashboard. If you do not click 'submit' by the deadline of **Friday, June 28th, 2019 at 11:59 pm PT**, the application will remain as a saved draft and will not be forwarded to the IRC for review.

## Important Dates

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- **Proposal submission deadline:** Friday, June 28th, 2019 at 11:59 pm PT.
  - Proposals submitted after the deadline will not be reviewed by the IRC or considered for a grant.
- **Notification of IRC decisions:** By September, 2019.
  - IRC decisions are final. Feedback from the IRC may be provided with decision notifications but no further correspondence will be entered into.

## Independent Review Committee

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An IRC composed of external, internationally-renowned experts in the fields of bone mineral disease and osteoporosis care will be responsible for reviewing all eligible proposals and selecting final funded proposals.

## Review Process

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- Proposals will be pre-screened for eligibility.

- Each eligible proposal will be reviewed by at least 2 members of the IRC, including the Chair, for its potential to improve quality of osteoporosis care and patient outcomes, novelty and innovation, scientific merit, and feasibility (including financial feasibility).
- Shortlisted proposals will be reviewed and discussed by all IRC members and the Chair at a meeting and a consensus will be reached on which proposals should receive funding.
- Final decisions rest with the IRC and the Chair.

## Conflict of Interest

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It is important that all decisions are fair and objective; therefore, IRC members with potential conflicts of interest for any proposal will not participate in the review or scoring of that proposal. The Chair is responsible for resolving any areas of uncertainty regarding potential conflicts of interest. The Chair is subject to the same conflict of interest guidelines as other IRC members.

A potential conflict of interest may arise when IRC members:

- Are from the same academic institution as the applicant.
- Have any past or present interaction(s) with an applicant as part of their duties as an employee at their academic institution.
- Are a personal friend or relative of the applicant.
- Have had long-standing scientific or personal differences with the applicant.
- Are in a position to gain or lose financially from the outcome of the application. *or,*
- For any other reason, feel they cannot provide an objective review of the application.

## Role of Amgen

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The Competitive Grant Program in Bone Research is supported and funded by Amgen.

In addition, Amgen is responsible for hosting the website and liaising with the vendor that manages the logistical and administrative support required to facilitate the application process,

the independent review process, and communication with investigators. Amgen will manage contracting and grant payments.

The IRC will identify the proposals of scientific merit worthy of funding, independently of Amgen.

Amgen will initiate contracting with successful Principal Investigators, which will include collection of additional information and any additional vetting required to comply with relevant laws and regulations.

Please note, any research grant will be contingent on:

- Fair Market Value Assessment.
- Execution by both parties of Amgen's standard research agreement.
- As required by law, Amgen must disclose financial support provided to researchers and their institutions.

## Queries/Contact Us

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Please email the Competitive Grant Program in Bone Research coordinator at [bone@envisionpharmagroup.com](mailto:bone@envisionpharmagroup.com) with any questions. We aim to respond to queries within 2 business days.