New Jersey Department of Health

Governor's Council for Medical Research and Treatment of Autism

Request for Application (RFA)
2027

I. Clinical Research Pilot Projects

II. Basic Research Pilot Projects

IMPORTANT DATES:

January 6, 2026	**RFA Release (on Autism website)**
January 29, 2026 12:00 PM	Technical Assistance Session (Mandatory)*
February 5, 2026	Letter of Intent Due (Required)**
March 5, 2026	Application Due in SAGE 4:00 p.m.
July 31, 2026	Notice of Grant Award
August 1, 2026 – June 30, 2028	Basic Research Pilot Project Grant Period
August 1, 2026 – June 30, 2029	Clinical Research Pilot Project Grant Period

*All grant applicants (including repeat applicants) must register for and attend the Technical Assistance (TA) virtual meeting January 29, 2026. 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 5, 2026 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 these research grant programs are to promote and support research capable of advancing the mission of the Council with the issuance of 2 research initiative opportunities:

1. Clinical Research Pilot Projects (3 years).
2. Basic Science Research Pilot Projects (2 years).

Applicants for the Clinical Research Pilot Projects may apply for a three (3)-year stipend of $100,000 per year for a total of $300,000. Basic Research Pilot Projects applicants may apply for a two (2)-year stipend for a total of $200,000. The ability of the Department to make grant awards is expressly dependent upon the availability of funds appropriated by the State Legislature from State and/or federal revenue or such other funding sources as may be applicable. Applicants that have current Council funding of any kind are eligible to apply for this opportunity if the funded project will be completed by June 30, 2026.

The awards for these research grant programs are intended to promote ASD research in New Jersey, not to provide long-term support. The data and results gained by using Council funds will allow investigators from New Jersey to develop stronger proposals for submission to the National Institutes of Health (NIH) and biomedical research foundations. Applicants shall recognize and agree that the initial provision of funding for all opportunities and the continuation of funding for research grants under the grant agreement is expressly dependent upon the availability of NJDOH funds appropriated by the State Legislature from State and/or Federal revenue or such other funding sources as may be applicable.

It is the understanding of the Council that all proposals and supporting materials are original ideas/language proposed by the applicant and their affiliated institution. The Council recognizes the National Institutes of Health (NIH) notice number: NOT-OD-23-149 June 23, 2023 (The Use of Generative Artificial Intelligence Technologies is Prohibited for the NIH Peer Review Process) and therefore restrict the Council's contracted Peer Reviewer to the same standard. To paraphrase that ruling, "reviewers must be accountable and aware that uploading or sharing content or original concepts from a grant application, contract proposal, or critique to online generative AI tools violates the peer review confidentiality and integrity requirements." Essentially, to use generative AI to analyze or critique grant

applications in Peer Review will be considered a breach of confidentiality.[1] Similarly while AI is not banned in the grant writing process itself, the Council **strongly cautions that Principal Investigators (PI) use AI tools at their own risk**. The PI must be aware of the potential for plagiarism, fabricated citations, and falsified information that may be embedded through the use of generative AI. This would be considered research misconduct, and will warrant the Council taking steps to address non-compliance according to your institution's Research Misconduct policy.

All applicants must read the *SAGE Terms and Conditions for Administration of Grants: Effective for Project Periods Beginning on or After July 1, 2024* 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.

[1] McKlveen, Jessica (2023, June 29). Think Again Before Using Generative AI During Peer Review or As you Prepare an Application. https://www.nccih.nih.gov/research/blog/think-again-before-using-generative-ai-during-peer-review-or-as-you-prepare-an-application

Applicants may not apply for any other grant opportunity in the same cycle, including NJACE SEED grants. Given the competitive nature of these grants, applicants must submit ***one*** well-developed and responsive application as opposed to multiple applications.

All non-funded applicants from any given grant cycle are eligible for resubmission. However, the applicant must revise the non-funded application based on reviewer feedback. All reapplications will be reviewed as new competing proposals.

