

NEW JERSEY GOVERNOR'S COUNCIL FOR MEDICAL RESEARCH AND TREATMENT OF AUTISM New Jersey Department of Health

Request for Applications (re-posted)

New Jersey Autism Center of Excellence

Funding Opportunity Number: CAUT18ACE

State Fiscal Year 2018

Letter of Intent Due Date: March 6, 2018 Application Due Date: April 10, 2018

Funding

Funding Opportunity Title	New Jersey Autism Center of Excellence
	(NJACE)
Funding Opportunity Number	CAUT18ACE
Due Date for Letter of Intent	March 6, 2018
Due Date for Applications	April 10, 2018
Estimated Annual Award Amount	Up to \$800,000 per year
Project Period	July 1, 2018-June 30, 2023 (five years)
Eligible Applicants	Research Qualified Institutions of higher
	education in the State of New Jersey,
	preferably an academic medical institution,
	public and private non-profit research
	institutions
Notification Date	June 7, 2018
Anticipated Start Date	July 1, 2018

Frequently Asked Questions (FAQs): During the application process, questions may be addressed to <u>NJGCA@doh.nj.gov</u> until April 2, 2018. The answers to questions from applicants will be posted weekly on the Council website at <u>http://www.nj.gov/health/autism/grant/index.shtml</u> under "Grant Opportunities/FAQs". A first set of FAQs is included in Appendix C.

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I. INTRODUCTION

Autism spectrum disorder (ASD) is a group of complex neurodevelopmental disabilities defined by significant impairments in social interaction and communication as well as the presence of unusual or restricted behaviors and interests. These disorders, for which there is presently no cure and only limited treatments, generally have lifelong effects. The Centers for Disease Control and Prevention (CDC) estimates an average of 1 in 68 children in the United States has ASD, as reported in the <u>MMWR Surveillance</u> <u>Summaries, April 1, 2016/ Vol. 65 / No. 3</u>. As part of the same CDC study, the prevalence rate for the New Jersey sites was established at 1 in 41 children, the highest among the sites studied. The prevalence of ASD continues to increase in New Jersey. New Jersey's higher rates can be attributed in part to increased awareness and detection.

The Governor's Council for Medical Research and Treatment of Autism (Council) was created by a State appropriation in 1999 and has been issuing research, clinical and educational enhancement grants since 2000. The mission of the Council is to "advance and disseminate the understanding, treatment, and management of ASD by means of a coordinated program of biomedical research, clinical innovation, and professional training in New Jersey."

As per P.L. 2007, c.174 monies from one-dollar surcharges on fines and penalties from traffic violations are deposited by the State Treasurer into the Autism Medical Research and Treatment Fund to sponsor the Council to fund autism research and treatment in the State of New Jersey. Currently, the Council funds 27 clinical research grants, 4 basic science research grants and 6 autism medical homes grants.

This Request for Applications (RFA), developed by the Council during their strategic planning process, addresses the requirements of its enabling legislation (P.L. 2007, c, 168, the New Jersey Autism Biomedical Research Act) to establish a Center of Excellence for Autism in the state. The statute defines the scope of activities to be undertaken by the Center including, but not limited to: 1) basic and clinical biomedical research, 2) professional training and continuing education programs for healthcare professionals and 3) public awareness, with the understanding that the work carried out at the Center will be comprehensive and collaborative. It is anticipated that the long-term impacts are expected to improve the lives of individuals with ASD across their lifespan.

II. FUNDING PRIORITY

The Council, through the New Jersey Department of Health (NJDOH), will fund a New Jersey Autism Center of Excellence (NJACE). The work carried out at the Center will support the Council's commitment to advance and disseminate the understanding, treatment, and management of ASD by (1) supporting and stimulating basic and clinical ASD research and (2) providing a statewide system of training and continuing education programs for health care professionals to improve the clinical care of children, adolescents and adults with ASD. The Council envisions that the NJACE will complement existing research and training programs, bringing them together, as appropriate, and creating new activities to stimulate cutting-edge ASD research and build a strong education component for the NJACE.

NJACE Goals

The activities of the NJACE will be comprehensive and coordinated to achieve the following three goals:

Goal 1: Strengthen Council funded projects by providing administrative and technical support, sharing best practices, and facilitating discussion of progress, lessons learned and challenges.

