



New Jersey Governor's Council for Medical Research and Treatment of Autism New Jersey Department of Health Request for Application (RFA) 2024

I. New Jersey Autism Center for Excellence

IMPORTANT DATES:

January 1, 2023	RFA Release	
January 26, 2023	Technical Assistance Session (Mandatory)*	
February 9, 2023	Letter of Intent Due (Required)**	
March 16, 2023	Application Due in SAGE 4:00 p.m.	
June 30, 2023	Notice of Grant Award	

^{*}All grant applicants must attend the Technical Assistance (TA) virtual meeting January 26, 2023. Additional information will be posted to council's website https://nj.gov/health/autism/index.shtml. The TA meeting will provide an opportunity for potential applicants to ask questions about the RFA and grants management process. TA will also include a presentation and overview from a SAGE team representative.

^{**}A Letter of Intent (LOI) must be received by February 9, 2023 for the applicant to open a grant application in SAGE. Please email: NJGCA@doh.nj.gov with your submission.



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PROGRAM DESCRIPTION AND GUIDELINES

The governing tenet for autism research grant awards stipulates that the Governor's Council for Medical Research and Treatment of Autism (Council) shall make awards of grants and contracts to public and nonprofit private entities (N.J.S.A. 30:6D-56). Additional information about the Council can be found at https://www.state.nj.us/health/autism/index.shtml.

The purpose of this grant program is to promote and support research capable of advancing the mission of the Council with the issuance of the following initiative:

1. New Jersey Autism Center for Excellence (5 years).

In compliance with P.L.1999, c.105, s.1; amended L.2007, c.168, s.1. (30:6D-60) Center of Excellence for Autism, this funding opportunity seeks applications for the 2023 New Jersey Autism Center of Excellence (hereafter referred to as NJACE) for the New Jersey Governor's Council for Medical Research and Treatment of Autism (hereafter referred to as "Council"). Applicants applying to establish a hospital based NJACE will be preferred.

The Council is pleased to announce \$2.5 million, contingent on the availability of NJDOH funds, for one (1) NJACE grant award for a five-year period (July 2023-June 2028), which will mark the Council's third cycle of funding for NJACE. Operating under the authority of the New Jersey Department of Health (DOH), the Office of Research Initiatives (ORI) shall be responsible for releasing and administering the NJACE grant and to ensure the chosen applicant (as the grantee) will maintain all regulatory, fiscal, programmatic, and administrative matters in accordance with the New Jersey Department of Health guidelines.

As children with ASD become young adults difficulties in developing and maintaining friendships, communicating with peers and adults, or knowing what behaviors are expected in school or on the job are likely occurrences. The successful applicant will include in its proposal a detailed description of how it intends to address the transition from pediatric to adulthood for autistic individuals and their families in the life cycle including the impact on health care, educational pursuits, and employment.

Additionally, the applicants proposal must describe how it will address the need for appropriate developmental support services such as early ASD identification and those differences that may exist based on a child having a co-occurring intellectual disability.

The primary focus of DOH is on the improvement of health outcomes for New Jersey residents at all life stages. With this focus in mind, community-oriented research tailored to the autism community need is essential. Core activities of the NJACE shall include:

• use of data to drive measurable health improvements



- identifying and targeting vulnerable populations for interventions to eliminate health disparities
- promotion of collaboration across sectors to develop health policies and achieve health equity.

Therefore, applicants shall also describe, in detail, how health equity will be addressed in the proposal.

All applicants must read the <u>SAGE Terms and Conditions for Administration of Grants: Effective for Project Periods Beginning on or After July 1, 2019</u> and review Appendix 5 before proceeding with the research proposal submission. All terms must be adhered to, with particular emphasis on the following:

- Subpart E. Standards for Grantee and Subgrantee Financial Management Systems (page 11)
- **Subpart F.** Cash Management (page 12)
- **Subpart H.** Allowable cost (page 15)
- **Subpart M.** Program Changes and Budget Revisions (page 23)
- Subpart N. Property, Equipment, Supplies, and Copyrights (page 26)
- **Subpart O.** Procurement (page 29)
- **Subpart P.** Subgrants (page 36)
- **Subpart Q.** Monitoring and Reporting Program Performance (page 37)
- **Subpart T.** Enforcement (page 43)
- **Subpart U.** After the grant (page 44)

NJDOH administers a diverse array of grant programs that address the missions of its several divisions. The awarding divisions within NJDOH are responsible for the award, administration, and monitoring of these programs under a variety of legislative authorities, governing regulations, policies, and procedures. Grants shall be made to a wide range of applicants, including local governments, institutions of higher education, hospitals, and nonprofit organizations. The administration of a grant not only requires adherence to the program objectives for which the grant was made, but also requires that objectives be accomplished in a businesslike manner. This is particularly important when the costs to applicants and the State are rising and NJDOH funds are limited. For these reasons, applicants must establish sound and effective business management systems to ensure proper stewardship of funds and activities. Applicants are expected to exercise the same degree of prudence in the expenditure of NJDOH funds as they use in expending their own funds.