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.

Clinical Research Pilot Projects (CAUT27CRP)

Clinical Research Pilot Projects are intended to explain the etiology, epidemiology, diagnosis, and optimal means of service delivery in relation to ASD, while improving the physical and/or behavioral health and well-being of individuals with ASD. Exploratory, novel studies that break new ground or extend previous discoveries toward new directions are appropriate for this opportunity. The projects must address one of the objectives listed in Appendix 1 "Selected IACC Objectives", which constitute a subset of the Interagency Autism Coordinating Committee (IACC) 2021-2023 Strategic Plan.

The Clinical Research Pilot Project grant program also intends to support new discoveries and the development of best practices to improve the lives of people with ASD in New Jersey while encouraging the development of new clinical inter- and multidisciplinary teams. Preference will be given to research projects that have been judged to have the potential to impact persons with ASD directly or attract grant support from federal or other organizations that promote health equity for vulnerable populations, i.e., disabled, LGBTQ, racial and ethnic minorities. Grant funding may also be used to support collaborative investigative teams or individual scientists who propose unusually innovative research projects, which, if successful, would have a major impact in developing, implementing, or disseminating innovative and effective interventions to prevent, reduce, or eliminate health disparities and advance health equity. Research projects addressing health equity are strongly encouraged and must clearly demonstrate, based on the strength of the logic, a compelling potential to produce a major impact in addressing health disparities and inequities. Additionally, research addressing community-prioritized questions, cross-cutting issues such as social determinants of health across sectors, multiple levels and systems that contribute to health disparities, and/or priority areas of autism are particularly encouraged.

The Council will fund Clinical Research Pilot Projects with an emphasis on encouraging (1) experienced investigators to pursue new directions in autism research, or (2) new investigators who want to gather preliminary data for larger research projects. Suitable projects include:

- Feasibility studies
- Secondary analysis of existing data
- Self-contained research projects
- Development of research methodology
- Development of new research technologies
- Investigation of novel scientific ideas, model systems, tools, agents, targets, and technologies that have the potential to substantially advance autism research.

Only projects defined by the National Institutes of Health (NIH) as clinical research *and* addressing an objective from Appendix 1 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

Projects that focus on the pathobiological mechanisms of ASD should be submitted to the basic research program even if they use human tissue. The detailed elements required in the narrative are described in Appendix 2.

Basic Research Pilot Projects (CAUT27BRP)

Basic Research Pilot Projects will explore the mechanisms underlying ASD. Basic Research Pilot Projects may explore genetic, biochemical, morphological, or other mechanisms contributing to the development and characterization of ASD. All projects that focus on the mechanism of disease should be submitted to the basic research program. The projects must address one of the objectives listed in Appendix 1 "Selected IACC Objectives", which constitute a subset of the Interagency Autism Coordinating Committee (IACC) 2021-2023 Strategic Plan.

This RFA is open to existing autism researchers and welcomes new investigators using approaches that are not currently widely reflected in autism research, as well as investigators who previously committed a major component of their research program to autism. Applicants are specifically invited to:

a) Take new technical or intellectual tactics that may link different levels of understanding with one another (genetic, developmental, circuit, behavioral, animal, human),
b) Propose work that may open long-term possibilities for eventual treatment or diagnostic options,
c) Propose work to understand the biological basis for heterogeneity in ASD, or
d) Explore the effects of the immune system, infectious disease, epigenetics, or the environment, including toxins, on brain development.

It is essential that this proposed research includes a statement in lay language of how successful completion of this research may ultimately impact people with autism. If the research will identify and target vulnerable populations for interventions to eliminate health disparities, it must also be noted in the statement. As part of their commitment to autism research, applicants must also describe plans for public outreach on how basic science informs the understanding of autism and early child development.