- Facilitate regular communication among Council grantees via regular conference calls and shared online resources (e.g. SharePoint site, listserv) to discuss progress, challenges and lessons learned as well as disseminate information such as science advances, funding opportunities, and available training.
- Assist grantees in achieving their scientific goals by provide support such as facilitating the recruitment of participants, the submission of data to National Database for Autism Research (NDAR) and statistical analyses. Grantees requiring technical assistance can self-identify or be identified by external reviewers during the initial application review or the annual progress review required for continuation funding. The NJACE grantee will develop a technical assistance process, including identifying grantees that require additional support to achieve project goals and objectives; provide a roster of experts that can provide both on site and telephone technical support to grantees; and conduct site visits and/or telephone assistance calls as needed.
- Develop key criteria for identifying best practices used by the researchers to achieve the goals and objectives in their projects, and implement a mechanism for sharing these best practices broadly with other researchers, as appropriate. A broad range of approaches could be considered for sharing best practices, from

newsletters and conferences to online discussion boards or a page on a NJACE website.

- Organize annual meetings of the researchers and autism medical homes grantees to: (1) share research approaches and lessons learned, (2) identify potential areas of collaboration or expansion, and (3) address newly identified areas of research and/or emerging issues impacting autism research and treatment.
- Provide administrative and technical support to Council grantees in complying with NJDOH and Council's grant requirements, such as submitting program and/or financial reports to the NJDOH through the System for Administering Grants Electronically (SAGE).

Goal 2: Stimulate cutting-edge ASD research in NJ by promoting awareness of emerging clinical issues and progress in ASD research and treatment.

- Promote ongoing basic and clinical research and medical homes projects to the public and the ASD community.
- Facilitate dialogue between researchers and the ASD community, including patients, families, teachers, and health care practitioners. Foster community engagement by enabling two-way communication between the ASD community in NJ and ASD grantees to improve ongoing and new projects. These activities should inform grantees about community concerns and feasibility of future studies while sharing with the community current research avenues and plans for future studies.
- Stimulate ASD research and collaboration in NJ by organizing two state-wide conferences (over 5 years) featuring national and state leaders in ASD research and treatment. Such conferences would highlight important clinical issues and emerging research areas, attract new researchers to the field, and facilitate collaborations both between researchers and clinicians, and between new and established ASD researchers.

Goal 3: Improve clinical care for individuals with ASD in NJ by strengthening knowledge and training of health care professionals in NJ regarding ASD treatment, diagnosis and prevention.

 Provide professional training programs on treatment, diagnosis and prevention for autism for physicians and other health care and allied health care professionals in the state, including but not limited to Council-funded autism medical homes professionals. The NJACE may identify and implement nationally recognized training programs and/or design programs to meet the specific needs of the target audience(s) (See Appendix A). The NJACE may provide stipends for health care professionals enrolled in training programs.

 Provide information and continuing education programs on autism for physicians and other health care and allied health care professionals who provide care for patients with ASD in the State. For example, the NJACE could sponsor periodic visiting professors, or grand rounds, as a way for a health system to have access to nationally renowned individuals. (See Appendix A).

NJACE Leadership

The NJACE leadership should have previous experience working together, preferably as collaborators on research or other projects. Descriptions of each of the three leadership positions are included in Appendix B; Principal Investigator (PI), Scientific Director (SD) and Clinical Liaison (CL).

The NJACE will designate a nationally recognized autism researcher as the Program Director/ Principal Investigator (PI) whose background demonstrates strong administrative and academic leadership. The PI has overall project responsibility and serves as a liaison to the Council and the Executive Director. The PI must be an employee of the institution awarded the grant. In addition to the PI, the NJACE leadership will include: 1) a Scientific Director (SD) with a strong background in autism research responsible for scientific research development, oversight and assistance, and 2) a Clinical Liaison (CL) responsible for developing and implementing professional training and education programs as well as provide oversight and technical assistance to autism medical homes grantees.

The Scientific Director and Clinical Liaison could be subcontractors from a NJ institution. Both the Program Director/PI and Scientific Director's roles may be performed by the same person; however, the applicant would have to demonstrate that the PI has the extensive skills, experience and time necessary to perform these roles.

If separate teams or departments at a large institution wish to apply for and receive grants under both the NJACE grant program and other Council funded grant programs, there can be overlap of personnel between the NJACE and other Council funded grants; however, no position can be funded for greater than a total of 100%.