NJDOH promotes the application of all Health in All Policies to ensure the best outcomes for New Jersey residents. As described by the Center for Disease Control and Prevention (CDC), Health in All Policies applies health consideration into policymaking processes outside of the health sector and where people live, work, and play. NJDOH is focused on improving health outcomes for New Jersey residents at all life stages. Core activities include the use of data to drive measurable health improvements, identify and target vulnerable populations for interventions, eliminating health disparities, and promoting collaboration across sectors to develop health policies and achieve health equity.



NJACE applicants shall not apply for any other grant opportunity in the same cycle. Given the competitive nature of these grants, applicants must submit <u>one</u> well-developed and responsive application as opposed to multiple applications.



New Jersey Autism Center for Excellence (CAUT24ACE)

Per the enabling legislation P.L. 2007,c,168, the Council shall make awards of grants and contracts to public and nonprofit private entities to pay all or part of the cost of planning, establishing, improving and providing basic operating support for a Center of Excellence for Autism in the State where basic and applied biomedical research, diagnosis and treatment for autism shall take place.

The Council has defined the scope of the programs to be undertaken at the center with the understanding that the center shall also conduct:

- (1) basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of autism, including research in the fields of developmental neurobiology, genetics, psychopharmacology, neuroimaging, immunology, infectious diseases, gastroenterology and endocrinology;
- (2) training programs on biomedical treatments, diagnosis and prevention for autism for physicians, scientists and other health care and allied health care professionals in the State;
- (3) information and continuing educational programs on the latest advances in biomedical research on autism for physicians and other health care and allied health care professionals who provide care for patients with autism in the State

NJACE will not be limited to only addressing the defined scope as outlined, as applicants are encouraged to be creative and innovative in their proposal design. Successful applicants will provide a comprehensive proposal that addresses all areas of the enabling legislation and include the specifications outlined below.

Applicants shall provide a five-year work plan identifying the statement of work (SOW) activities, preplanned roll-out dates, and related marketing strategies, in adherence to but not limited to the SOW identified below. The work plan shall be subject to approval by the ORI/Council before implementation. Applicants shall determine and include an NJACE organizational chart and job descriptions for each position identified.

The Council shall require the NJACE be led by an experienced Executive Director who may also serve as the PI if all qualifications are met. Specifically, the NJACE PI shall be a nationally recognized autism researcher who may also function as the Executive Director, providing he/she has a minimum of 7 years management experience at the senior level. Required staffing must include:

- Executive Director
- PI (if not the Executive Director)
- IT Manager
- Community Liaison/Program Manager (NJACE subgrants)



One additional staff member vital to the program's operations (if applicable)

The promotion of a more equitable system of care for autistic individuals and family members, particularly those in low-resource communities where related challenges of access to care, quality and costs of care can be exacerbated by cultural and linguistic differences, low health literacy and racial/ethnic social determinants of health shall be addressed, by the NJACE, through the solicitation of translational research applications. In doing so, the NJACE will establish a pool of subgrantees. NJACE shall be responsible for awarding grants to public and nonprofit private entities per N.J. S.A. 30:6D-56, by allocating grant funding to subgrantees no later than September 1, 2024. The NJACE translational research funding opportunity may include a range of activities to encourage translation of basic research findings to have a practical impact on the diagnosis, treatment and screening of ASD. Multi-institutional, multi-disciplinary, and academic-business collaborations studies are encouraged. Inclusion of community-based organizations (CBOs) is also encouraged. NJACE grant awards shall only be made to New Jersey based organizations and may not be awarded to subsidiaries of a NJ based organization that resides outside of New Jersey. However, contracted services for the provision of marketing, educational training, or other services can be made with organizations and, or entities that are not New Jersey based.