Basic research into the pathophysiology of ASD, including research on brain mechanisms is of special interest. Also of high priority are applied investigations that may lead to the development of new treatments and interventions. Areas of interest include, but are not limited to:

- Epidemiology
- Screening, early identification, and diagnosis
- Genomic studies
- Brain mechanisms
- Shared neurobiology of ASD with Fragile X syndrome, and other related disorders
- Cognitive science
- Communication skills
- Services research

Grant awards for this funding cycle are intended to promote pilot studies of basic research that may begin to inform the biological underpinnings of autism. Funding is not meant to provide long-term

support. The data and results gained should allow investigators from New Jersey to develop strong proposals for submission to NIH and biomedical and international funding sources.

The detailed elements required in the narrative are described in Appendix 2.

ELIGIBILITY CRITERIA

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. 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 NJGCA@doh.nj.gov prior to applying for a research grant award.

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 (see Appendix 7).

FUNDING AVAILABILITY, OBLIGATIONS AND DEADLINES

Maximum stipend for Clinical Research Pilot Projects and the Basic Research Pilot Projects is $100,000 per year. The ability of the Department to make grant awards is expressly dependent upon the availability of funds appropriated by the State Legislature from State and/or federal revenue or such other funding sources as may be applicable. Indirect costs may not exceed 10% of the total budget. **Personnel costs for PIs (including administrative and contracted personnel) are capped at $15,000 per year (this amount includes fringe).** Fringe rates for salaried staff (including contractors and employees of contracted entities directly working on the funded project) hired under the awarded grant shall not exceed 15%.

Letters of intent are required and may be submitted at any time; however, letters are due no later than February 5, 2026. Applications must be submitted by March 5, 2026. The anticipated project start date is August 1, 2026.

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 required and may be submitted at any time; however, all LOIs are due no later than February 5, 2026. 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 29, 2026 at 12:00 PM. This session will provide an overview of the role of the Council as the funding agent for this opportunity, as well as an in-depth tutorial of the New Jersey System for Administering Grants Electronically (SAGE). **The annual TA session is mandatory for *all* applicants; those who do not register and attend will have their application removed from consideration**.

To register for the webinar, an email with the following information must be sent to NJGCA@doh.nj.gov no later than January 28, 2026:

I. Name (with credentials)
II. Organization
III. Email
IV. Telephone

Researcher/ Key Personnel Bio-sketch(es) and CVs

Bio-sketches and CVs must be provided for all key personnel involved in the project.

The Council endorses the use of NIH's standard bio-sketch template for its use in the Research Pilot grant application. Download the current templated form here.

Additional information for the Biographical Sketch (bio-sketch) for each key personnel named must include:

1. Active support
2. Applications and proposals pending review or funding
3. Applications and proposals planned or being prepared for submission. Include all Federal, non-Federal, and institutional grant and contract support. If none, state "None."

For each item, give the source of support, identifying number, project title, and name of the principal investigator, time, or percent of effort on the project by professional named, annual direct costs, and entire period of support. Describe the contents of each item listed. If any of these overlap, duplicate, or are being replaced or supplemented by the present application, delineate and justify the nature and extent of the scientific and budgetary overlaps or boundaries.

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 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 as the state of New Jersey continues to operate under the constraints and restrictions of the COVID-19 pandemic.

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 Appendix 2.

*Refer to reviewer questions in Appendix 3 for additional criteria that may be beneficial to your narrative.

While AI is not banned in the grant writing process itself, the Council **strongly cautions that Principal Investigators (PI) use AI tools at their own risk** (see pages 3-4 for more details).

Objectives and Activities

A listing of the project's Objectives and Activities (O&A) based on the project's aims is required 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 for salaried staff (shall not exceed 15%), personnel costs/justifications for full-time and part-time employees/consultants/employees of consulting (contracting) firms directly working on the funded project where applicable. **Personnel costs for PIs (including administrative and contracted personnel) are capped at $15,000 per year (this amount includes fringe).** 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 ***required*** to complete your application and must be uploaded in the "Attachments" section of SAGE:

- Organizational Letter of Support
- Board of Directors/Trustees
- NJ Charities Registration
- Proof of Non-Profit Status (501C3)
- Proof of Indirect Rate
- Salary Policy
- Annual Audit Report (Most Current)
- Audit Engagement Letter
- Tax Clearance Certificate

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

- Travel Policy
- Telephone Policy

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

Applications must be submitted ***electronically*** 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.