III. ELIGIBILITY, FUNDING, SUBMISSION, AND REPORTING REQUIREMENTS

Eligibility

Qualifying Individuals:

Individuals with the skills, knowledge, and resources necessary to carry out the proposed program as the Principal Investigator are invited to work with their organizations to develop an application. Applicants must be affiliated with an academic institution, research organization or public or private non-profit entity, preferably an academic medical institution, located in the State of New Jersey with a demonstrated capability to conduct grant funded research. The Council shall not award grants to unaffiliated individuals. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply. Individuals of any nationality or citizenship status may apply provided they hold employment or affiliate with a qualifying research entity, as described below.

Qualifying Entity:

Public and private non-profit research entities in the State of New Jersey may apply under this program. A qualifying research entity is defined as any academic institution, research organization, public or private non-profit entity, preferably an academic medical institution, located in the State of New Jersey, with a demonstrated capability to conduct and monitor grant funded research. In no case can an individual be a qualifying research entity. The qualified research entity shall have established procedures to receive and administer Federal and State grants, including a Grant Administrative Office (or equivalent) that is responsible for overseeing grant programs, and procedures for the protection of human subjects as regulated by the NIH and an Institutional Review Board (IRB) that will approve proposed research activities.

Proof of Eligibility:

Applicants are required to submit financial documents, in accordance with the NJDOH Cost Controlling Initiatives and Terms and Conditions. Failure to provide required documentation by the date of the application submission shall result in the application being deemed non-responsive. Please attach the requested documents in Word or PDF to your application through the NJDOH System for Administering Grants Electronically (SAGE):

1. Valid Internal Revenue Service (IRS) 501(C) (3) tax exempt status.

2. Statement of total gross revenue and/or annual report (if applicable).

3. Tax Clearance Certificate is to be submitted – Applications for Tax Clearance can be obtained at <u>http://www.state.nj.us/treasury/taxation/busasst.shtml</u>.

Funding Amount

A total of up to \$4,000,000 (up to \$800,000 per year) will be made available for the five years of the program. The award will begin on or about July 1, 2018.

Funding Availability

The award is subject to the availability of funds to the Department. The grantee recognizes and agrees that continuation of funding under a grant is expressly dependent upon the availability of future funds to the Department appropriated by the State legislature from state or federal revenue or such other funding sources as may be applicable. The Department shall not be held liable for any breach of agreement due to absence of available funding appropriation. The Council shall reserve the right not to fund any grant to the maximum amount or not to fund any grant program at all.

Multi-year Award & Progress Report Requirements

Multi-year awards are made through one-year contracts. Each yearly award within the multi-year period will be contingent upon the availability of funds. Support for the continuing years of the grants is contingent upon submission and approval of an annual comprehensive progress report. All progress reports must detail the actions towards meeting the grant requirements. The NJACE will meet the grant requirements or clearly demonstrate how they are moving towards achieving those requirements, as a condition of funding for the following year. The PI shall attend quarterly Council Meetings and report on progress upon request.

Progress reports must be favorably reviewed by a NJDOH Review Panel and be recommended to the Council for continued funding. The Council shall reserve the right to bring in outside reviewers to assess whether progress is adequate and, as may be necessary, design a remediation plan. A final progress report is required within three months of termination of the grant.

Applicants shall adhere to the Council's Code of Ethics which can be found at <u>www.nj.gov/health/autism</u>. In addition, applicants shall adhere to all applicable State and Federal laws and regulations governing the privacy, security and confidentiality of all research and participant's health information. The laws and regulations include, but are not limited to, the Health Insurance Portability and Accountability Act of 1966 (HIPAA) – Privacy and Security Rules and the Patient Safety and Quality Improvement Act of 2005 (PSQIA) – Patient Safety Rule. Lastly, all applicants shall comply with applicable Federal Cost Principles and Scientific Research governing human participants.

Letter of Intent

A Letter of Intent is <u>required</u> and due by March 6, 2018. Although a Letter of Intent is not binding and does not enter the review of a subsequent application, the information that it contains allows the Council staff to estimate the potential review workload and plan the review.

The letter of intent must include the following information:

- 1) Descriptive title of proposed project
- 2) Name, address, email and telephone number of the Principal Investigator
- 3) Participating institutions and organizations
- 4) Title of the funding opportunity CAUT18ACE
- 5) Overview of project (2-3 pages) Goals, aims, activities and evaluation The letter should be sent to <u>NJGCA@doh.nj.gov</u>. If you do not receive an acknowledgement of receipt within 2 business days, please call 609-633-8740.