NJACE will be responsible for managing its subgrantees, providing oversight management, and reporting to the Council, in writing and in person, regarding the progress of each of its subgrantees. NJACE shall determine the grant cycle for its subgrantees as year-to-year or multi-year grants coinciding with the duration of the NJACE grant cycle (July 2023 – June 2028). Per its governing legislation, the Council has defined the scope of the programs to be conducted at the center to include the following:

- 1.) Basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of autism, including research in the fields of developmental neurobiology, genetics, psychopharmacology, neuroimaging, immunology, infectious diseases, gastroenterology and endocrinology.
- 2.) A Health Equity focused platform of services; must describe, in detail, how NJACE intends to measure program outcomes to improve health equity in the proposal:
 - a. Training programs on biomedical treatments, diagnosis, and prevention of autism for physicians, scientists and other health care and allied health care professionals in the State with adherence to Culturally and Linguistically Appropriate Services (CLAS).
 - b. Principal Standard: 1) Provide effective, equitable, understandable and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy and other communication needs. Self-directed online training and other web page information must be built with a translation application. As an example, the State of NJ website incorporates optional links, information, services and/or content from other websites operated by third parties that are provided as a convenience, such as Google Translate



(translate.google.com) or Google Extensions. Google Translate is an online service for which the user is not charged to obtain a purported language translation- OR, a similar service must be employed.

- 3.) Information and continuing educational programs on the latest advances in biomedical research on autism for physicians and other health care and allied health care professionals who provide care for patients with autism in the State.
- 4.) The Center may carry out programs to make individuals in the State aware of opportunities to participate as subjects in research conducted by the Center. The program may provide fees to these subjects. The program may, in accordance with guidelines established by the Council, provide to these subjects health care, referrals for health and other services and such incidental services as will facilitate the participation of individuals as subjects.
- 5.) The Center may provide stipends for health care professionals enrolled in training programs established under this section.
- 6.) The Council shall require the preparation of reports on the activities of the Center and the submission of the reports to the Council (see Appendix 1).
- 7.) The Center shall use the facilities of a single medical facility or higher education medical institution, or be formed from a consortium of cooperating facilities or institutions, and shall meet any requirements as may be prescribed by the Council, with the understanding that the work carried out at the center shall be comprehensive and fully collaborative (P.L. 1999, c.105, s.5:amended L.2007, c.168, s.5.).
- 8.) Identify measurable outcomes that will enhance the quality of life for the ASD community.

Project Work Plan

Incorporate the approaches for Goals 1-8 into the project work plan. Provide a detailed description of the work plan and attach as an appendix to the proposal. The plan must outline all ongoing processes toward the long-term goals and aims of NJACE's progress. Include descriptions of:

- organizational profile
- collaborating partners
- key staff
- budget and other resources
- key processes
- expected outputs and outcomes
- how measurable outcomes will be evaluated

Complete a timeline (Gantt chart) that includes activities described in the goals. Include the timeline:

- the Center's plan to submit timely quarterly and annual reports (see Appendix 1 for scheduled due dates)
- the identification of responsible staff and partners



- in detail, how NJACE intends to measure program outcomes to improve health equity in the proposal
- identify support and collaboration with key stakeholders in the planning, designing and implementation of all activities

Projects defined by the National Institutes of Health (NIH) as <u>clinical research</u> <u>and</u> addressing Goals 1-8 will be considered for funding. NIH defines clinical research as research with human subjects that is:

- 1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes:
 - a. Mechanisms of human disease
 - b. Therapeutic interventions
 - c. Clinical trials
 - d. Development of new technologies
- 2. Epidemiologic and behavioral studies
- 3. Outcomes research and health services research



Applicants must comply with the Council's Code of Ethics (www.nj.gov/health/autism). Applications that are not compliant with the Code of Ethics will be disqualified.

Qualified Individuals

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research as the Principal Investigator are invited to work with their sponsors and organizations to develop an application. Investigators at the postdoctoral level or higher are eligible to apply. Multiple PIs are not allowed, but co-PIs are allowed for each project. Applicants must be affiliated with a New Jersey State medical school, a New Jersey State academic institution, a New Jersey State research organization or a New Jersey State public or private non-profit entity with a demonstrated capability to conduct grant-funded research. The Council will not award grants to unaffiliated individuals. However, contracted services for the provision of marketing, educational training, or other services can be made with organizations and, or entities that are not New Jersey based. 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 entity, as described below. If the research project will be provided through collaboration, the structure of the collaborative arrangement must be described in the application.

Qualified Research Institutions

Only those entities credentialed as a public and/or private non-profit organization in the State of New Jersey may apply for a Council grant under this RFA. The institution must be a New Jersey academic institution, New Jersey research organization, or New Jersey public or private non-profit entity with a demonstrated capability to conduct grant-funded activities that have obtained a Council/NJDOH research credential status. The research-credentialed entity must have established procedures to receive and administer Federal and State grants and adhere to procedures for the protection of human subjects as regulated by NIH. The research-credentialed entity must also have an Institutional Review Board (IRB) that will approve the proposed research activities.

The Council will not accept grant applications from non-credentialed research institutions. However, non-credentialed research institutions may request an application from MJGCA@doh.nj.gov prior to applying for a research grant award.