APPLICATION INQUIRIES

Questions regarding applications may be addressed to NJGCA@doh.nj.gov. Inquiries and responses will end March 3, 2026.

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 5, 2026. 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.

GRANT REVIEW AND FUNDING DECISIONS

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. Independent Relevance Review (Independent Relevance Review Panel):

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.

It is the understanding of the Council that all proposals and supporting materials are original ideas/language proposed by the applicant and their affiliated institution. The Council recognizes the National Institutes of Health (NIH) notice number: NOT-OD-23-149 June 23, 2023 (The Use of Generative Artificial Intelligence Technologies is Prohibited for the NIH Peer Review Process) and therefore restrict the Council's contracted Peer Reviewer to the same standard. To paraphrase that ruling, "reviewers must be accountable and aware that uploading or sharing content or original concepts from a grant application, contract proposal, or critique to online generative AI tools violates the peer review confidentiality and integrity requirements." Essentially, to use generative AI to analyze or critique grant applications in Peer Review will be considered a breach of confidentiality.[2] Similarly while AI is not banned in the grant writing process itself, the Council **strongly cautions that Principal Investigators (PI) use AI tools at their own risk**. The PI must be aware of the potential for plagiarism, fabricated citations, and falsified information that may be embedded through the use of generative AI. This would be

[2] McKlveen, Jessica (2023, June 29). Think Again Before Using Generative AI During Peer Review or As you Prepare an Application. https://www.nccih.nih.gov/research/blog/think-again-before-using-generative-ai-during-peer-review-or-as-you-prepare-an-application

considered research misconduct, and will warrant the Council taking steps to address non-compliance according to your institution's Research Misconduct policy.

3. Scientific Merit Review (Independent Scientific Merit Review Panel):

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).

Funding Decision

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

Domestic travel to 1 (one) conference is allowed and capped at $2500. If presenting, the subject matter ***must*** be the Council funded project.

Recipients shall NOT use funds for the following:

- Purchasing vehicles
- International travel
- Food or refreshments
- Interest on loans for the acquisition and/or modernization of an existing building
- Tuition reimbursement for students
- Construction

RESULTS NOTIFICATION

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 July 31, 2026 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. *Selection of an application for award is not an authorization to begin performance.* Any costs incurred before receipt of the Notice of Grant Award (NOGA) are at the recipient's risk.

Please note that all awarded applicants will be required to attend, provide, and present a poster presentation of their research at the annual Autism Symposium. Autism grant funds can be used to purchase materials for presentations. Additional information will be provided to awarded applicants after results have been sent.

APPENDIX 1 – SELECTED IACC OBJECTIVES

The selected questions below can be found in the Interagency Autism Coordinating Committee (IACC) 2021-2023 Strategic Plan.

	QUESTION 1 HOW CAN WE IMPROVE IDENTIFICATION OF AUTISM? ***SCREENING AND DIAGNOSIS***
1	Support research on how early detection of autism influences outcomes.
2	Reduce disparities in early detection and access to services.
3	Develop and adapt screening and diagnostic tools, including tools that incorporate new technologies to increase efficiency, accuracy, and timeliness of identification.

	QUESTION 2 WHAT IS THE BIOLOGY UNDERLYING AUTISM? ***BIOLOGY***
1	Foster research to better understand the processes of early development, molecular and neurodevelopmental mechanisms, brain circuitry, and cognitive development that contribute to the structural and functional basis of autism.
2	Support research to understand the underlying biology of co-occurring conditions in autism and to understand the relationship of these conditions to autism.
3	Support large-scale longitudinal studies to answer questions about the development and natural history of autism across the lifespan, from pregnancy through childhood, adolescence, adulthood, and older adulthood.

