PCSK9 Competitive Grant Program

An independently-reviewed competitive grant program supported by Amgen to fund innovative research advancing the understanding of PCSK9 and atherosclerosis
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>3</td>
</tr>
<tr>
<td>Eligible Research Criteria</td>
<td>4</td>
</tr>
<tr>
<td>In Scope Proposals</td>
<td>4</td>
</tr>
<tr>
<td>Out of Scope Proposals</td>
<td>5</td>
</tr>
<tr>
<td>Investigator Eligibility Criteria</td>
<td>5</td>
</tr>
<tr>
<td>Proposal Eligibility Criteria</td>
<td>6</td>
</tr>
<tr>
<td>Eligibility Exclusions</td>
<td>6</td>
</tr>
<tr>
<td>Budget Information</td>
<td>6</td>
</tr>
<tr>
<td>How to Apply</td>
<td>7</td>
</tr>
<tr>
<td>Important Dates</td>
<td>8</td>
</tr>
<tr>
<td>Independent Review Committee</td>
<td>8</td>
</tr>
<tr>
<td>Review Process</td>
<td>8</td>
</tr>
<tr>
<td>Conflict of Interest</td>
<td>9</td>
</tr>
<tr>
<td>Role of Amgen</td>
<td>9</td>
</tr>
<tr>
<td>Queries/Contact Us</td>
<td>10</td>
</tr>
</tbody>
</table>
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.

Amgen is therefore delighted to announce the launch of the PCSK9 Competitive Grant Program, which will provide an opportunity for investigators from around the world to compete for individual Amgen-funded research grants of up to 200,000 USD for novel research proposals that seek to advance the understanding of PCSK9 and atherosclerosis.

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, May 11th, 2018 (11:59 pm US Pacific Time).
Eligible Research Criteria

Carefully review the eligible research criteria below to confirm that your proposal is within scope for the PCSK9 Competitive Grant Program. 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 PCSK9 Competitive Grant Program aims to encourage innovation.

In Scope Proposals

The PCSK9 Competitive Grant Program aims to advance the science of PCSK9, especially at the junction with atherosclerosis and atherosclerosis-related mechanisms.

Specific scientific areas of research eligible for a PCSK9 Competitive Grant Program award include:

- Interaction between PCSK9 and lipoprotein and remnant particle.
- PCSK9 and non-low-density lipoprotein receptor effects.
- PCSK9 and immune function.
- Effects of PCSK9 on vascular wall biology through genetic, proteomic, and metabolic studies.
- Lipid kinetics and PCSK9 in patients with familial hypercholesterolemia, metabolic syndrome, or diabetes.
- PCSK9 homeostasis.
- PCSK9 and pancreatic β cells.
- PCSK9 and neurocognition.
- Other potential areas of PCSK9 research that are not out of scope.
**Out of Scope Proposals**

The following topics are considered out of scope and thus are **not** eligible for the PCSK9 Competitive Grant Program:

- All proposals **not related to PCSK9** are out of scope.
- Any research proposal involving the use of a **PCSK9 inhibitor**.

**Investigator Eligibility Criteria**

- 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 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 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 PCSK9 Competitive Grant Program. 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

• Proposals must be submitted in English.
• Budgets must be submitted in USD and should not exceed 200,000 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.
• 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

Proposals must meet all eligibility criteria (i.e., research, investigator, and proposal eligibility criteria, as above) to be considered for a PCSK9 Competitive Research Grant. Proposals outside these parameters will not be considered.

Budget Information

• Budgets must be submitted in USD.
  o Budgets submitted in other currencies will be rejected.
• Total budgets should not exceed 200,000 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 PCSK9 Competitive Grant Program. 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 submission portal, which can be accessed from the PCSK9 Competitive Grant Program home page at https://www.amgenscientificgrants.com/pcsk9. 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 PCSK9 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 Friday, May 11th, 2018 at 11:59 pm US Pacific Time then the application will remain as a saved draft and will not be forwarded to the IRC for review.
Important Dates

- **Proposal submission deadline**: Friday, May 11th, 2018 at 11:59 pm US Pacific Time.
  - Proposals submitted after the deadline will not be reviewed by the IRC or considered for a grant.
- **Notification of IRC decisions**: By end of July 2018.
  - 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, internationally-renowned experts in the fields of atherosclerosis, inflammation, lipid metabolism, and cardiovascular disease will be responsible for reviewing all eligible proposals and selecting final funded proposals.

Review Process

- Proposals will be pre-screened for eligibility.
- Eligible proposals will be reviewed by at least 2 members of the IRC, including the Chair, for their potential to advance the understanding of PCSK9 science, 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

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 that they cannot provide an objective review of the application.

Role of Amgen

The PCSK9 Competitive Grant Program 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 PCSK9 Competitive Grant Program coordinator at PCSK9@envisionpharmagroup.com with any questions. We aim to respond to queries within 2 business days.