The Council requires compliance with NIH, the <u>HHS Office for Human Research Protections</u>, and institutional guidelines defined for the protection of human subjects in research (see Appendix 6).



FUNDING AVAILABILITY, OBLIGATIONS AND DEADLINES

Maximum funding for the New Jersey Autism Center for Excellence is \$500,000 per year for a five (5) year period and shall not exceed a total of \$2,500,000 for the duration of the five-year grant. Award amounts are contingent on the availability of NJDOH funding. Indirect costs may not exceed 10% of the total budget.

Letters of intent are required and are due February 9, 2023. Applications must be submitted by March 16, 2023. The anticipated project start date is July 1, 2023.

Successful applicants must abide by all programmatic and fiscal requirements of NJDOH, including:

- 1. Terms and Conditions for the Administration of Grants;
- 2. General and specific grant compliance requirements issued by the granting agency; and
- 3. Applicable Federal Cost Principles relating to the applicant.
- 4. Immediate notification if the grant award cannot be accepted, is canceled, or encounters any difficulties that would prevent its completion prior to the expenditure of funds. Failure to fully comply in this area may result in a charge back to the institution.
- 5. Publications, patents, clinical applications and/trials resulting from research supported by the Council shall contain acknowledgment of funding source such as: "research funding provided by the New Jersey Governor's Council for Medical Research and Treatment of Autism (grant #xxxxx"). Grantees must provide 3 reprints of Council -supported research materials to the Council Program Management Officer.



APPLICATION AND SUBMISSION INFORMATION

Applicants are required to submit the following information to move their proposal forward to external review. Applications that do not include all required documents will be regarded as incomplete and will not be reviewed.

Letter of Intent

A Letter of Intent (LOI) is <u>required</u> and is due by February 9, 2023. The LOI template can be found on the Council website at https://www.state.nj.us/health/autism/documents.shtml. Applicants must download and fill the form and send the letter in PDF format to NJGCA@doh.nj.gov. If you do not receive an acknowledgement of receipt within 2 business days, please call 609-913-5002.

Technical Assistance Session

A mandatory Technical Assistance (TA) Session is scheduled for January 26, 2023. This session will provide an overview of the role of the Council as the funding agent for this opportunity, as well as an indepth tutorial of the New Jersey System for Administering Grants Electronically (SAGE). The TA session is mandatory for all applicants; those who do not attend will have their application removed from consideration.

Staff Resumes/CVs

The Council requires the upload of resumes and/or CVS for the following positions:

- 1. Executive Director
- 2. PI (if not the Executive Director)
- 3. IT Manager
- 4. Community Liaison/ Program Manager (NJACE Subgrants)

Resources and Environment

Identify the facilities to be used at the applicant organization (i.e., laboratory, clinical, animal, computer, office, and/or other) and briefly indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Also describe facilities at any other performance sites, and at sites for field studies. In addition, list the most important equipment items already available for this project, noting the location and pertinent capabilities of each, as well as support services such as consultants, secretarial, machine shop and electronics shop, and the extent to which they will be available to the project.

It is the Executive Director's and/or PI's responsibility to plan accordingly (in advance and in consideration of the need to use space at a facility other than its own, and/or additional resources, such as appointments with specialty providers, etc.) and determine a realistic timeline for project completion.



Collaborative Arrangements

If applicable, describe the involvement of collaborators in the proposed project. Attach copies of letters from the collaborators, including time commitments and agreed upon responsibilities. Collaborators must be NJ based. Inclusion of collaborators from outside of the state of New Jersey will be denied.

Full Project Proposal with Figures

The proposal is comprised of the sections listed in pages 6-8.

*Refer to reviewer questions in Appendix 2 for additional criteria that may be beneficial to your narrative.

Objectives and Activities

A listing of the project's Objectives and Activities (O&A) based on the project's aims is <u>required</u> as part of the full project proposal. The O&A template can be found on the Council website at https://www.state.nj.us/health/autism/documents.shtml. Applicants must download and fill the form and send as an appendix to the full project proposal.

Budgetary Requirements

Budgets must include fringe rate calculations, personnel costs/justifications for full-time and part-time employees/consultants where applicable. Direct/indirect costs for the duration of the grant must be detailed.

Officers and Directors

A complete listing of all officers and board members of the applicant is required.