	QUESTION 3 WHAT ARE THE GENETIC AND ENVIRONMENTAL FACTORS THAT CONTRIBUTE TO AUTISM AND ITS CO-OCCURRING CONDITIONS? ***GENETIC AND ENVIRONMENTAL FACTORS***
1	Strengthen understanding of genetic factors that influence autism and its co-occurring conditions across the full diversity of individuals on the autism spectrum.
2	Understand the influence of environmental factors on the onset and progression of autism and its co-occurring conditions, enabling the development of strategies to maximize positive outcomes.
3	Expand knowledge about how multiple environmental and genetic factors interact through specific biological mechanisms to manifest in autism phenotypes.

QUESTION 4 WHICH INTERVENTIONS WILL IMPROVE HEALTH AND WELL-BEING?

INTERVENTIONS

1	Develop and improve pharmacological and other medical interventions that will maximize positive outcomes for individuals on the autism spectrum.
2	Create and improve a variety of psychosocial, developmental, occupational, and educational interventions that will maximize positive outcomes for individuals on the autism spectrum.
3	Develop and improve technology-based interventions that will maximize positive outcomes for individuals on the autism spectrum.

QUESTION 5 WHAT SERVICES AND SUPPORTS ARE NEEDED TO MAXIMIZE HEALTH AND WELL-BEING?

SERVICES AND SUPPORTS

1	Develop service approaches and scale up and implement evidence-based interventions in community settings.
2	Address disparities in service provision and improve access to services for all, including low-resource and underserved communities and individuals and families with high support needs.
3	Improve service delivery to ensure quality and consistency of services across many domains with the goal of maximizing positive outcomes and the value that individuals get from services.

QUESTION 6 HOW CAN WE ADDRESS THE NEEDS OF PEOPLE ON THE AUTISM SPECTRUM THROUGHOUT THE LIFESPAN?

LIFESPAN

1	Support development and coordination of integrated services to help people on the autism spectrum successfully transition to adulthood and progress through the lifespan with appropriate services and supports.
2	Support research and develop and implement approaches to improve physical and mental health outcomes across the lifespan, with the goal of improving safety, reducing premature mortality, and enhancing health and well-being.
3	Support research, services activities, and outreach efforts that facilitate and incorporate accessibility, as well as acceptance, accommodation, inclusion, independence, and integration of people on the autism spectrum.

QUESTION 7 HOW DO WE EXPAND AND ENHANCE RESEARCH INFRASTRUCTURE SYSTEMS TO MEET THE NEEDS OF THE AUTISM COMMUNITY?

INFRASTRUCTURE AND PREVALENCE

1	Promote growth, linkage, coordination, and security of biorepository and data repository infrastructure systems, equitable access to these systems, and inclusion of diverse samples.
2	Expand and enhance the research workforce, with attention to diversity and inclusion, and accelerate the pipeline from research to practice.
3	Strengthen statistical data gathering systems to advance understanding of the autistic population, while allowing comparisons and linkages across systems as much as possible.

CROSS-CUTTING RECOMMENDATIONS

1	Support research to understand sex and gender differences in autism.
2	Support diversity, equity, inclusion, and accessibility efforts in research, services, and policy that reduce disparities and increase equity for underrepresented, underserved, and intersectional populations within the autism community and enhance opportunities for autistic people.

APPENDIX 2 – ABSTRACTS AND NARRATIVE QUESTIONS – CLINICAL AND BASIC RESEARCH PILOT PROJECTS (CAUT27CRP AND CAUT27BRP)

Proposal Abstract: State the plan's long-term objectives and specific aims, making reference to the autism relatedness of the project, and concisely describe the methods for achieving the goals. Avoid summaries of past accomplishments and the use of the first person. The abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application.

