

New Investigator Award Policies

At the core of FAST's mission is a commitment to supporting individuals living with AS and their caregivers, with the ultimate goal of helping them realize their full potential and bring scientific and therapeutic advancements that help to translate to the human condition.

FAST is committed to bringing practical treatments for Angelman syndrome (AS) into current medical practice as quickly as possible. While our priority is on funding translational and clinical research, we also support high-risk/high-reward discovery projects. FAST's research program awards grants to the world's best scientists who are focused on discovering and developing treatments, technologies and ultimately a cure benefiting those with AS. The focus of FAST-funded research is in supporting projects that have the potential for immediate and high impact on the Angelman community; therefore, priority will be given to research-based translational grants or those showing high promise for translating basic biomedical knowledge into clinical application.

New Investigator Awards

FAST is dedicated to broadening its network of researchers in the Angelman syndrome (AS) field and providing assistance to exceptional scientists who are eager to explore and study AS. These awards will be granted to promising new scientists seeking to establish a significant research program focusing on translational research in Angelman syndrome, or on technologies specifically relevant to advancing Angelman syndrome treatment modalities. The Applicants for New Investigator Awards should be new Primary Investigators, within their first five years of an academic position at an institution/university.

New Investigator Awards are either one- or two-year grants, made in one-year allocations, with a maximum recommended funding of \$150,000 per year. This award is not intended for those entering industry. Eligible Applicants should have either accepted an offer or already been appointed to an academic position at a university/institution, and have a history of research in a relevant field consistent with FAST's goals. Recipients of this funding are expected to generate data that can be utilized for future grants and publications. Furthermore, it is anticipated that Awardees will attend and present their findings at the annual FAST Science Summit.

Letter of Intent



Applicants are encouraged to submit a Letter of Intent (LOI) to FAST at <u>science@cureangelman.org</u> to determine the feasibility of a potential request prior to applying. LOI's must be submitted as one PDF file containing the following information:

- 1. A brief description of the project including objectives and rationale;
- 2. An estimate of proposed budget and duration of the project;
- 3. Preliminary data to support the project; and
- 4. A biosketch.

The entire LOI (minus the CV) should be no more than 3 pages.

Key Dates

All grant applications have a rolling deadline. Please contact: <u>science@cureangelman.org</u> for more information.

Eligibility

The applicants for the New Investigator Awards should be new Primary Investigators, within their first five years of an academic position at an institution/university. Institutions receiving grants are generally recognized as nonprofit organizations. In the US, this means institutions that do not operate to make a profit. In rare circumstances funding is given to contract research organizations or industry scientific teams. Individuals should have training and experience at least equal to the Ph.D. or M.D. level.

Duration of Support

New Investigator Awards are allocated based on the proposed needs of the project. Expedited timelines are encouraged, which will be made in either one- or two-year allocations, pending on the scope of work. Either one or two year grants have a maximum recommended funding of \$150,000 per year. In exceptional circumstances where larger grant amounts are needed, Applicants may submit an inquiry, along with a letter of intent, to <u>science@cureangelman.org</u>. This letter should provide a justification for the increased funding requirement.

FAST Reporting Policy

Progress updates will occur on a quarterly (3-month, 6-month, 9-month, 11-month) basis from the project start date for each awarded year. For the first (3-month) and third (9-month) quarters of an awarded project, semi-formal updates may be delivered via email or video calls. These updates will include the provision of interim data and preliminary results.



Bi-yearly (6-month) progress updates will be conducted via video call with the FAST Scientific Panel and will include all updates relevant to the research project's objectives. The Bi-Yearly Progress Report Form can be utilized for these progress updates. The Principal Investigator (PI) will be required to submit the written report and financial report to FAST due at 6-months from the project start date. A formal, year-end progress update will be conducted in a similar fashion to the bi-yearly report and include a formal written and financial report due 11 (eleven) months from the project start date. The Year-End Progress Report should focus on progress made toward meeting the milestones outlined in the grant and include any no-cost extension, carry forward, or grant renewal requests. Year-end reports are due 11-months from the project date to account for any no-cost extension, carry forward, grant renewal, or amendment requests that require additional processing time.

Once a grant is completed, a final report must be submitted within 60-days following the project termination date and should include all information requested in the Final Report template, as well as a detailed accounting of the funds awarded. Upon submission of the written and financial report, a meeting will be scheduled with the FAST Scientific Panel to review all progress made throughout the duration of the award.