Disclosures and Certifications

In projects utilizing human or animal subjects the following may be required:

- Animal Welfare Assurance Number
- Recombinant DNA Assurance Number
- Human Subject Assurance Number

Additional Documentation

The following forms are <u>required</u> to complete your application and must be uploaded in the "Attachments" section of SAGE:

- Organizational Letter of Support
- o NJ Charities Registration
- Proof of Non-Profit Status (501C3)



- Proof of Indirect Rate
- Salary Policy
- Annual Audit Report (Most Current)
- Audit Engagement Letter
- o Tax Clearance Certificate

The following supplemental forms are required **only** if your proposal contains the specified elements:

- o Travel Policy
- Telephone Policy
- Computer Security Policy
- o Policy on Protecting Human Subjects and Genomics
- o IRB Policy
- o Statement of Local Governmental Public Health Partnership

Applications must be submitted <u>electronically</u> by the due date per the instructions described in "APPLICATION INQUIRIES". Applications that do not include all required documents will be regarded as incomplete and will not be reviewed.



Questions regarding applications may be addressed to NJGCA@doh.nj.gov. Inquiries and responses will end March 13, 2023.

ORI will only accept applications submitted electronically through the New Jersey System for Administering Grants Electronically (SAGE) at www.sage.nj.gov until 4:00 PM on March 16, 2023. All questions related to your SAGE application (uploads, attachments, etc.) must be directed to the SAGE Help Desk Monday through Friday, 9:00 AM – 4:00 PM; (609) 376-8508 or njdoh.grants@doh.nj.gov.



Review Process

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 three-step review process:

1. Administrative Review (Office of Research Initiatives):

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. <u>Independent Relevance Review (Independent Relevance Review Panel):</u>

The Council subcontracts the Peer Review process through an outside entity. An independent relevance review will be conducted by a three-person external expert panel. The panel will determine the relevance of all applications to the Council's mission, priorities, and Research Guidelines, and will assign expert scientific reviewers for each proposal that meets those relevancy requirements. In the event the panel determines that an application does not meet those requirements, the application will be triaged, and will not be forwarded for independent scientific merit review. The decision to forward an application for independent scientific merit review is based only on relevance to the Council's mission, priorities, and research guidelines, and does not guarantee that an award will be made. All applications will receive a written critique, and the panels will assign overall impact scores to each application.

3. <u>Scientific Merit Review (Independent Scientific Merit Review Panel):</u>

Members of the Independent Scientific Merit Review Panel will convene to evaluate all research grant applications. The Panel will judge the applications on significance to ASD and feasibility (see details in Abstracts and Narrative Questions) and make funding recommendations to the Council.

Grants triaged by either the Independent Relevance Review Panel 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 according to New Jersey statute P.L. 2007, c.168 (NJSA C.30:6D-60).



The Scientific Advisory Committee (SAC) will conduct a scientific merit review of the results of the Relevance Review Panels and may provide additional advice to the Council based on the scientific and technical merit of the proposed projects, as well as the relevance of the proposed projects to program priorities. Through the Executive Director, the results of the scientific merit review will be forwarded to the Council for final review and action. Based on SAC advice, the Council may decide to fund a project only under certain conditions, including but not limited to funding only the first specific aim.

The Council will make the final funding recommendations, considering its mission and the potential impact of the grant on the understanding, prevention, evaluation and treatment of ASD. The authority to authorize or not authorize grants is fully vested in the Council according to New Jersey statute P.L. 2007, c.168 (NJSA C.30:6D-60).

Funding Restrictions

Recipients shall NOT use funds for the following:

- Purchasing vehicles
- Travel outside of New Jersey
- Food or refreshments
- Interest on loans for the acquisition and/or modernization of an existing building
- Tuition reimbursement for students
- Construction



At the conclusion of the selection process, all applicants including Principal Investigators and institutions will be formally notified of the outcome of their application no later than June 30, 2023 via a Letter of Intent to Find or a Letter of Denial. At that time, formal notification will be made to the institutions of successful applicants. NJDOH contracts (Attachments A and C) will be initiated shortly thereafter and sent to applicants who receive a Letter of Intent to Fund. Blinded critiques and scores will be provided to both funded and non-funded applicants; no further information shall be provided. <u>Selection of an application for award is not an authorization to begin performance</u>. Any costs incurred before receipt of the Notice of Grant Award (NOGA) are at the recipient's risk.



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MANDATORY PROGRESS REPORT SCHEDULE

- The first Progress Report will include a report from *July 1, 2023 to May 31, 2024 and will be due on June 10, 2024*.
- The second Progress Report will include a report from *June 1, 2024 to May 31, 2025* and will be due on June 10, 2025.
- The third Progress Report will include a report from *June 1, 2025 to May 31, 2026 and will be due on June 10, 2026.*
- The fourth Progress Report will include a report from *June 1, 2026 to May 31, 2027* and will be due on *June 10, 2027*.
- The Final Progress Report will include a report from June 1, 2027 to June 30, 2028 and will be due July 31, 2028.