Proposal Lay Abstract: Describe your project in simple, non-technical language that is understandable by a person not trained in science. Include how your project will advance the understanding, prevention, evaluation, and treatment of autism spectrum disorders, enhancing the lives of individuals across their lifespans. This abstract is meant to serve as a public description of the proposed project. Should the award be made, it will be used in press releases and various Council publications.

Proposal Narrative with Figures (*see Appendix 5 for page limits and formatting requirements*):

A. **IACC Objective:** State the IACC objective (see the subset of IACC objectives in Appendix 1) that is addressed by the proposed project and summarize the expected outcomes.

B. **Scientific Rationale and Significance:** Explain how this project has the potential to effect, impact, and advance the current knowledge in ways that can improve the physical and/or behavioral health and well-being of individuals with ASD. How will scientific knowledge or public health be advanced? Explain why the literature/your research leads you to a need to study this topic. Relate the payoff to science AND to public health. Mention what makes the project unique and innovative, especially in light of any similar projects and the refereed literature.

C. **Innovation:** Does the proposed research include novel concepts, approaches and/or methods? If so, please describe. Does the research challenge and seek to shift current research or clinical practice paradigms? If so, please describe. Describe how the project will challenge and seek to shift current research paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions. Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? Discuss how the research project provides novel or innovative insights into improving the health of one or more populations, especially those experiencing health disparities. Note that the relevance of the project to public health needs is more important than its innovation.

D. **Approach, Experimental Design and Capability:** Clearly state the purpose and nature of the research project including:
   - Your plan to develop hypothesis driven research, when appropriate, as well as specific aims
   - Background and significance
   - The population (age range, gender, race, selective characteristics), interventions, controls, measures, etc. that will enable testing your hypotheses. Estimate the required sample and

power (N, levels of analysis). Justify the statistical approach that will ensure a fair test of your hypotheses

- Preliminary data (optional)
- Experimental design and research methods, including data collection methods, and planned analyses potentially resulting in statistically sound conclusions for each specific aim.
- Discuss potential problems and alternative strategies. If the project is in the early stages of development describe any strategy to establish feasibility and address the management of any high-risk aspects of the project.
- Describe your plan for recruiting and retaining patients. Include, as an "Appendix" in your proposal, a targeted/planned enrollment table confirming the availability of an adequate number of subjects. As part of their commitment to autism research, applicants should also describe plans for public outreach on how their work informs the understanding and treatment of autism. Briefly describe your community engagement plan (e.g., how the community will be engaged from the first step to the completion of the project). Refer to the Research Subjects" criteria in Appendix 3.
- If applicable, describe the translational aspects of your application (evidence-based research that will provide new interventions for all age groups across the spectrum with a focus on the transition to adulthood). Also, briefly describe the cost-effectiveness of the clinical approach being tested.

E. **Environment and Key Personnel:** Describe the overall environment – features of the institutional environment that are or would be relevant to the effective implementation of the proposed pilot project. As appropriate, describe available resources, such as clinical and laboratory facilities, equipment, and other physical resources. Describe participating and affiliated units, patient populations, geographical distribution of space and personnel, and consultative resources. Describe the proposed structure and the relationships with clinical sites, collaborators and consultants as related to the scientific objectives and project needs.

Note: Please attach a letter of support from a president, dean, or other authority, as evidence of institutional support, labeled and attached as "Attachments" in SAGE.

Describe the qualifications and time commitments of Principal Investigator and key staff commensurate with the proposed project. Describe their complementary and integrated expertise, leadership approach, governance, and organizational structure as appropriate for the project. Describe the specific roles, responsibilities, and expertise of key personnel. Describe how each collaborator will be engaged in the development and/or implementation of the pilot study. Include letters from collaborators as "Attachments" in SAGE. In addition, briefly present experience in ASD research. If the research team is new to autism research, indicate how it proposes to acquire the knowledge necessary to put the proposed study into the appropriate context, whether through literature reviews, relevant experimental data, collaboration with established autism researchers, or other means.

F. **Additional Funding:** Briefly describe any past or current funding for this or similar research studies and how this study will move the work forward.