Allowable Costs

Potential allowable costs include:

- **Reagents and Materials**: These may include but are not limited to: gene chips, chemical libraries, acquisition of cell lines, acquisition of animal model lines.
- **Services**: These may include, but are not limited to: deep sequencing, proteomics, metabolomics, mass spectrometry, antibody production, and drug/chemical manufacturing.
- **Equipment**: FAST will consider the purchase of specialized pieces of equipment or software purchases for specific purchases for specific projects when necessary.
- **Personnel**: Including salary and fringe benefits. Additionally, FAST will fund postdoctoral and graduate students at a salary no higher than the current NIH guidelines.
- Indirect Costs: FAST allows up to 5% indirect cost rate to the budget's modified total direct costs (less those costs specifically excluded) to be included in the total cost of the project. FAST will not pay any indirects on tuition, equipment, software or software licenses. Example: modified total direct costs of \$100, 5% indirects would be \$5; total cost of project is \$105.
- **Travel Costs**: Each award will include a \$3,000 travel stipend to allow for the PI and one trainee, when applicable, to travel to the annual FAST scientific



symposium, where they may be required to present their current research progress.

Application and Submission Information

Write the Research Plan: Applicants should download the grant application form and prepare a Research Plan utilizing the following outline format:

Abstract: A succinct description of the proposed work that includes the project's broad, long-term objectives and specific aims, and a description of the research design and methods.

Lay Summary: This should include your research objectives and your preliminary work that can be easily interpreted by a lay person. The focus should be on the translational component of your research objectives (1-page maximum). We are committed to educating the public about the importance of this research and this will be posted on the FAST website if the project is funded.

Budget Justification: One page budget with justification is required.

Other Support: List all active and pending support to ensure there is no scientific, budgetary, or commitment overlap.

Facilities and Resources: This section should include any organizational resources available to perform the proposed studies. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work.

Budget: Applicants must use the budget sheet provided in application materials. If the proposal is multi-year, Applicants must use separate budget sheets per year, fill in the start and end date and applicable amounts for each year of support separately, summing for total amount requested.

Hypotheses and Specific Aims: Include specific research questions, objectives and hypotheses. The focus of the applications should be aligned with the FAST mission.

Background and Significance: Provide rationale for the research with emphasis on what is needed and why this project would benefit a translational therapeutic research program for Angelman syndrome.



Preliminary Studies: Include any preliminary data you have gathered which supports the specific research question(s).

Research Design and Methods: Include study design, methods, and expected results.

Limitations and Potential Pitfalls: Discuss potential difficulties and/or limitations in achieving aims and alternative approaches to achieving aims.

Milestone Timeline: A research timeline will be provided with milestone goals to be reached during the funding period. These milestones will measure progress made throughout the award period and help determine Year 2 funding if applicable.

Biosketch: The biosketch of the PI and any collaborative personnel for the project.

Formatting

Formatting guidelines for a FAST grant submission include:

- Proposal in Arial or Times New Roman size 11 point font, single or 1.15 spacing;
- Margins no less than 0.5";
- Include a header on each page indicating name of PI (Last, First), page number;
- Figures and figure legends included within the 5 page limit; and
- Only PDF files accepted for review.

Submit Application Materials

Applications must be submitted electronically to sciencegrants@cureangelman.org. Only PDF files will be accepted and reviewed. Applications will be accepted on a rolling basis. Any questions about the application process should be directed to sciencegrants@cureangelman.org.

Similar or Identical Applications

FAST will not consider grant applications with essentially the same research focus from the same applicant organization. This includes derivative or multiple applications that aim to create a single product, process, or service that can be applied to various purposes with minor modifications. Applicants must confirm and ensure that the materials they submit are original and have not been utilized elsewhere in the preparation and submission of a similar grant application. If another grant is approved during the grant review process with any overlap to the submitted grant the Chair of the



SAB should be notified immediately for withdrawal or objective and aim modifications to be made.

Human and Animal Subjects

Human subjects studied in the course of research conducted under a research award are under no circumstances the responsibility of FAST. Human subjects in a program supported by FAST shall be volunteers in any survey, study, or procedure. FAST requires recipients of any award using human subjects to demonstrate institutional review board (IRB) approval of the research project prior to dispersal of the awarded funds. If IRB approval cannot be obtained within 6 months of the award, the award may be rescinded by the Board of Directors.

If animals are used in the proposed study, written certification must be provided to FAST indicating that proper treatment, care, and humane conditions will be provided. FAST requires recipients to receive approval from the Institutional Animal Care and Use Committee (IACUC) prior to starting any animal work on the FAST grant.

