New Jersey Governor's Council for

Medical Research and Treatment of Autism

New Jersey Department of Health

Request for Applications (RFA)

I. Clinical Research Pilot Projects

II. Basic Research Pilot Projects

III. Postdoctoral and Graduate Student Fellowship Program

IMPORTANT DATES:
Publication of RFA: September 3, 2019
Letter of Intent due (required): October 22, 2019
Application due: December 2, 2019
Notification of award: April 1, 2020
Project start date: May 1, 2020

PO Box 360, Trenton, NJ 08625-0360
Telephone 609-633-8740 Fax 609-943-4213 www.nj.gov/health/autism/

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INTRODUCTION

Autism spectrum disorder (ASD) is a group of complex neurodevelopmental disabilities defined by significant impairments in social interaction and communication as well as the presence of unusual or restricted behaviors and interests. These disorders, for which there is presently no cure and only limited treatments, generally have lifelong effects. The Centers for Disease Control and Prevention (CDC) estimates an average of 1 in 59 children in the United States has ASD, as reported in the **MMWR Surveillance Summaries, April 27, 2018/ Vol. 67 / No. 6**. As part of the same CDC study, the prevalence rate for the New Jersey sites was established at 1 in 34 children, the highest among the sites studied. The prevalence of ASD continues to increase in New Jersey. New Jersey's higher rates can be attributed in part to increased awareness and detection.

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

As per P.L. 2007, c.174 monies from one-dollar surcharges on fines and penalties from traffic violations are deposited by the State Treasurer into the Autism Medical Research and Treatment Fund to sponsor the Council to fund autism research and treatment in the State of New Jersey. Currently, the Council funds 18 clinical research grants, 4 basic science research grants,2 autism medical homes grants, and the New Jersey Autism Center of Excellence (NJACE).

The Council is in the New Jersey State Department of Health. The Department is responsible for releasing and administering all Council Grant Programs and is responsible for ensuring that grantees are in compliance with all regulatory, fiscal, programmatic and administrative matters according to the New Jersey Department of Health guidelines. To learn more about the work of the Governor's Council for Medical Research and Treatment of Autism please visit http://www.state.nj.us/health/autism/index.shtml.

The Department of Health 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 the health sector and where people live, work and play. The Departments' focus is on improving health outcomes for New Jersey residents at all life stages. Core activities are to use data to drive measurable health improvements, identify and target vulnerable populations for

interventions, to eliminate health disparities and promote collaboration across sectors to develop health policies and achieve health equity.

PROGRAM DESCRIPTION AND GUIDELINES

The purpose of this grant program is to support research capable of advancing the mission of the Council and offer funding for three initiatives: Clinical Research Pilot Projects, Postdoctoral and Graduate Student Research Fellowships and Basic Science Research Pilot Projects. Applicants for the Clinical Research Pilot Projects and the Basic Research Pilot Projects can apply for a one-year award of $200,000, or a two-year award of $200,000 per year for a total of $400,000. Postdoctoral Fellowships are two-year awards of $65,000 per year for a total of $130,000. Graduate Student Fellowships are two-year awards of $30,000 per annum. A total of up to $2,800,000 will be awarded to for all three initiatives. At the end of the grant, grantees may request no more than one no-cost extension for the maximum of one year.

The awards for this funding cycle are intended to promote ASD research in New Jersey, not to provide long-term support. The data and results gained by using the Council's 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 may not apply for both a Fellowship and a Clinical Research or a Basic Science Research grant in the same cycle. Given the competitive nature of these grants, applicants are encouraged to submit one well-developed and responsive application as opposed to multiple applications.

All non-funded applicants in any given grant cycle are eligible to resubmit once in the next application cycle. The applicant must revise the non-funded application based on reviewer feedback. All reapplications will be reviewed as new competing proposals.

Clinical Research Pilot Projects (CAUT20APL)

The Clinical Research Pilot Projects will aim to improve the physical and/or behavioral health and well-being of individuals with ASD. The projects will address one of the objectives listed in Appendix 1 "Selected IACC Objectives", which constitute a subset of the Interagency Autism Coordinating Committee (IACC) 2016-2017 Strategic Plan.

