



## Guidance

### 1 SUBMITTING AN APPLICATION

#### 1.1 Instructions

All applications should be submitted by email to [applications@PathwaysResearchAwards.com](mailto:applications@PathwaysResearchAwards.com)

The following items should be included in the submission email:

- Completed Pathways Research Awards Application Form
- Completed Pathways Research Awards Budget Form
- NIH Biosketch of applicant
- Letter (1 page) of mentor support
- Letter (1 page) from Division Chief or Department Head confirming academic appointment (or postdoctoral fellowship)
- Up to 3 optional supporting documents (in pdf)

Attachments may be sent as individual files or in a zip file.

The [Pathways Research Awards Application Form](#) should be downloaded from the Pathways Research Awards program website.

The [Pathways Research Awards Budget Form](#) should be downloaded from the Pathways Research Awards website.

Please note, you may need to right-click and select “save target as” to download the files.

#### 1.2 Key Dates

##### 1.2.1 Application Deadline

July 31, 2019 (by 11:59 pm Eastern Daylight Time)

##### 1.2.2 Notification of Review Committee Decision

November 2019

##### 1.2.3 Public Announcement of Awardees

Quarter 1, 2020

### 1.2.4 Funding

Grants will be funded after execution of a Research Agreement and receipt of all regulatory or institutional approvals (as applicable).

## 2. SCOPE OF AWARD

### 2.1 Scope of Awards

The program is designed to support clinical and basic research in therapeutic areas that are of interest to Alkermes, focusing on central nervous system disorders. In the future, other therapeutic areas may be considered.

The 2019 areas of scientific interest are:

- **Substance Use Disorders (SUDs)**
  - Research on SUDs treatment, management, and prevention
  - Research on SUDs and its complications in special populations
  - Preclinical, clinical, translational, and epidemiological research related to SUDs
  - Short-term and long-term economic and clinical outcomes using real-world data in SUDs
  
- **Schizophrenia**
  - Research on assessment methods addressing barriers to optimal outcomes for persons with schizophrenia
  - Research on patient-centered outcomes
  - Preclinical and translational research related to pathophysiology of schizophrenia or its treatment
  - Health economic outcomes research related to schizophrenia

Please note that research is not required to include an Alkermes product; however, therapeutic treatment studies using an Alkermes product will require additional review by Alkermes.

It is anticipated that at least 4 individual grants of up to \$100,000 will be awarded for each area of interest. The duration of the grant will be 2 years.

Projects should yield results that merit submission as abstracts to scientific meetings and, subsequently, publication in peer-reviewed journals.

### 2.2 Eligibility

This grant is for investigators who are in the early stages of their career; specifically, they may be the recipient of a career development (K) award or other mentored research grant, but not a funded R01 grant or equivalent at the time of application.

Researchers with an academic position above assistant professor are not eligible.

Pathway Research Awards will be awarded to researchers who have demonstrated a commitment to SUD or schizophrenia research. Eligible applicants must meet the following criteria:

- Have an MD, PhD, or equivalent
- Affiliated with a medical or research center within the United States at the time of application
- Within 5 years of initial academic appointment (e.g., assistant professor) or current postdoctoral fellow
- Research focuses primarily on furthering our knowledge of SUDs or schizophrenia
- Have a research mentor with extensive experience in the field of SUDs or schizophrenia
- Have not received an NIH R01 grant at the time of award
- Able to complete the proposed research within 2 years
- Citizen or permanent resident of the United States or holder of a temporary non-immigrant visa that is valid for the duration of the 2-year grant period.

Applications should show the commitment and ability to follow local and international requirements as applicable (GCP/ICH), including, but not limited to the following: 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 58, 21 CFR Part 312, ICH-E6.

### 2.3 Criteria for Selection

Alkermes fully funds the Pathways Research Awards program. Additionally, Alkermes and its agency partner provide the infrastructure and administrative support required to facilitate the application process and the independent review process, in addition to notifying applicants and distributing Awards. All applications will be formally reviewed by, and only by, an independent Review Committee comprising prominent researchers in the field. The Review Committee has final responsibility for selection of Awardees.

