

Request for Applications 2019

Why Autism

The Center for Disease Control estimates that 1 in 59 people under 21 living in the United States are on the autism spectrum, making it the fastest growing developmental disorder. For the Eagles owner and CEO, Jeffrey Lurie, it is personal. With autism in his own family, Lurie knows his is just one of many families dealing with this condition and is committed to funding breakthroughs in research and cutting edge programs.

Mission

The Eagles Autism Challenge is dedicated to raising funds for innovative research and programs to help unlock the mystery of autism. By providing the necessary resources to clinicians and scientists at leading institutions, we will be able to assist those currently affected by autism as well as future generations. Our Challenge event aims to inspire and engage the community, so together, we can provide much needed support to make a lasting impact on the field of autism.

Introduction

The Eagles Autism Challenge (EAC) invites investigators in the City of Philadelphia, as defined by the ZipCode Map (enclosed) to apply for support of basic and clinical research of Autism Spectrum Disorders, studying affected individuals and families and/or diverse model systems. This year's funding will support 2-year Pilot Grants and 2-year Postdoctoral Fellowship awards. Each applicant may serve as Principle Investigator of only a single application for competitive review by a panel of field experts.

The EAC is interested in all areas of basic, population, and clinical research and programs that are designed to elucidate the etiology, diagnosis, treatment, and prevention of Autism Spectrum Disorders. The mission of the EAC is to support the highest quality and most impactful autism research that will improve the lives of affected individuals and families now as well as foster the acquisition of knowledge, technologies, and discoveries that will bring new opportunities in the future. While proposed research may build on current ongoing and effective programs, a priority will be given to topics and approaches that are novel, exploratory, and/or innovative. In addition, we are also interested in applications from researchers whose work has been outside the autism field, who see an opportunity to apply new and different approaches and concepts to systems and studies relevant to ASD. Given this broad range of study, applications may vary in the extent of provided published or included preliminary data but the level of experience and evidence of

feasibility must be commensurate with the studies that are proposed, especially those bearing considerable risk.

The EAC supports all areas of basic and clinical research including but not limited to human development and behavior (social interaction, motor and repetitive behaviors, language), cognition and memory, genetics (genomics, transcriptomics, epigenetics, polysome biology), "omic" technologies, biomarkers, outcome measures, pharmacological therapies, behavioral therapies, service delivery, population science, toxicology, neuropathology, immunology, structural and functional brain imaging, neurophysiology, neurobiology, cellular, biochemical, and molecular mechanisms, translational research, stem cell technologies, and model organisms. Within the basic research domain, preference will be given to mechanistic studies over descriptive or correlational approaches.

Awards

EAC will make awards determined by the quality of the submitted proposals and the available financial resources, which this year exceeds \$3.3 million. There will be two (2) types of awards, each of two years duration. Pilot Grants will be at the level of up to \$200,00/yr for 2 years (\$400,000 total). Postdoctoral Fellowships will be support salary at the level of \$45,000/yr for 2 years (\$90,000 total). There will be the option of a one-time No Cost Extension of up to one year for the Pilot Awards. An amount not to exceed 15% of the Pilot Award may be used for the Institution's indirect costs. There will be no indirect cost support for Postdoctoral Fellowships. While the final decision will depend on the number and quality of submissions, it is the intent of the EAC to distribute total research funds as approximately 25% clinical and 75% basic research.

Eligibility

For Pilot Grants, the applicant must have a PhD, MD, or equivalent degree, and have a full-time tenured or tenure-track faculty appointment or equivalent full-time non-tenure track appointment at an accredited academic, medical, or research institution in the City of Philadelphia, though non-residents may serve as collaborating investigators. The research proposals may include resources and personnel from their affiliated organizations and service providers as long as the PI maintains final experimental control and responsible research authority.

For Postdoctoral Fellows, the applicant must have completed their doctoral or medical degree and have been accepted as a Postdoctoral Fellow in a laboratory or program in an academic department of an accredited university or health/medical institution in the City of Philadelphia as of the award start date. The Postdoctoral Mentor must have a PhD, MD, or equivalent degree, and have a full-time tenured or tenure-track faculty appointment or equivalent full-time non-tenure track appointment at an accredited academic, medical, or research institution. The Postdoctoral Mentor must be an active investigator with a productive research program in some aspect relevant to autism. A Postdoctoral Mentor may sponsor only a single applicant, and may not submit in parallel a Pilot Grant application.