Proposal Submission and Delivery

To be considered, proposals must be responsive to all the requirements of this RFA. Incomplete grant applications will not be considered and shall be disqualified. All proposals must be submitted via the NJDOH System for Administering Grants Electronically (SAGE) no later than 3:00 PM on April 10, 2018. The online application is expected to be available through SAGE by late February. Refer to "Instructions for Online Grant Applications" under "Grant Opportunities" on the Council's website (www.nj.gov/health/autism). The narrative questions are included in this RFA.

In addition, the Council must receive one hard copy of the application (a signed original) at the Council's office by 3:00 PM on April 13, 2018. No exceptions will be made. Please use the following address for all regular and overnight mail deliveries:

New Jersey Department of Health

New Jersey's Governor's Council for Medical Research and Treatment of Autism 225 East State Street

Second Floor-West

PO Box 360, Trenton, NJ 08608

System for Administering Grants Electronically (SAGE)

The Council will only accept applications submitted electronically through the New Jersey SAGE at <u>www.sage.nj.gov</u>. The Council will not accept grant applications sent by telefacsimile. After an applicant logs on to the SAGE, the applicant's Authorized Official must authorize the PI as an approved user and assign the PI to the grant before the PI can access the application. Before logging on to SAGE, applicants should refer to "Instructions for On-line Grant Applications" under "Grant Opportunities" on the Council's website (<u>www.nj.gov/health/autism</u>). For the grant applications, character

limits for the proposal abstract and proposal narrative are included in SAGE. To ensure equity among applications, character limits cannot be exceeded. Applicants should be cautious while utilizing the cut and paste function of most word processing programs to transfer text into narrative boxes within the SAGE application. The SAGE will not recognize certain formatting, including tables, graphs, photographs, bullets, certain scientific notations and tabs. In addition to completing the text boxes in SAGE, it is strongly recommended to attach the full proposal (abstracts and narrative) as a Word or PDF document with tables, charts and illustrations as a "Miscellaneous Attachment." In many SAGE pages, a "View PDF" button will be available that will automatically create a PDF. These dynamic PDFs can be printed or saved to your computer for reference. It is useful to review the PDF files for accuracy prior to submitting the application electronically.

IV. REQUIRED NARRATIVE AND QUESTIONS

Organization Information

Provide information on your organization's mission, structure, and scope of current research and education activities. For the research activities, include the sources and amount of funding for autism research during the past 5 years and topical areas of research related to autism. For the education activities, include professional training and continuing education programs related to autism or similar conditions, and community engagement. Describe how these contribute to the ability of the organization to support the aims of the NJACE and address the expectation that, over the cumulative 5-year period of the award, the award will result in improving the lives of individuals with ASD across their lifespans. Include an organization chart in "Miscellaneous Attachments." Please attach a letter of support from a president, dean or other authority, as evidence of institutional support, labeled and attached as "Miscellaneous Attachments" in SAGE.

Management

Describe the qualifications of the leadership team including evidence of strong administrative and academic leadership as a nationally recognized autism researcher (Program Director/PI), expertise in the oversight of scientific research projects and development of new collaborations and broad research program (Scientific Director) and expertise in the development and implementation of professional training on treatments, diagnosis and prevention of autism and continuing education programs on the latest advances in research on autism for physicians and other healthcare providers (Clinical liaison). Describe the qualifications of the Clinical Liaison to provide oversight and technical assistance to autism medical homes grantees. Describe the three leaders' previous experience working together, preferably as collaborators on research or other projects. Highlight staff who will be responsible for evaluation of the NJACE program and its specific goals.

If the Program Director/PI will function as both PI and Scientific Director, the applicant would have to demonstrate that the PI has the extensive skills and experience necessary to perform both roles.