This grant program aims 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 projects that have been judged to have the potential to impact persons with ASD directly or attract grant support from

federal or other organizations particularly any that promote health equity for vulnerable populations; i.e. disabled, LGBTQ, racial and ethnic minorities.

The Council will fund Clinical 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; and 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 NIH as clinical research and addressing an objective from Appendix 1 will be considered for funding. NIH defines clinical research as:

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 (CAUT20BSP)

The 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 will address one of the objectives listed in Appendix 1 "Selected IACC Objectives", which constitute a subset of the Interagency Autism Coordinating Committee (IACC) 2016-2017 Strategic Plan.

This RFA is open not just to existing autism researchers, but 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. And, if the research will identify and target vulnerable populations for interventions to eliminate health disparities, it should also be noted in the statement. As part of their commitment to autism research, applicants should also describe plans for public outreach on how basic science informs the understanding of autism and early child development.

Council 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 the NIH and biomedical and international funding sources.

The detailed elements required in the narrative are described in Appendix 3.

Postdoctoral and Graduate Student Fellowships (CAUT20AFP)

The Council welcomes investigators with new approaches to examine the origins, mechanisms, and treatment of Autism Spectrum Disorders (ASD). The fellowships are intended to promote collaboration among researchers currently working on ASD-related projects and to encourage researchers in other fields to enter this compelling area of research. Projects will address one of the objectives listed in Appendix 1, which constitute a subset of the Interagency Autism Coordinating Committee (IACC) 2016-2017 Strategic Plan. The data and results gained should allow investigators from New Jersey to develop strong proposals for submission to the NIH and biomedical and international funding sources. Preference will be given to projects judged to have the potential for attracting grant support from federal or other organizations particularly any that promote health equity for vulnerable populations; i.e. disabled, LGBTQ, racial and ethnic minorities.

Postdoctoral Fellowships are two-year awards of $65,000 per year provide an annual stipend of $50,000, a research allowance of $14,000, and a travel budget of $1,000. No part of the award may be used for institutional overhead or indirect costs. Non-research activities, such as teaching, may not occupy more than 10% of the fellow's time. Postdoctoral candidates must

hold a Ph.D., M.D., or equivalent graduate degree prior to activation of fellowship, and must be accepted for postdoctoral training under the supervision of an appropriate mentor at a qualifying academic research institution in New Jersey.

Graduate Student Fellowships are two-year awards of $30,000 per year. They provide an annual stipend of $25,000, a research allowance of $4,000, and a travel budget of $1,000. No part of the award may be used for institutional overhead or for tuition. Applicants must be full-time graduate students in residence in a proposed course of study directly related to autism. Students must begin study in the semester following fellowship activation unless special permission is received prior to activation date. The Council prefers to support graduate student candidates who have completed the first year of graduate study and are concentrating on research projects at least 80% of their time. Applicants may serve as teaching assistants while holding a Graduate Student Fellowship without special permission.

Fellowships will not be awarded to applicants with other simultaneous or overlapping fellowships. A candidate may not apply for a Fellowship and a Clinical or Basic Research grant in the same grant cycle. If a first-year fellow is awarded a Clinical or Basic Science Research Grant, funding will be contingent upon cancellation of the second year of the fellowship.

Funding for the second–year of the Fellowship is contingent upon the availability of funds, the submission and approval of a Progress Report, and a recommendation from the mentor. The Progress Report must be favorably reviewed by an independent scientific merit review panel and recommended to the Autism Council for continued funding. Postdoctoral and Graduate Student Fellowship awards will begin on or about May 1, 2020. A Final Narrative Report is required and must be submitted to the office within 60 days of termination of a Fellowship. The detailed elements required in the narrative are described in Appendix 4.

ELIGIBILITY

Applicants cannot conflict 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.

Qualifying Individuals

Individuals with the skills, knowledge, and resources necessary to carry out the proposed program as the Principal Investigator are invited to work with their organizations to develop an application. **Applicants must be affiliated with 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. Applicants are encouraged to collaborate with researchers in the United States or out of the country who could contribute additional professional expertise or consultation. The structure of the collaborative arrangement should be described in the application.