Note: A preliminary review of submissions will be completed by Alkermes in order to ensure that there are no regulatory/legal restrictions on the Applicant and that there are no concerns with the proposed work from a compliance or patient safety perspective.

When the Review Committee evaluates a proposal, they will consider criteria, including but not limited to:

- **Overall impact**
- Candidate
  - Whether applicant is qualified in terms of education, experience, and background to conduct the proposed research
  - Career development plan/career goals
- Mentor
  - Are the qualifications of the mentor in the area of the proposed research appropriate to the development of independent investigators?
  - Does the mentor adequately address the candidate's potential and his/her strengths and areas needing improvement?
- Environment and institutional commitment to the applicant
- Research plan
  - Is the research proposal scientifically sound?

- The scientific rigor and medical value of the proposed research, including likelihood that it will be completed within specified timelines and outcomes will be published or otherwise publicly presented to the scientific and medical communities

## 2.4 Budget

Total budget should not exceed \$100,000, including direct study-related costs and institutional overhead.

### **Funds may be used for:**

- Personnel necessary to complete the project. This cost may not exceed 50% of the direct cost.
- Funding for hours of work, which are specified in the research project.
- Supplies and consumables necessary to fulfill the research project's aims.
- Travel to a scientific meeting for presentation of data from the project may be included. This may be up to \$1,500.
- Overhead costs.
  - Additional documentation is required for overhead costs greater than 30% for clinical projects and greater than 50% for non-clinical projects.

**Funds may not be used for** any expenses unrelated to the research project, including equipment, office supplies, tuition, fees, dues, subscriptions, and salary or travel expenses related to other projects.

This is a competitive grant program. Each grant is non-renewable and paid as described below. A competitive grant awarded by the Review Committee cannot later be amended upwards with additional funding. Grants will be paid in USD at these milestones:

- Upon successful execution of the contract and receipt of institutional or ethics approvals (as applicable)
- Upon the receipt of an appropriate progress report at 6 months
- Upon the receipt of an appropriate progress report at 12 months
- Upon completion of the research and receipt of a final report or draft publication

Additionally, funding provided through the program may be subject to reporting to the Centers for Medicare and Medicaid Services (CMS) as part of the Sunshine Act. In compliance with the Sunshine Act, Alkermes will report annually on payment and other transfers of value made to covered recipients. A final financial report is due 60 days after the end of the funding period reconciling the proposed budget with the actual expenditure. In the event that unexpended funds remain at the end of the funding period, these funds must be returned to Alkermes program.

**Note:** Grants will be awarded to each grantee's institution. Grants distributed under this program may not have industry funding or duplicate funding from any other source, including government or non-governmental sources. To avoid overlap with a Pathways Research Award, no other government, non-governmental, or industry-sponsored projects may cover the same work scope as that for which funding is requested in the application to the Pathways Research Award program. However, a Pathways Research Awards program grant may be related to other funding from foundations or government agencies, as long as there is no direct overlap. It is the responsibility of the applicant to justify the novelty of the proposal and provide evidence that the application does not overlap with any current or



pending funding. Pathways Research Awards program grants cannot be provided to studies that are already in progress.

### **3. RESEARCH ON ALKERMES PRODUCT**

If Alkermes marketed product is requested and is available, it will be provided at no cost in a sufficient quantity to complete the research project. Alkermes will not provide funding to purchase Alkermes product. Proposals for research utilizing pharmacotherapy will be considered for a Pathways Research Award regardless of the manufacturer of the study agent. Use of Alkermes product is not required.

### **4. PUBLICATION OF RESULTS**

The Pathways Research Awards program encourages investigators to publish results from supported research projects (journal or congress submissions) with acknowledgement: "Funded by a Pathways Research Award, an independent competitive grants program supported by Alkermes." For publications including an Alkermes product, Alkermes reserves the right to review and possibly comment on the publication before submission.

### **5. FURTHER INFORMATION**

If you require clarification of any information, please contact the Pathways Research Awards Program Manager by the email [info@PathwaysResearchAwards.com](mailto:info@PathwaysResearchAwards.com)