<u>Vision</u>

Describe the vision for the NJACE, considering the commonality of goals between existing research and professional training programs and those of the NJACE. The NJACE will complement the strengths of existing programs bringing them together, as appropriate, and creating new activities to build a comprehensive and coordinated statewide system for stimulating cutting edge ASD research and improving clinical care for individuals with ASD. The application should clearly state:

- What the gaps are in existing research and professional education/training
- How to address the gaps by complementing existing activities and creating new activities
- The mechanism/incentive for bringing existing programs together under the NJACE if from other departments/sections of the institution or from other NJ institutions
- Previous working relationships and collaborations with leaders of existing programs who have agreed to participate in the NJACE

Goal 1: Strengthen Council funded projects by providing administrative and technical support, sharing best practices, and facilitating discussion of progress, lessons learned and challenges

- a) What is the plan to communicate with Council grantees to discuss progress, challenges and lessons learned as well as disseminate information such as science advances, funding opportunities, and available training? How will the success of these efforts be measured? Briefly describe prior experience.
- b) Describe the technical assistance process to be developed to assist grantees in achieving their scientific goals. Briefly describe prior experience.
- c) How will support be provided to assist grantees with the recruitment of participants, the submission of data to National Database for Autism Research (NDAR), statistical analyses and other possible issues? Briefly describe prior experience.
- d) How will key criteria for best practices in research be identified? What mechanism(s) will be developed to share these best practices broadly with other researchers, as appropriate? Briefly describe prior experience.

- e) Describe the steps in planning annual meetings of the researchers and autism medical homes grantees to: (1) share research approaches and lessons learned, (2) identify potential areas of collaboration or expansion, and (3) address newly identified areas of research and/or emerging issues impacting autism research and treatment. Briefly describe prior experience.
- f) What is the plan, including staffing, to provide administrative and technical support to Council grantees in complying with NJDOH and Council's grant requirements, such as submitting program and/or financial reports to the NJDOH through the SAGE? Briefly describe prior experience.

Goal 2: Stimulate cutting-edge ASD research in NJ by educating and promoting awareness of emerging clinical issues and progress in ASD research and treatment

- a) Describe plans to promote ongoing basic and clinical research and medical homes projects to the public and the ASD community. How will various audiences be reached? How will the efforts articulate with human subject recruitment? How will success be measured? Briefly describe prior experience.
- b) Describe plans to enable two-way communication between the ASD community in NJ and grantees to improve ongoing and new Council funded projects. How will these programs inform grantees about community concerns and feasibility of future projects? How will the improvements in research, treatment and community awareness be measured? Briefly describe prior experience.
- c) Describe the steps in planning state-wide conferences (2 over 5 years) to highlight important clinical issues and emerging research areas, attract new researchers to the field, and facilitate collaborations both between researchers and clinicians, and between new and established ASD researchers. Briefly describe prior experience.

Goal 3: Improve clinical care for individuals with ASD in NJ by strengthening knowledge and training of health care professionals in NJ regarding ASD treatment, diagnosis and prevention

- a) Describe plans to provide professional training programs on ASD treatments, diagnosis and prevention for physicians and other health care and allied health care professionals in the state. How will specific audiences be targeted? How will the professional training programs reflect the specific needs of the target audiences? How will the Center choose to implement existing programs and/or develop additional programs? Will the NJACE provide stipends for health care professionals enrolled in training programs? How will the success of the trainings be evaluated? Briefly describe prior experience.
- b) Describe plans to provide information and continuing education programs on autism for physicians and other health care and allied health care professionals

who provide care for patients with autism in the State. How will the topics be chosen? How will the information and programs be distributed (webinars, seminars, newsletters etc.)? How will the success of these efforts be measured? Briefly describe prior experience.

c) Distinguish among programs designed to provide basic information (knowledge), positive interactions with persons who have autism (attitudes) and those to increase proficiency in professional interactions (skills). Briefly summarize prior experiences in developing and evaluating professional training and continuing education programs.

Project Work Plan

Incorporate the approaches for Goals 1-3 into a project work plan. Provide a brief description of the work plan. Using a timeline or chart include each activity described in the goals, identify responsible staff and partners, proposed outcomes, intended impact and how the activity's outcome and impact will be evaluated. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities. Attach as a "Miscellaneous Attachment" in SAGE.

Evaluation of the long-term impact of the NJACE

How will improvements in the lives of individuals with ASD be measured over the fiveyear period of the award? Describe the plan for the Center's performance evaluation and provide a detailed logic model as a "Miscellaneous Attachment" in SAGE. The plan should monitor ongoing processes and progress toward the long-term goals of the Center. Include descriptions of the inputs (organizational profile, collaborating partners, key staff, budget and other resources), key processes and expected outputs and outcomes.

Note that the Center is required to draft a questionnaire for its own self-evaluation twice during the first year and every year thereafter. Following approval by the Council's Executive Director, the Center will send these questionnaires to the researchers. The responses from the researchers will be sent to the Council's Executive Director, who will use this data as an adjunct to monitor the NJACE's performance. A summary of the results will be provided to the NJACE to ensure improved performance.