Qualifying Entities

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

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 grantees.

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 sponsored 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.

Grantees 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.

FUNDING AVAILABILITY, OBLIGATIONS AND DEADLINES

Approximately $2,800,000 will be made available for the Clinical Research Pilot Projects, the Basic Research Pilot Projects, and the Postdoctoral and Graduate Student Fellowships. Maximum funding for the Clinical Research Pilot Projects and the Basic Research Pilot Projects is $200,000 per year including a 15% maximum for indirect costs. The Postdoctoral Research Fellowships are two-year awards of $65,000 per year including the stipend, research allowance and travel; no part of the award may be used for institutional overhead or indirect costs. The Graduate Student Fellowships are two-year awards of $30,000 per year including a stipend of $25,000, a research allowance of $4,000, and a travel budget of $1,000. No part of the award may be used for institutional overhead or tuition. Fellowships will not be awarded to applicants with other fellowship awards.

Letters of intent are required and are due October 22, 2019. Applications will be submitted by December 2, 2019. The anticipated start date is May 1, 2020.

Eligibility requirements are stated in the eligibility section above. Multi-year awards are made through one-year contracts. Each funding award within the two-year period will be contingent upon the availability of funds. Support for the second year of all grants is contingent upon submission and approval of the first-year comprehensive progress report due by November 15, 2021. Progress reports must detail the actions towards meeting the yearly project objectives. Applicants will meet their stated objectives, or clearly demonstrate how they are moving towards achieving those objectives, as a condition of funding for the following year. Progress reports must be favorably reviewed by an external review panel, convened by the Office of the Executive Director, and recommended to the Council for continued funding. A final progress report is required within 60 days of termination of the grant.

Successful applicants must abide by all programmatic and fiscal requirements of the NJ Department of Health, 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.

LETTER OF INTENT

A Letter of Intent is required and is due by October 22, 2019. Although a letter of intent is not binding and does not enter into the review of a subsequent application, the information that it contains allows the Council staff to estimate the potential review workload and plan the review.

The letter of intent must include the following information:

1. Descriptive title of proposed project
1. The specific IACC question and objective being addressed (selected from Appendix 1)
2. Principal Investigator name, address, email and telephone number
3. Participating institutions and organizations
4. Title of the funding opportunity selected:
    a. Clinical Research Pilot Project (APL)
    b. Basic Science Research Pilot Project (BSP)
    c. Postdoctoral and Graduate Student Fellowship (AFP)
5. Brief overview of project (1-page maximum): Significance, aims and approach

Send the letter to NJGCA@doh.nj.gov. If you do not receive an acknowledgement of receipt within 2 business days, please call 609-633-8740.

APPLICATION SUBMISSION AND FAQs

During the application process, questions may be addressed to NJGCA@doh.nj.gov until November 25, 2019 The answers to questions from applicants will be posted on the Council website at www.nj.gov/health/autism under "Grant Opportunities/FAQs".

The Council will only accept applications submitted electronically through the New Jersey System for Administering Grants Electronically (SAGE) at www.sage.nj.gov by December 2, 2019. The detailed narrative questions for each grant program are described in **Appendices 2-4**.

After an applicant logs on to the SAGE, the applicant's Authorized Official must authorize the applicant as an approved user and assign the applicant to the grant before the applicant can access the application. Before logging on to SAGE applicants should refer to "Instructions for On-line Grant Applications" under "Grant Opportunities" on the Council's website (www.nj.gov/health/autism).

For the grant applications, character limits for the proposal abstract, proposal lay abstract and proposal narrative are included in SAGE. The character limits do not represent the expected length of the response. They are merely maximal lengths allowed in the online form.

Applicants should be cautious while utilizing the cut and paste function of most word processing programs to transfer text into narrative boxes within the SAGE application. The SAGE will not recognize certain formatting, including certain scientific notations, bullets, tabs, tables, graphs, and photographs. Therefore, in addition to completing the text boxes in SAGE, it is **required** to attach the full proposal (abstracts and narrative) with tables, charts and illustrations as a Word or PDF document, uploaded in the "Miscellaneous Attachment" section.