MANDATORY EPENDITURE REPORT SCHEDULE

Quarterly Expenditure Reports

Fiscal Year 2023-2024

- First Expenditure Report July 1, 2023 to September 30, 2023 must be input into SAGE by October 13, 2023.
- 2nd Quarter Expenditure Report *October 1, 2023 to December 31, 2023* must be input into SAGE by *January 12, 2024*.
- 3rd Quarter Expenditure Report *January 1, 2024 to March 31, 2024* must be input into SAGE by *April 12, 2024*.
- 4th Quarter Expenditure Report April 1, 2024 to June 30, 2024 must be input into SAGE by July 12, 2024.

Fiscal Year 2024-2025

- First Expenditure Report *July 1, 2024 to September 30, 2024* must be input into SAGE by *October 14, 2024*.
- 2nd Quarter Expenditure Report *October 1, 2024 to December 31, 2024* must be input into SAGE by *January 14, 2025*.

^{*}Note: NJDOH SAGE grant system will not allow Progress Reports after the final due date.



- 3rd Quarter Expenditure Report January 1, 2025 to March 31, 2025 must be input into SAGE by April 14, 2025.
- 4th Quarter Expenditure Report *April 1, 2025 to June 30, 2025* must be input into SAGE by *July 14, 2025*.

Fiscal Year 2025-2026

- First Expenditure Report *July 1, 2025 to September 30, 2025* must be input into SAGE by *October 14, 2025*.
- 2nd Quarter Expenditure Report *October 1, 2025 to December 31, 2025* must be input into SAGE by *January 14, 2026*.
- 3rd Quarter Expenditure Report *January 1, 2026 to March 31, 2026* must be input into SAGE by *April 14, 2026*.
- 4th Quarter Expenditure Report *April 1, 2026 to June 30, 2026* must be input into SAGE by *July 14, 2026*.

Fiscal Year 2026-2027

- First Expenditure Report *July 1, 2026 to September 30, 2026* must be input into SAGE by *October 14, 2026*.
- 2nd Quarter Expenditure Report *October 1, 2026 to December 31, 2026* must be input into SAGE by *January 14, 2027*.
- 3rd Quarter Expenditure Report *January 1, 2027 to March 31, 2027* must be input into SAGE by *April 14, 2027*.
- 4th Quarter Expenditure Report *April 1, 2027 to June 30, 2027* must be input into SAGE by *July 14, 2027*.

Fiscal Year 2027-2028

- First Expenditure Report *July 1, 2027 to September 30, 2027* must be input into SAGE by *October 14, 2027*.
- 2nd Quarter Expenditure Report *October 1, 2027 to December 31, 2027* must be input into SAGE by *January 14, 2028*.
- 3rd Quarter Expenditure Report *January 1, 2028 to March 31, 2028* must be input into SAGE by *April 14, 2028*.
- 4th Quarter Expenditure Report April 1, 2028 to June 30, 2028 must be input into SAGE by July 14, 2028.



Grantees will be required to be on a cost reimbursement method of payment only and will not be eligible for advance payments.

*Note: The final grant award payment will be distributed upon submission of the Final Progress report in the SAGE system.

MANDATORY SPENDING PLAN SCHEDULE

Semiannual Spending Plans

The Spending Plan template can be found and downloaded from the Council's <u>autism</u> <u>website</u>.

Fiscal Year 2023-2024

- Initial Spending plan must be input into SAGE by August 4, 2023.
- First semiannual spending plan *July 1, 2023 to December 31, 2024* must be input into SAGE by *January 12, 2024*.
- 2nd semiannual spending plan *January 1, 2024 to June 30, 2024* must be input into SAGE by *July 12, 2024*.

Fiscal Year 2024-2025

- First semiannual spending plan *July 1, 2024 to December 31, 2024* must be input into SAGE by *January 14, 2025*.
- 2nd semiannual spending plan January 1, 2025 to June 30, 2025 must be input into SAGE by July 14, 2025.

Fiscal Year 2025-2026

- First semiannual spending plan *July 1, 2025 to December 31, 2025* must be input into SAGE by *January 14, 2026*.
- 2nd semiannual spending plan January 1, 2026 June 30, 2026 must be input into SAGE by July 14, 2026.

Fiscal Year 2026-2027



- First semiannual spending plan *July 1, 2026 to December 31, 2026* must be input into SAGE by *January 14, 2027*.
- 2nd semiannual spending plan *January 1, 2027 to June 30, 2027* must be input into SAGE by *July 14, 2027*.

Fiscal Year 2027-2028

- First semiannual spending plan *July 1, 2027 to December 31, 2027* must be input into SAGE by *January 14, 2028*.
- 2nd semiannual spending plan *January 1, 2028 to June 30, 2028* must be input into SAGE by *July 14, 2028*.