V. APPLICATION REVIEW

All proposals will be reviewed in accordance with the Grant Review Process set forth herein. The determination of grant awards will be made through a two-step review process:

1. Administrative Review (Council office)

Upon receipt, all grant applications will be reviewed by the Council office for compliance with all applicable New Jersey State statutes and regulations, and to ensure completeness and accuracy. In the event a grant application needs correction due to a budgetary issue, the applicant will be contacted to provide a revised budget. In the event the Council office determines that an application does not meet the administrative requirements, the application will be denied, and will not be forwarded for independent scientific merit review.

2. Scientific Merit Review (Independent Scientific Merit Review Panel) Members of the Independent Scientific Merit Review Panel will convene to evaluate the grant applications. The Reviewers will consider and score the applicant's response to each of the narrative questions and the budget justification in the determination of the merit of the NJACE proposal. An overall impact score will be assigned to each application reflecting the likelihood the Center will successfully accomplish the goals of the NJACE.

The results of the review will be forwarded to the Council, through the Executive Director, for final review and action. The Scientific Advisory Committee (SAC) will review the results of the Review Panel and may provide additional advice to the Executive Director and the Council. Grants triaged by either Administrative Review and/or the Independent Scientific Merit Review Panel will not be forwarded to the Council, and will not be funded. The authority to authorize or not authorize grants is fully vested in the Council per New Jersey statute P.L. 2007, c.168 (NJSA C.30:6D-60).

VI. AWARD ADMINISTRATION INFORMATION

Award Notices

All applicants including Principal Investigators and organizations/institutions will be formally notified of the outcome of his/her application after the selection process, anticipated to be no later than June 30, 2018. At that time, formal notification will be made to the institution of the successful applicant and a grant will be initiated shortly thereafter by the Council with a project start date of approximately July 1, 2018. Non-funded applicants also will be notified. There is no appeal process.

Reporting

The NJACE will provide quarterly and annual progress reports to the NJ Department of Health. The Council's Executive Director will attend quarterly Council meetings to report on progress upon request. Twice during the first year and every year thereafter the Center will draft a questionnaire for its own self-evaluation. Following approval by the

Council's Executive Director, the Center will send these questionnaires to the researchers. The responses from the researchers will be sent to the Council's Executive Director, who will use this data as an adjunct to monitor the NJACE's performance. A summary of the results will be provided to the NJACE to ensure improved performance.

VII. APPENDIX

Appendix A: Examples of existing resources for training healthcare providers

The Certified Autism Specialist (CAS) offered by International Board of Credentialing and Continuing Education Standards at <u>http://www.certifiedautismspecialist.com/</u>

The Interdisciplinary Technical Assistance Center (ITAC) on Autism and Developmental Disabilities at <u>http://www.aucd.org/itac/template/index.cfm</u>

The American Academy of Pediatrics home for information and resources on autism at https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/Council-on-Children-with-Disabilities/Pages/Autism.aspx

The Accreditation Council for Graduate Medical Education (ACGME) at https://www.acgme.org

Alliance for Continuing Education in the Health Professions at http://www.acehp.org

The Cleveland Clinic Autism Research Institute at http://www.clevelandclinicmeded.com/online/autism-spectrum-disorders/

The Kennedy Krieger Center for Autism and Related Disorders at <u>https://www.kennedykrieger.org/patient-care/patient-care-centers/center-autism-and-related-disorders</u>

Appendix B: Descriptions of the Leadership Positions

Program Director/Principal Investigator (PI):

The PI is responsible for the management and integrity of the conduct and reporting of the NJACE activities and for managing, monitoring, and ensuring the integrity of any collaborative relationships. The PI's responsibilities are to:

- Implement the vision of the NJACE
- Work collaboratively with Scientific Director and Clinical Liaison, other staff, advisors and collaborators to ensure adequate and timely progress

- Lead the building and nurturing of working practices, collaborations and capacity to produce a level of impact from the NJACE's research commensurate with its overall ambitions
- Develop and oversee the implementation of a knowledge exchange strategy in support of the NJACE's growth for research
- Ensure the integrity of grant activities, promoting ethics, rigor and reproducibility in research and training
- Direct and oversee compliance, financial, personnel, and other related aspects of the project and coordinate with university and NJACE staff to assure research in is conducted in accordance with State and Federal regulations and NJDOH policies and procedures.
- Lead the external promotion of the NJACE's research profile through relevant channels including press and media, in liaison with the Council and the NJ State Communications Office.

