

Competitive Grant Program in Migraine Research

An independently-reviewed competitive grant program supported by Amgen to fund innovative research advancing the medical knowledge of migraine

Contents

Introduction	1
Eligible Research Criteria	1
In Scope Proposals	2
Out of Scope Proposals	2
Investigator Eligibility Criteria.....	3
Proposal Eligibility Criteria.....	3
Eligibility Exclusions	4
Budget Information.....	4
How to Apply.....	5
Important Dates	5
Independent Review Committee.....	6
Review Process.....	6
Conflict of Interest	7
Role of Amgen.....	8
Queries/Contact Us	8

Introduction

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.

The Competitive Grant Program in Migraine Research provides an opportunity for early career investigators in the United States to compete for individual Amgen-funded grants of **US\$50,000–150,000** for novel research proposals that seek to **advance the medical knowledge of migraine**.

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 limited to proposals from US-based early career investigators defined as interns, residents, fellows, and healthcare professionals within 5 years of completion of the most recent training/academic program. Early career investigators may not be medical students.

The deadline for applications is **May 31, 2019 (11:59 pm PT)**.

Eligible Research Criteria

Carefully review the eligible research criteria below to confirm that your proposal is within scope for the Competitive Grant Program in Migraine 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 Migraine Research aims to encourage innovation.

In Scope Proposals

The Competitive Grant Program in Migraine Research aims to advance the medical knowledge of migraine in predefined areas of interest.

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

- Non-interventional clinical research with a focus on early diagnosis and treatment, epidemiology, and Patient Reported Outcomes (PRO)/Quality of Life (QOL) measures.
- Biomarkers for diagnosis and prognosis.
- Preclinical research focused on mechanism of disease not including:
 - Calcitonin gene-related peptide (CGRP)
 - Pituitary adenylate cyclase-activating polypeptide (PACAP)

Out of Scope Proposals

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

- All proposals **not related to migraine research** are out of scope.
- Any research proposal involving the use of an **interventional drug treatment for migraine**.

Investigator Eligibility Criteria

- Proposals are limited to those from US-based early career investigators.
 - Early career investigators may be interns, residents, fellows, and healthcare professionals within 5 years of completion of the most recent training/academic program and must provide a letter of recommendation from their department or laboratory head. Early career investigators who completed their training in another related area other than headache (e.g., pain) and are proposing migraine research are eligible to apply. Early career investigators may not be medical students.
- There should be 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 must not have received or plan to receive funding from other pharmaceutical companies in respect of the research proposal submitted to the Competitive Grant Program in Migraine Research. Proposals that have previously been funded or are in the process of being funded by other pharmaceutical companies will be excluded from consideration. See 'Budget Information' below for additional details.
- Proposals are limited to investigators and institutions from within the United States.
- Members of the IRC are not eligible to submit a proposal as a Principal Investigator and may not be a co-investigator.

Proposal Eligibility Criteria

- Proposals must be submitted in **English**.
- Budgets must be submitted in USD and should not exceed **US\$150,000** (including administrative costs to the institution associated with the conduct of the research funded by the grant [i.e., 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.
- Documentation of Institutional Review Board (IRB) review and approval for proposals involving human subjects must be submitted with the Competitive Grant Program application. Proposals without IRB approval will not be reviewed and considered by the IRC.

Prior to conducting research involving human subjects, IRB review and approval are required before the Competitive Grant can be funded.

- If the study includes the use of a copyrighted instrument, permission to use the instrument must be confirmed.
- 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

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

Budget Information

- Budgets must be submitted in USD.
 - Budgets submitted in other currencies will be rejected.
- Total budgets should not exceed **US\$150,000**. Total budget includes direct costs (e.g., labor and study costs), administrative costs to the institution associated with the conduct of the research funded by the grant (i.e., institutional overheads), 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-governmental, or industry-sponsored projects can cover the proposed research submitted to the Competitive Grant Program in Migraine Research. Funding from foundations or government agencies is permitted for related research if there is no direct overlap with the submitted proposal.

How to Apply

Applications must be submitted through Amgen's Scientific Grants submission portal, which can be accessed from the Competitive Grant Program in Migraine Research home page at <https://www.amgenscientificgrants.com/migraine/>. 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 'migraine' 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 then return to your application at a later time 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 May 31, 2019 at 11:59 pm PT, then the application will remain as a saved draft and will not be forwarded to the IRC for review.

Important Dates

- **Proposal submission deadline:** May 31, 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 August 31, 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

An IRC composed of external experts in migraine will be responsible for reviewing all eligible proposals and selecting final funded proposals.

Review Process

- In the first round of review, eligible proposals will be reviewed by at least 2 members of the IRC, including the Chair. Reviewers will assess the potential of the research proposal to advance the medical knowledge of migraine, novelty and innovation, scientific merit, and feasibility (including financial feasibility). Proposals will be scored by the reviewers on these criteria and the highest-ranked proposals will be shortlisted for the second round of review.
- In the second round of review, shortlisted proposals will be further evaluated, reviewed and discussed by all IRC members and the Chair at a meeting. The IRC members and the Chair will select the proposals which will receive funding.
- Final decisions rest with the IRC and the Chair.

Conflict of Interest

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 specific 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 and will not participate in the review of a proposal with a conflict of interest. In the event that the Chair has a conflict of interest, the Chair will assign a deputy to assume the Chair's responsibilities while that proposal is being discussed.

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 that they cannot provide an objective review of the application.

Role of Amgen

The Competitive Grant Program in Migraine 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.

All decisions related to which proposals are selected for funding are made by the IRC and are completely independent 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

Please email the Competitive Grant Program in Migraine Research coordinator at amgen-migraine-competitive-grant-program@amgen.com with any questions related to the Competitive Grant Program in Migraine Research. We aim to respond to queries within 2 business days.