Instructions for Submission

Investigators applying for either the Pilot Grant or the Postdoctoral Fellowship will submit a Letter of Intent (LOI) that will serve as the basis for subsequent selection of applicants to submit a full application. The LOI will be due by July 3, 2019, and the EAC will make application

invitations by July 22, 2019. The LOI will also serve the EAC in constituting the Scientific Advisory Board. The LOI document will not be included in the review process of the full proposal.

Text Requirements

Proposals will be written in Arial font size 11 or greater, on pages with margins of 0.5 inches or greater, with single-spaced text. The PI name should appear in the header of each page. Figure and Table legends may be of smaller font size. Use of smaller or more difficult to read fonts will result in the application being returned without review.

Deadlines and Projected Schedule

Release of RFA: June 4, 2019 Letter of Intent (LOI): July 3, 2019

Notification of full proposal invitation: July 22, 2019 Full Application Submission due date: September 16, 2019

Projected Proposal Review: November, 2018 Projected Notification of Award: December, 2019 Projected Grant Award Funding: January, 2020

Letter of Intent (LOI)

The LOI will be limited to two (2) pages including any figures, tables, and references and should include:

Proposal Title/Type of Proposal: Pilot Grant or Postdoctoral Fellowship Names, titles, affiliations, and contacts of PI and key collaborators Research Project description that includes the scientific question/premise and its significance/relevance, specific aims, experimental approach and preliminary results as appropriate, expected outcomes and timeline, and potential impact on current individuals or future opportunities. The brevity of the LOI precludes significant referencing.

It should be noted that the LOI will not be used in the review process for invited full proposal submissions. Invited proposals in turn should be consistent with the original LOI.

The LOI should be submitted to the Executive Director of EAC as a single PDF via email to the following address: rhammond@eagles.nfl.com by midnight July 3, 2019. The PI will receive a confirmation email within 1-2 business days of its reception.

Proposal Format for Pilot Grant

The Proposals submitted in response to invitation will include these items in the following order:

Cover Page: Title of the Proposal; Type of Proposal: Pilot Grant; Term of the proposal; Name, title, affiliation, and contact of PI; Institution and Department/Unit of the applicant; Name and contact of the Financial Officer and/or Signing Official; whether research is Human or Animal, and whether IRB or IACUC is Approved or Pending.

Abstract: The abstract should be intelligible to a knowledgeable lay person or non-expert and must describe the scientific question/premise and its significance/relevance, specific aims, experimental approach, expected outcomes and timeline, and potential impact on current individuals or future opportunities (Maximum of 500 words).

Resources, Facilities, and Environment: Provide the following information for each major research site, including the PI and affiliated site(s) of Key Personnel. This will describe the intellectual and material resources of the research institution; available equipment and relevant facilities, both on-site and affiliated; shared institutional cores; research and clinical centers; private and federal grant programs that provide complementary support of the proposed research. (Two page limit for each site)

Biographical Sketches of the Principle Investigator, Co-Investigator(s), and Key Personnel. Biosketches of other non-Key Personnel (those whose positions may be temporary or not required for research performance) may also be optionally included. (Standard NIH Biosketch, 5-page limit each).

Current and Pending Research Support of Principle Investigator, Co-Investigator(s), and Key Personnel: Include funding organization; grant title and identification number; role on the grant; total amount and period of support, as well as yearly available direct costs to PI; goals of the research; description of the relationship of the funding to the current proposal which may be a statement of No Overlap, as indicated.

Research Plan: The Research Plan will consist of a one-page Specific Aims plus a Narrative of 7-pages (Eight pages in total). All figures and tables will be included within this page limit, with references not included. While a specific format is not required, the Plan should describe the scientific question/premise and its significance/relevance, specific aims, experimental approach and preliminary results as appropriate, participant characterization (as applicable, describe subject inclusion/exclusion criteria, methods of recruitment, and prior program recruitment success), expected outcomes, pitfalls and alternatives, timeline, and potential impact on current individuals or future opportunities. Research Plans should describe how accepted standards to achieve rigorous, reproducible, and transparent results will be implemented, including well-controlled experimental design, unbiased methods, randomization, blinding, sample size estimation, and statistical analysis of data. As needed, indicate adequate administrative support, regulatory procedures, and data coordination processes. The applicant should also consider the criteria that the reviewers will use to evaluate the proposal, as described below.