Scientific Director (SD):

The SD shall be an experienced ASD researcher with demonstrated skill in research development and leading change, and an excellent ability to interface with project leaders. The SD's key responsibilities are to:

- Provide scientific leadership in developing the ASD research program in NJ
- Build on experience as ASD researcher to develop approaches to address current issues in ASD research in NJ, in collaboration with the PI
- Leverage strong research contacts in and outside of the NJACE into research collaboration opportunities
- Facilitate the development and support of new research programs, including the development of applications for funding
- Strengthen existing research programs
- Promote scientific rigor and good conduct in all research activities, including reference to the Council's and the NJ State policies and procedures in relation to research conduct, ethics and integrity
- Guide investigators on research design in a variety of areas that may include intervention studies, secondary data analysis, collection and analysis of qualitative data, or statistical modeling
- Support grantees in the dissemination of research results through publications, workshops, and presentations at scientific meetings

Clinical Liaison (CL):

The CL shall be a clinician with extensive experience working with people with ASD and providing professional training programs to health care professionals. The CL's main responsibilities are to:

- Develop and implement professional training and continuing education programs for a variety of audiences
- Provide technical assistance to autism medical homes grantees

Appendix C: Frequently Asked Questions

General:

Q. Does involvement in the NJ Autism Center of Excellence (NJACE) preclude receiving or participating in any other Council funded grants?

A. NJACE personnel may receive and/or participate in other Council funded grants.

Q. When will research grants be offered again?

A. We anticipate offering fellowship and clinical research grants in SFY19 with applications available in June 2018.

Q. As a public university of higher education and entity of the State of NJ, we have tax exempt status (other than 501(c)3. Our Foundation also has a 501(c)3 tax exempt status. Is the 501(c)3 status the only non-profit status acceptable for this submission, or can we use our other tax exempt status?

A. Typically when a public institution of higher education applies for a grant they would simply upload a word document stating that they are a public entity of the State of New Jersey instead of the 501(c)3 as the application cannot be submitted without a justification uploaded in this spot.

Staff:

Q. Do NJACE leadership need to be in New Jersey and be employed by the NJ applicant organization or may they have an affiliation with the applicant NJ institution to perform the duties of the NJACE (and be primarily located in a different state/ work for an out-of-state entity)?

A. The Principal Investigator (PI) must be an employee of the NJ institution awarded the grant. The Scientific Director (SD) and Clinical Liaison (CL) could be subcontractors from a NJ institution.

Q. Can there be more than one PI? Can the Scientific Director or Clinical Liaison also be the Co-PI or the Co-I?

A. There can be only one Principal Investigator (PI). The PI is responsible for the execution of the project.

Q. Does the PI have to be employed by the lead institution?

A. Yes, the PI must be employed by the lead institution.

Q. Can sub awardees be for-profit (as opposed to non-profit) entities?

A. Yes, sub-grants can be to for-profit entities.

Q. Can you clarify the difference between your definition of 'Professional Training programs' and 'Continuing Education programs' for physicians and allied health professionals in goal 3 of the RFA?

A. For purposes of this RFA, the difference between professional training programs and continuing education programs depends on the expected outcome(s). Professional training programs are those resulting in increasing proficiency in specific skill(s) upon successful completion of a structured program with goals, objectives and activities. The evaluation of outcome(s) will include measurements of what skills participants learned and what skills they transferred to the job. The NJACE may offer stipends for health care professionals enrolled in the training programs. Continuing education programs are those providing information through a variety of formats resulting in increasing participants' knowledge of topic(s). Although a continuing education program includes learning objectives the evaluation of outcomes is at a more basic level with participants rating content, speaker(s), format etc. and self-evaluation of what they learned and how (or if) they will use the information. Continuing education programs can take many different forms ranging from the NJACE sponsoring visiting professors and grand rounds at institutions throughout the state to lectures, webcasts, webinars, and videoconferencing, as examples.

Q: Are there any guidelines in terms of % effort for the various positions?

A: The RFA does not include specific requirements regarding the percent effort of the leadership and other staff members to allow flexibility in the organization of the team. The final proposal will depend on the specific goals of the program and the capability of the staff members. The specifics of the budget can be revised during the project period based on the evolving needs. The NJACE should have highly-accomplished and nationally known people to perform the three leadership roles. Considering the responsibilities of the Program Director/PI and the Scientific Director, one or both positions could be full time.