In many SAGE pages a "View PDF" button will be available that will automatically create a PDF. These dynamic PDFs can be printed or saved to your computer for reference. It is useful to review the PDF files for accuracy prior to submitting the application electronically.

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 two-step review process:

1. Administrative Review (Council office):

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

2. Scientific Merit Review (Independent Scientific Merit Review Panel)

Members of the Independent Scientific Merit Review Panel(s) will convene to evaluate all research grant applications. The Panel(s) will judge the applications on significance to ASD and feasibility (see details in Appendixes 5 and 6). The panels will assign scores to each application.

Funding decision

The results of the review will be forwarded to the Council, through the Executive Director, for final review and action. The Scientific Advisory Committee (SAC) will review the results of the Review Panels and may provide additional advice to the Executive Director and the Council. Based on that advice, 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, taking into account the mission of the Council 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).

RESULTS NOTIFICATION

All applicants including Principal Investigators and institutions will be formally notified of the outcome of their application at the conclusion of the selection process, anticipated to be no later than April 1, 2020. At that time, formal notification will be made to the institutions of successful applicants. Contracts will be initiated shortly thereafter by the NJ Department of Health. Non-funded applicants also will be notified. Blinded reviews will be provided to both funded and non-funded applicants; no further information shall be provided.

APPENDICES

Appendix 1 – Selected IACC objectives

QUESTION 1 HOW CAN I RECOGNIZE THE SIGNS OF ASD, AND WHY IS EARLY DETECTION SO IMPORTANT?

1. Reduce disparities in early detection and access to services.
2. Improve/validate existing, or develop new tools, methods, and service delivery models for detecting ASD in order to facilitate timely linkage of individuals with ASD to early, targeted interventions and supports.
3. Support research to understand the underlying biology of sex differences in ASD, possible factors that may be contributing to underdiagnosis, unique challenges that may be faced by girls/women on the autism spectrum, and develop strategies for meeting the needs of this population.

QUESTION 2 WHAT IS THE BIOLOGY UNDERLYING ASD?

1. Foster research to better understand the processes of early development, molecular and neurodevelopmental mechanisms, and brain circuitry that contribute to the structural and functional basis of ASD.
2. Support research to understand the underlying biology of co-occurring conditions in ASD and to understand the relationship of these conditions to ASD.
3.Support large-scale longitudinal studies that can answer questions about the development of ASD from pregnancy through adulthood and the natural history of ASD across the lifespan.

QUESTION 3 WHAT CAUSES ASD, AND CAN DISABLING ASPECTS OF ASD BE PREVENTED OR PREEMPTED?

1. Strengthen understanding of genetic risk and resilience factors for ASD across the full diversity and heterogeneity of those with ASD, enabling development of strategies for reducing disability and co-occurring conditions in ASD.
2. Understand the effects on ASD risk and resilience of individual and multiple exposures in early development, enabling development of strategies for reducing disability and co-occurring conditions in ASD.
3. Expand knowledge about how multiple environmental and genetic risk and resilience factors interact through specific biological mechanisms to manifest in ASD phenotypes.

QUESTION 4 WHICH TREATMENTS AND INTERVENTIONS WILL HELP?

1. Develop and improve pharmacological and medical interventions to address both core symptoms and co-occurring conditions in ASD.
2.Create and improve psychosocial, developmental, and naturalistic interventions for the core symptoms and co-occurring conditions in ASD.

3. Maximize the potential for technologies and development of technology-based interventions to improve the lives of people on the autism spectrum.

QUESTION 5 WHAT KINDS OF SERVICES AND SUPPORTS ARE NEEDED TO MAXIMIZE QUALITY OF LIFE FOR PEOPLE ON THE AUTISM SPECTRUM?

1. Reduce disparities in access and in outcomes for underserved populations.
2. Improve service models to ensure consistency of care across many domains with the goal of maximizing outcomes and improving the value that individuals get from services.

QUESTION 6 HOW CAN WE MEET THE NEEDS OF PEOPLE WITH ASD AS THEY PROGRESS INTO AND THROUGH ADULTHOOD?