APPENDIX 2 – REVIEW CRITERIA – NEW JERSEY AUTISM CENTER FOR EXCELLENCE (CAUT24ACE)

Grant applications will be judged on scientific and technical merit, relevance to the IACC priorities, Council's mission, and public health.

The Independent Scientific Merit Review Panel will perform two levels of review:

- 1. Each panel member will review his/her assigned proposals for scientific and technical merit and significance and determine an initial score for each proposal.
- 2. The panel will then convene for group discussion and scoring.

The reviewers will heavily consider the aspects listed below to judge the likelihood that the proposed research will have an impact on the field of autism. Each of these criteria will be addressed and considered by the reviewers in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. In particular, the relevance of the project to public health needs is more important than its innovation.

Scientific Rationale & Significance:

- If clinical research studies are conducted, does the project meet the NIH definition of clinical research (see page 9)?
- Does the research proposal address an important problem or a critical barrier to progress in the field?
- How will the successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventive interventions for ASD? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

Innovation:

- Does the application challenge and seek to shift current research or clinical practice by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Is the proposed research innovative, including novel concepts, approaches, and/or methods?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Does the application challenge and seek to shift current research or clinical practice paradigms?

Approach, Experimental Design and Capability:

• Is the proposed project adequate in terms of the anticipation of potential problems, consideration of alternative approaches, and benchmarks for success?



- Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- If there are flaws in the design and/or analyses, can they be remediated? If so please indicate how.
- Have the investigators presented adequate plans to address relevant biological variables, such disparities in access to care and screening?
- Are potential ethical issues regarding research subjects adequately addressed? Is the protection of subjects appropriate considering 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials?

• Animal Research Subjects:

- Are the descriptions of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used detailed? Have interventions to minimize discomfort, distress, pain, and injury been identified?
- Are justifications for the use of animals versus alternative models and for the appropriateness of the species proposed given?
- o Is justification for euthanasia method inconsistent with the AVMA Guidelines for the Euthanasia of Animals?

Human Research Subjects:

- o Is the process for obtaining informed consent or assent appropriate?
- Are the plans for inclusion of children, minorities, and members of both sexes/genders justified in terms of the scientific goals and research strategy proposed?
- Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits and losses to follow-up appropriate to ensure robust data collection?

Environment, Key Personnel:

- Will the scientific environment in which the work will be done contribute to the probability of success? Are the administrative, data coordinating, enrollment, and laboratories appropriate for the project proposed?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Does the application adequately address the capability to conduct the project at the proposed sites?
- Are the PI(s), collaborators, and any other researchers well suited to the project? Do the Investigators and key staff have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
- If the project is collaborative or multi-PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?
- Are the proposed structure and the relationships with clinical sites, collaborators and consultants adequate given the objectives and project needs?
 - Are the qualifications, productivity, and time commitments of Principal Investigator and key staff commensurate with the proposed project?

<u>Translational Research:</u>



• Comment on the potential of the evidence-based research that will provide new interventions for all age groups across the spectrum with a focus on health disparities and the transition to adulthood.

Budget:

- Is the budget reasonable and justified for the project proposed?
- Is there evidence of institutional commitment and/or cost-sharing in the proposal?

Overall Impact

• Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research involved, in consideration of the scored and additional review criteria.



APPENDIX 3 – PRINCIPAL INVESTIGATOR – NEW JERSEY AUTISM CENTER FOR EXCELLENCE (CAUT24ACE)

Requirements

- Principal Investigators shall comply with the submission of required progress and expenditure reports.
- Principal Investigators should use the National Institutes of Health, "Guidelines and Policies for the "Conduct of Research in the Intramural Research Program at NIH" to serve as a reference for fellows and trainees. These Guidelines and Policies can be found at: https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelin_es-conduct_research.pdf
- All Principal Investigators shall notify and make available publication of their research in peerreviewed journals and any pending patents to the Council.
- All Principal Investigators are subject participate in scheduled Council meetings.



APPENDIX 4 – PAGE LIMITS & REQUIREMENTS

Follow the page limits specified below for the attachments for each grant application; unless otherwise specified in the request for applications (RFA) or related guide notice. If no page limit is listed in the table below, applicants may assume the attachment does not have a limit.

The applications and attachments MUST follow these minimum requirements:

- **Text Color**: No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.
- **Font size**: Must be 11 points or larger. Smaller text in figures, graphs, diagrams, and charts is acceptable, as long as it is legible when the page is viewed at 100%.
- Font Type: Arial, Calibri, Helvetica
- **Type density**: Must be no more than 15 characters per linear inch (including characters and spaces).
- Line spacing: Must be no more than six lines per vertical inch.
- Format: All files MUST be formatted in Adobe PDF and concatenated.