Q. Can you provide any guidance or detail on the criteria for the 'nationally recognized autism researcher' that is cited in the RFA?

A. The NJACE Program Director/PI is known at a national level for his/her accomplishments in autism research through publications in peer reviewed journals, invitations to present at national autism conferences and awards/recognition by organizations such as Autism Speaks and other leading ASD organizations. Equally important is the Program Director/PI's background that demonstrates strong administrative and academic leadership.

Q. Can the Clinical Liaison also have the role of PI?

A. The Clinical Liaison cannot serve as the PI. The skills, experience and responsibilities of the Program Director/PI differ significantly from those of the Clinical Liaison. The Clinical Liaison reports to the Program Director/PI.

Budget:

In general, there are no specific budgetary caps or restrictions, except that all requests must be necessary and justified for the grant. The SAGE application contains links to relevant Department of Health (DOH) policies.

Q. Is there a cap on Principal Investigator's (PI) Salary?

A. There are no specific budgetary caps or restrictions regarding the salaries of the leadership and other staff members to allow flexibility in the organization of the team. The specifics of the budget can be revised during the project period based on the evolving needs.

Q. Is there a cap on Travel each year?

A. There is no cap. Travel also must be justified.

Q. Are there restrictions on supplies/equipment such as computers, printers, etc.?

A. Supplies and equipment can be included only if they are necessary for the project. Applicants proposing to purchase equipment which will be used across multiple grants/programs should pro-rate the costs of the equipment across programs and show the calculation of this pro-ration in their justification. If an irregularity is found where equipment is being used by other programs without reimbursement, funding will be reduced accordingly.

Q. Are there restrictions on staff (i.e., administrative staff, students, and postdocs)?

A. Administrative staff that will support the project can be included in the application. Students or postdocs would similarly need to be specifically working on the project.

Note: Upon acceptance of a grant award, the applicant's organization assumes legal and fiscal responsibility for awarded funds and the conduct of supported activities. It is the responsibility of the applicant's institution and principal investigator to assure the accuracy and validity of all fiscal, programmatic and administrative information pertaining to the awarded grant. Failure to comply with these terms may result in grant termination.

Q. Can we divide the \$4M unevenly between the five years with justification?

A. The budget can be no more than \$800,000/year so you would have to budget evenly. If you don't use the \$800,000 the first year it will roll over to the second year and so on assuming Council approves continuation funding based on your progress reports.

Funds will continue to roll over annually if Council approves continuation funding. If the \$4M is not spent by the end of year 5 you can request a no cost extension.

Q. I did not see a section for budget justification in the RFA.

A. The justification for the first-year budget is part of Schedules A-C in SAGE. As you complete each schedule you will need to complete the corresponding justification page(s). Applicants should prepare for expenditures for five years. The budgets for the remaining years can be submitted without the corresponding narrative justification if general descriptions of how funding will be used in years two though five is included in the narrative as part of the program plan.

The first-year budget request should include, at a minimum, with corresponding narrative justification, (1) salary and justification for the Principal Investigator and other staff needed to meet the first-year responsibilities; (2) information about any sub-awards; (3) expenses related to communications, trainings, consultants, supplies, equipment; (4) travel funds for key personnel to attend ASD-related professional meetings. Indirect costs cannot exceed 15% annually and are included in the maximum funding.

Q. Can the grant award be used to provide fellowship support to residents or researchers?

A. Residents or researchers would need to be specifically working on the project.

Q. How about using part of the Center award for a pilot grant funding program to support autism research projects of PIs at Rutgers?

A. The NJACE grant does not fund autism research projects.

Q. If we include sub-awards in our project, can each sub-award charge 15% indirect costs, and then us as the lead charge 15% indirect costs on the total project costs on top of that? Please advise how to apply indirect costs in the case of a project with sub-awards.

A. Your sub-grant/contract can charge the 15% indirect, but the Council does not pay indirect on any flow through funds.

Institutional Support:

Q. Where is the statement about providing a letter from an institutional official indicating that there was support and space for the proposed work, such as a Department Chair, or a Dean of research?

A. The statement is included as a note at the end of Organization Information. "Please attach a letter of support from a president, dean or other authority, as evidence of institutional support, labeled and attached as "Miscellaneous Attachments" in SAGE."