G. **Literature:** Literature cited.

APPENDIX 3 – REVIEW CRITERIA – CLINICAL AND BASIC RESEARCH PILOT PROJECTS (CAUT27CRP AND CAUT27BRP)

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:

- Is the research proposal relevant to the selected IACC priority and does it advance the current knowledge pool in ways that may improve clinical practice for patients with ASD?
- If responsive to the Clinical Research program, does the project meet the NIH definition of clinical research (see page 6)?
- Does the research proposal address an important problem or a critical barrier to progress in the field?
- Is the prior research that serves as key support for the proposed project rigorous?
- 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 applicable, will the proposed pilot project lead to an intervention that can be adopted and implemented in community settings should it prove effective? 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 experimental design and analyses, anticipation of potential problems, consideration of alternative approaches, and benchmarks for success?
- Does prior research and theory provide a rational basis for the proposed project?
- Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Does the design have adequate methodological quality and power to increase the likelihood of producing statistically sound conclusions?
- 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 as sex, for studies in vertebrate animals or human subjects?
- 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?
    - Is justification for euthanasia method inconsistent with the AVMA Guidelines for the Euthanasia of Animals?
- Human Research Subjects:
    - 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 scientific objectives and project needs?
  - Are the qualifications, productivity, and time commitments of Principal Investigator and key staff commensurate with the proposed project?

Translational Research:

- 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 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 4 – PRINCIPAL INVESTIGATOR – CLINICAL AND BASIC RESEARCH PILOT PROJECTS (CAUT27CRP AND CAUT27BRP)

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/guidelines-conduct_research.pdf
- All Principal Investigators shall notify and make available publication of their research in peer-reviewed journals and any pending patents to the Council.
- All Principal Investigators are subject to participate in scheduled Council meetings.

APPENDIX 5 – PAGE LIMITS & GRANT SUBMISSION CHECKLIST

Please refer to the following table to see the checklist of the required document(s) for each type of grant and the word/page limits. The page/character limits do not represent the expected length of the response. They are the **maximum** lengths allowed. If no page limit is listed in the table, you can assume the attachment does not have a limit.

The applicant MUST submit all attachments (including tables and graphs) in **Adobe pdf format** (not docx or other format) and ***concatenated***. The attached file must be labeled properly with appropriate Prefix file description. For example, the submission of a resume for a Basic Research grant would be e.g., CAUT27BRP_resume_ JacksonPhD, or Table 1 for Predoc would be CAUT27GFP_Table1_Brown. Any additional information must be uploaded to the "Attachment" section in SAGE and labeled accordingly (e.g., CAUT27CRP_FringeBenefits_DowningPhD in Schedule A, Part I – Personnel Costs).

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.

Document size is limited to 13MB.

Grant Submission Checklist (Page Limits & Requirements)

Section of Application (Page Limits)	AMH	BRP	CRP	Postdoc	Predoc
Research Project Type	✓	✓	✓	✓	✓
Organization Profile	✓	✓	✓	✓	✓
Project Contacts	✓	✓	✓	✓	✓
Grant Period and Payment	✓	✓	✓	✓	✓
Researcher Profile • Name of Researcher • Biosketch ***and*** CV (5 pages each personnel) • Research Experience (4,000 characters) • References – *pre and postdoc only* (2 Letters of Reference/Recommendation [excluding the Mentor/Supervisor])	✓	✓	✓	✓	✓
Description of Research Project • Project Title • Project Description (3 sentences [500 characters]) • Lay Abstract (1 page maximum [250 words]) • Abstract and Proposal Narrative ○ Abstract (1 page maximum) ○ Specific aims (1 page) ○ Research Strategy (not to exceed 20 pages) ▪ Significance ▪ Preliminary Studies/Data ▪ Research Design ▪ Method/s for Enhancing Reproducibility (Translational Nature) Basic and Clinical Research ***only*** ○ References • Facilities (20,000 characters) • Major Equipment (20,000 characters) • Equipment Needs • Additional Information (20,000 characters)	✓	✓	✓	✓	✓
Written response to reviewer critiques (when applicable)	✓	✓	✓	✓	✓
Comments of Sponsor **(for pre and post doc only)** - not to exceed 6 pages • Name of Sponsor • Sponsor's Biosketch ***and*** CV (5 pages [max.] each) • Training Plans (8,000 characters) • Researcher Qualifications (4,000 characters) • Institutional Commitment (2,000 characters) • Career Development (2,000 characters) • Independent Research (2,000 characters) • Mentoring Process (4,000 characters) • Research Funding Support of Sponsor (16,000 characters)	N/A	N/A	N/A	✓	✓
Schedule A, Part 1 – Personnel Costs Budget Year 1	✓	✓	✓	✓	✓
Schedule A, Part 1 – Personnel Costs Budget Year 2	✓	✓	✓	✓	✓
Schedule A, Part 1 – Personnel Costs Budget Year 3 (Clinical Research and Postdoc ***only***)	✓	✓	✓	✓	✓