References: references should be complete including all authors in correct order, title, year, journal and pages, and citation link when available. (Three page limit)

Budget and Justification: Pilot Grants will be funded at the maximum level of \$200,000/yr x 2yrs in total. Institutional indirect costs may be included in those totals up to a level of 15%. Direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award. Direct costs may be requested for investigator(s) salary (NIH PI Salary Cap will be respected), other research personnel including graduate and postdoctoral fellows, research

materials and supplies, subject costs, facilities/core usage fees, minor equipment (<\$5000.00), consultant costs, publication fees, and travel for one investigator to one scientific meeting. Requests for equipment above \$5000 will require full justification as necessary for the specifically proposed research project and approval by EAC. Funds may not be used for physical construction, furnishing, institutional infrastructure, or tuition support. Budget justification should describe the specific functions of all key personnel, collaborators, consultants, and support staff. Explain and justify all expense categories for each year and present the total budget. (Two page limit)

Human Participants and/or Vertebrate Animals: Using standard formats of NIH grants, provide relevant information to address these regulations. For human participants, describe justification for human involvement; the risk of the proposed research; adequacy of protection against risks; potential benefits to subjects or others; importance of knowledge to be gained; and as indicated, data and safety monitoring. For vertebrates, describe justification for use; species and numbers; sex as biological variable; veterinary care conditions; procedures to minimize discomfort and pain; and methods of euthanasia. Do not use these pages to circumvent page limitations of the research and experimental plan, as all such information is to be wholly contained within the Research Plan as above. Reviewers will be instructed to disregard any such misplaced information in their critical evaluation. NOTE: EAC does not require IRB or IACUC certification at the time of application submission, but grant funding will not begin until appropriate institutional IRB or IACUC certification has been received. (Two page limit)

Letters of Collaboration: Provide a signed letter for each collaborator or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

Data and Resource Sharing Plan: Describe how data and resources generated during this project will be shared with the research community, following standard NIH procedures.

Proposal Format for Postdoctoral Fellowship

The Proposals submitted in response to invitation will include these items in the following order:

Cover Page: Title of the Proposal; Type of Proposal: Postdoctoral Fellowship; Term of the proposal; Name, title, affiliation, and contact of PI; Institution and Department/Unit of the applicant; Name, title, and affiliation of Postdoctoral Mentor; Institution and Department/Unit of the Mentor; Name and contact of the Financial Officer and/or Signing Official; whether research is Human or Animal, and whether IRB or IACUC is Approved or Pending.

Abstract: The abstract should be intelligible to a knowledgeable lay person or non-expert and must describe the scientific question/premise and its significance/relevance, specific aims, experimental approach, expected outcomes and timeline, and potential impact on current individuals or future opportunities (Maximum of 500 words).

Resources, Facilities, and Environment: Provide the following information for each major research site, including the PI and affiliated site(s) of Key Personnel. This will describe the

intellectual and material resources of the research institution; available equipment and relevant facilities, both on-site and affiliated; shared institutional cores; research and clinical centers; private and federal grant programs that provide complementary support of the proposed research. (Two page limit for each site)

Research Plan: The Research Plan will consist of a 4-page document in total with a Specific Aims section of no more than 1-page. All figures and tables will be included within this page limit, with references not included. While a specific format is not required, the Plan should describe the scientific question/premise and its significance/relevance, specific aims, experimental approach and preliminary results as appropriate, participant characterization (as applicable, describe subject inclusion/exclusion criteria, methods of recruitment, and prior program recruitment success), expected outcomes, pitfalls and alternatives, timeline, and potential impact on current individuals or future opportunities. Research Plans should describe how accepted standards to achieve rigorous, reproducible, and transparent results will be implemented, including well-controlled experimental design, unbiased methods, randomization, blinding, sample size estimation, and statistical analysis of data. As needed, indicate adequate administrative support, regulatory procedures, and data coordination processes. The applicant should also consider the criteria that the reviewers will use to evaluate the proposal, as described below. (Four page limit)

References: references should be complete including all authors in correct order, title, year, journal and pages, and citation link when available. (Three page limit)

Letters of Collaboration: Provide a signed letter for each collaborator or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

Data and Resource Sharing Plan: Describe how data and resources generated during this project will be shared with the research community, following standard NIH procedures.