Pilot Grants:

Section of Application	Page Limits
Project Lay Abstract	30 lines of text
Project Summary/Abstract	30 lines of text
Project Narrative Description	Three (3) sentences
Resubmission or Revision Application (when applicable)	One (1) page
Specific Aims	One (1) page
Research Strategy/Program Plan	35 pages
Method/s for Enhancing Reproducibility (Translational Nature)	3 pages
Biographical Sketch*	5 pages per individual
Literature Cited	5 pages

^{*} Resumes/CVs from multiple PIs/collaborators must be uploaded within the same section of the application (i.e. Researcher Profile)

Proposal narratives must be <u>concatenated</u> and uploaded as one complete PDF (including tables and graphs). Document size is limited to 13MB.

Nomenclature:

Attachments must be clearly named and appropriately uploaded in the corresponding form of the application (e.g. CAUT24APL065_Biosketch_JacksonPhD uploaded in *Researcher Profile*; CAUT24APL065_Proposal_JacksonPhD in *Description of Research Project*). Any additional information must be uploaded to the "Attachment" section in SAGE and labeled accordingly (e.g., CAUT24APL065_FringeBenefits_JacksonPhD in *Schedule A, Part I – Personnel Costs*).



APPENDIX 5 - INSTRUCTIONS FOR COMPLETING SAGE GRANT APPLICATION

Initiate a Grant Application in SAGE

- 1. Accept the NJDOH SAGE agreement after reading it in its entirety.
- 2. Click Save and next.
- 3. Click the "View Opportunities" button to begin the process to complete your grant application.
- 4. Select the appropriate grant opportunity (DOH Standard Research Application 2024 for NJDOH Test Organization).
- 5. Select "I Agree" to begin the application process.
- 6. Using the appropriate checkbox in the "Research Project Type" form, indicate the type of grant you are seeking (Concept, Pediatric or Pilot Grant [Autism or Cancer]).
 - Note: Years of Experience are not necessary to your application. Leaving the field blank will not affect your application.
- 7. If your application is a resubmission, select yes and proceed as required while saving your information.
- 8. In order to fill in the information in the "Organization Profile" form, you must select the check box located at the end and then hit "Save" to populate the information.
- 9. As you continue through the application, hit "Save" to save your information and check for any errors that need to be corrected before moving to the next form. Then hit "Next".
 - Note: You may also hover your mouse above the "Forms Menu" option at the top of the page to command each form of the application.
- 10. Using the forms menu drop-down menu is the best way to view which (if any) pages contain errors that will prevent you from submitting your application.
- 11. If you skip or miss a field that requires information input, you will be informed that you need to reenter the form to correct the mistake by either amending or adding the required information. SAGE will not allow you to submit your application if a mistake is detected.
- 12. **PLEASE NOTE**, you will not be able to submit your application unless all forms are populated with the required information.
- 13. If any information is missing, **A Red Box** will appear indicating the page(s) that must be corrected before submission can occur.
- 14. As a reminder, you <u>must</u> have all attachments uploaded upon submission of your application. Organizational Letters of Support and/or Reference Letters must be uploaded into the "Attachments" section of the application. The Council will not contact references for their letters.
- 15. If you encounter any problems completing your SAGE application, please contact the SAGE Help Desk Monday through Friday, 9:00 AM 4:00 PM; (609) 376-8508 or njdoh.grants@doh.nj.gov.



APPENDIX 6 - PROTECTION OF HUMAN SUBJECTS AND GENOMICS INFORMATION

Compliance with NIH regulations for the protection of human subjects, and the inclusion of women, children and minorities in clinical studies is required for all applicants.

The Council requires compliance with NIH, the HHS Office for Human Research Protections, and institutional guidelines defined for the protection of human subjects in research. Violations of these regulations and guidelines must be reported and reviewed by the appropriate institutions and the Council, including but not limited to IRB overseeing the research, the associated institution, and the laboratory's senior scientist.

The Council shall have the right to arrange for observation and/or auditing without prior notice of any research activity and research records associated with research funded by the Council. It is the responsibility of the applicant as a potential recipient of a Council grant to assure that the rights and welfare of all human subjects used in any Council-Mentored research are protected. Any applications involving human subjects must be reviewed and approved by the appropriate IRB. IRB approval must be obtained before patient enrollment can start, at the latest by the end of the first year.

Applicants are strongly encouraged to share human data with the <u>NIMH Data Archive</u> (NDA) if compatible with the design of the pilot project. The NDA has sample language for informed consent, as well as other resources.