Section of Application (Page Limits)	AMH	BRP	CRP	Postdoc	Predoc
Schedule B – Other Direct Costs Budget Year 1	✓	✓	✓	✓	✓
Schedule B – Other Direct Costs Budget Year 2	✓	✓	✓	✓	✓
Schedule B – Other Direct Costs Budget Year 3 (Clinical Research and Postdoc ***only***)	✓	✓	✓	✓	✓
Cost Summary	✓	✓	✓	✓	✓
Disclosures and Certifications	✓	✓	✓	✓	✓
Additional Certifications for Research Applicants	✓	✓	✓	✓	✓
Suggested Reviewers (not applicable for FY2025 grants)	N/A	N/A	N/A	N/A	N/A
FFATA Certification	✓	✓	✓	✓	✓
Attachments • Organizational Letter of Support • Board of Directors/Trustees • NJ Charities Registration • Budget Justification • Annual Audit Report • Proof of Nonprofit Status • Proof of Indirect Rate • Audit Engagement Letter • Tax clearance Certificate • Salary Policy • Travel Policy • Computer Policy • Telephone/Mobile Communication Policy • Human Subjects and Genomics Policy • IRB policy • Statement of Local Governmental Public Health Partnership • Proof of U.S. Citizen or legal resident (for Predoctoral Fellowship Grant only)	✓	✓	✓	✓	✓

APPENDIX 6 - INSTRUCTIONS FOR COMPLETING SAGE GRANT APPLICATION

Initiate a Grant Application in SAGE

1. Click the "Manage My Organization's Account" link to view and update your organization's system profile and user accounts.
2. Click the program name underneath “Start a New Grant Application” button to begin the process to complete your grant application.
3. Select “I Agree” to begin the application process.
4. In the “Forms” section of the left navigation pane, select “Research Project Type” form, and using the appropriate checkbox in the indicate the type of grant you are seeking (Concept, Pediatric or Pilot Grant [Autism or Cancer]).
5. If your application is a resubmission, select yes and proceed as required while saving your information.
6. 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.
7. 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 Form”.
   - Note: You may also use the left navigation pane to command each form of the application.
8. Using left navigation pane is the best way to view which (if any) pages contain errors that will prevent you from submitting your application.
9. 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.
10. **PLEASE NOTE**, you will not be able to submit your application unless all forms are populated with the required information.
11. If any information is missing, **an exclamation mark (!)** will appear in the left navigation pane indicating the page(s) that must be corrected before submission can occur.
12. As a reminder, you ***must*** have all attachments uploaded upon submission of your application. Organizational Letters of Support must be uploaded into the “Attachments” section of the application. *The Council will not contact references for their letters*.
13. In order to submit your application, scroll to the bottom of the left navigation pane and select “Application Submitted.”
14. 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 7 - 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 NIMH Data Archive (NDA) if compatible with the design of the pilot project. The NDA has sample language for informed consent, as well as other resources.