FAST Grant Review Process

The first stage of providing fair and expert review for research funding applications submitted to FAST consists of scientific peer review by a group of highly esteemed basic and clinical scientists and clinicians that form our Scientific Advisory Board (SAB). If the topic of the grant is not within the area of expertise of the SAB, consultants will be recruited in a confidential manner to support the review. The panel uses standard guidelines established by the National Institutes of Health (NIH) for scoring applications with an emphasis on innovation, scientific rigor, impact, and relevance to the mission of FAST. All Reviewer conflicts of interest must be revealed prior to the review. All members of the SAB have signed a nondisclosure/confidentiality agreement. If the SAB Chair deems there to be a conflict of interest, the SAB member in conflict will be recused from the review process. Conflicts of interest include, but are not limited to, employment at the same sponsoring institution and collaboration on recent or current research projects, a competing research proposal or area in AS, and anything else that the chair of the SAB determines to be a conflict.

Applications undergo scientific peer-review by the SAB and will receive scores based on scientific merit, innovation, translational impact and alignment with FAST's mission. Applications will also be reviewed based on the experimental design, methods, rationale, budget and feasibility. Applicants should concisely and adequately detail how the hypotheses will be tested, demonstrating adequate power for testing the hypothesis, and clearly define all variables and aims. If SAB critiques have follow-up questions or



recommendations, the Applicant will provide a response to each question and/or recommendation. The SAB recommendations are then reviewed and compiled independently by the Scientific Panel. This panel consists of the Chair of the SAB, the Chief Science Officer and the Science Director. All recommendations for funding are then assessed from each individual, and are shared with the FAST Board of Directors (BOD). Funding recommendations are based on scientific merit (as evaluated by the SAB), budgetary considerations and discussion of relevancy and priority to the mission of FAST. Final approval is required by the FAST BOD before funding may occur.

FAST strives to review and give a funding response to all submitted grants within six weeks of receiving the grant submission. This allows for the grants to be initially reviewed and for any concerns raised by the SAB to be properly addressed by the Applicant before final funding decisions are made.

No-Cost Extensions

A no-cost extension (NCE) extends the project period beyond the original end date of the award. A NCE may extend the allotted project time, but does not allow for additional funding. This extension may be requested if there is a programmatic need to continue the research and there are sufficient funds left to complete the proposed work. A NCE request should be made at least 30-days prior to the end of the project period by the PI. The request should include a FAST Year-End progress report, a financial report detailing to-date grant expenditures and funding available to complete the project, and a formal request letter co-signed by the PI and an authorized signing official from the university/institution. The request letter should also include 1) Detailed amount of remaining funds to be used during the extension period, 2) Initial and amended budget periods of funding, (from initial budget period of 01/01/2021-12/31/2021 to amended period 01/01/2021-12/31/2022), and a 3) Detailed justification for the request. NCEs may be requested for up to 12-months.

Carry Forward Policy

A carryover allows unobligated funds remaining at the end of the budget period to be carried forward to the next budget period. The carryover would allow the grantee to use the unused prior year funds for the following budget period. A carryover request should be made at least 30-days prior to the end of the project period by the PI. The request should include a FAST Year-End Report, a financial report detailing to-date grant expenditures and funding available to complete the project, and a formal request letter co-signed by the PI and an authorized signing official from the university/institution. The request letter should also include 1) Detailed amount of funds to be carried forward, 2) Budget period for which the funding will be carried forward into, and a 3) Detailed



justification for the request. A carryover request will only be allowed for grants longer than one year.

Grant Renewal

Any FAST award extending beyond a one-year project period requires an annual grant renewal to ensure alignment with the initial grant objectives and satisfactory progress. A grant renewal, once approved, will release funding for the upcoming budget period and for the continuation of proposed research. A grant renewal request should be made at least 30-days prior to the end of the project period by the PI. The request should include a FAST Year-End Report, a financial report detailing to-date grant expenditures, and a formal request letter co-signed by the PI and an authorized signing official from the university/institution. The request letter should include 1) Budget request for the upcoming project period, 2) Project period dates for the upcoming year, and a 3) Detailed justification for the request.

Grant Amendment

Any adjustments impacting an award contract require a grant amendment request from the PI. These include, but are not limited to, budget revisions, key personnel changes, and changes in the scope of work. Budget revisions and key personnel changes should be requested by a formal letter co-signed by the PI and an authorized signing official from the university/institution. Changes in the scope of a research project that either require additional work outside of what was originally proposed, key personnel or budget revisions that change project objectives, or supplemental funding will require a brief project proposal. Grant amendment requests may be made at any time during a project period.

Prohibition of Discrimination

No person shall be excluded from participation in or denied the benefits of any program or activity receiving financial assistance from FAST because of race, ethnic origin, religion, age, sex or sexual orientation.

Amendment of Policies

FAST reserves the right to modify its policies governing research awards at any time. The recipient agrees to abide by any changes or to terminate the grant at the time when such changes become effective. Failure to abide by the policies governing awards shall be considered sufficient grounds for cancellation of an award or refusal to consider any pending application by the grantee.