Postdoctoral Fellow Information:

Personal Career Statement: The applicant should provide a statement of their background, research experience, scientific goals and motivations, and career plans related to neurodevelopmental disorders. Explain how this specific research, training, and mentor will support your growth and development. (One page limit)

Biographical Sketch of the Postdoctoral Fellow, that should include the scores of the GRE and/or MCAT, as well as graduate and/or medical school GPA. (Standard NIH Biosketch, 5-page limit format is acceptable but not required).

Postdoctoral Mentor Information:

Fellow Training Plan and Qualifications: The Postdoctoral Mentor should provide a comprehensive description of the research knowledge, technology, and training that this 2-year fellowship will provide to the applicant, and how it relates to their specific career plans. Discuss the relevance of this research project and approach to understanding the etiology, diagnosis,

treatment, and prevention of Autism Spectrum Disorders, and how the mentor's past research has contributed to this field. Please describe past experience with training researchers at all levels that will support the feasibility and value of the proposed fellowship program. Provide an evaluation of the qualifications of the Postdoctoral Fellow for performing this research program, as well as expectations for their future contributions. (Four page limit)

Current and Pending Research Support of Postdoctoral Mentor: Include funding organization; grant title and identification number; role on the grant; total amount and period of support, as well as yearly available direct costs to PI and available to support the Fellow research and salary; goals of the research; description of the relationship of the funding to the current proposal. (One page limit)

Biographical Sketch of the Mentor. (Standard NIH Biosketch, 5-page limit).

Letter of Recommendation: A letter of recommendation from a single individual (not the Mentor) should be sent directly to the EAC Director from the reference's personal email account. This letter will not be shared with the applicant. The reference should describe their relationship with the applicant, and the Fellow's past research experience, training, strengths and challenges, and career goals, and how this Postdoctoral Fellowship will promote their career advancement.

Submission

The LOI should be submitted online through the following link: https://www.eaglesautismchallenge.org/loi/

Projects selected for full proposals will receive separate submission instructions with notification.

Review Criteria for Pilot Grants

The research proposals will be reviewed by an independent peer review panel of autism investigators who have expertise relevant to the proposed research studies. Reviewers will consider the following criteria in evaluating the merit of each application:

Significance: Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion change the concepts, methods, technologies, treatments, services, or interventions that drive this field?

Investigator(s): Are the PIs, collaborators, and other researchers well suited to the project? Do they have appropriate experience and training? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Does the investigative team have complementary and integrated expertise? Are the leadership, governance, and organizational structures appropriate for the project?

Innovation: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation,

or interventions? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? Will the strategy establish feasibility and adequately manage risky aspects? Have the investigators presented adequate plans to address relevant biological variables, such as age and sex, for studies in vertebrate animals, or for human subjects, the inclusion of women, children, minorities, race, and ethnicity?

Environment: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Review Criteria for Postdoctoral Fellowships

In addition to the above five criteria, Reviewers will also evaluate the Mentor's qualifications and expertise in research and training, as well as the quality of the proposed Training Plan to promote development of the Fellow and success of the Research Program.

Notification: Applicants and their institutions will receive email notification from the Executive Director of the Eagles Autism Challenge at the conclusion of the review process. If there are questions about a proposal or additional information needed to make an award, applicants and their institutions will be contacted to provide appropriate supporting materials.

Payment of Awards: The tentative date of award payment will be January, 2020. Year two award payments will be made approximately on year later.

Acknowledgments: Publications resulting from projects supported by the EAC must carry the following acknowledgment: "This work was supported by a grant from the Eagles Autism Challenge (Grant Number, Awardee Initials)." The support of the Eagles Autism Challenge should be acknowledged by the grantee and by the institution in all public communications of the supported research including scientific abstracts, posters, press releases, or other media and internet avenues.

Annual and Final Progress Reports: An Annual Progress Report for each year of the grant (research and financial; see Guidelines for format) will be submitted by the end of each year of funding. A Final Progress Report will be submitted within 2 months of the grant termination. The second year of funding may be at risk should substantial progress be lacking at the one-year evaluation.