1. Support research and implement approaches to reduce disabling co-occurring physical and mental health conditions in adults with ASD, with the goal of improving safety, reducing premature mortality, and enhancing quality of life.
2.Support research, services activities, and outreach efforts that facilitate and incorporate acceptance, accommodation, inclusion, independence, and integration of people on the autism spectrum into society.

QUESTION 7 HOW DO WE CONTINUE TO BUILD, EXPAND, AND ENHANCE THE INFRASTRUCTURE SYSTEM TO MEET THE NEEDS OF THE ASD COMMUNITY?

1. Expand and enhance the research and services workforce, and accelerate the pipeline from research to practice.

Appendix 2 – Abstracts and Narrative Questions – Clinical Research Pilot Projects (CAUT20APL)

Note: Concise, complete responses are encouraged. The character limits do not represent the expected length of the response. They are merely maximal lengths allowed in the online form.

Proposal Abstract: State the application's long-term objectives and specific aim(s), making reference to the project's focus on autism, and describe concisely the methods for achieving these 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. (4,000 characters maximum)

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 publications. (2,000 characters maximum)

Narrative:

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. (800 characters maximum)

B. **Significance:** Explain how this project has the potential to effect direct clinical 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, clinical care or public health be advanced? Briefly summarize how the project meets the definition of clinical research. (2,000 characters maximum)

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. Note that the relevance of the project to public health needs is more important than its innovation. (1,500 characters maximum)

D. **Approach, Experimental Design and Capability:** Clearly state the purpose and nature of the research project including (1) your plan to develop hypothesis driven research, when appropriate, as well as specific aims, (2) background and significance, (3) preliminary data (optional), (4) experimental design and research methods, including data collection methods and planned analyses potentially resulting in statistically sound conclusions for each specific aim. (48,000 characters maximum)

E. **ASD Knowledge:** 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. (1,500 characters maximum)

F. **Preliminary Data:** If applicable, discuss the PI's preliminary studies, data, and/or experience pertinent to this application. (3,000 characters maximum)

G. **Potential problems:** 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. (3,000 characters maximum)

H. **Additional Funding:** Briefly describe any past or current funding for this or similar research studies and how this study will move the work forward. (2,000 characters maximum)

I. **Literature:** Literature cited. (3,000 characters maximum)

J. **Research Subjects:** Describe your plan for recruiting and retaining patients. Include, as a "Miscellaneous Attachment" in SAGE, 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 "Criteria for Independent Scientific Review" in the Guidelines and address each of the criteria under "Research Subjects". (3,000 characters maximum)

K. **Environment:** 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. (3,000 characters maximum)
Note: Please attach a letter of support from a president, dean or other authority, as evidence of institutional support, labeled and attached as "Miscellaneous Attachments" in SAGE.

L. **Key Personnel:** 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 "Miscellaneous Attachment" in SAGE. (3,000 characters maximum)

M. **Experience:** 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. (2,000 characters maximum)

N. **Resource Sharing Plan:** Describe: (1) data that will be collected including clinical data, diagnostic data, and physiological measurements such as MRI, (2) description of what biospecimens will be collected, if applicable (3) if biospecimens will be collected, description of the data that will be derived from the biospecimens such as genotyping, sequence, metabolomic measures and proteomic measures (4) description of what data and/or biospecimens will be made available in NDAR, other databases or in a repository accessible to the research community, (5) a timetable for deposition of the data and/or biomaterials, and a time interval after which those data and materials can be released to the research community. (2,000 characters maximum)

O. **Yearly Project Objectives:** Describe the project's yearly objectives, the steps planned to accomplish these objectives and the methods and metrics used to evaluate successful completion (i.e. outcomes and deliverables) of yearly objectives. Provide benchmarks as needed. Yearly objectives will include but are not limited to process objectives such as hiring and training the necessary staff and obtaining IRB approval. Attach a realistic timeline for the entire project period showing key activities and responsible staff. Label charts and graphs and attach as "Miscellaneous Attachments "in SAGE. (3,000 characters maximum)

Appendix 3 – Abstracts and Narrative Questions – Basic Research Pilot Projects (CAUT20BSP)

Note: Concise, complete responses are encouraged. The character limits do not represent the expected length of the response. They are merely maximal lengths allowed in the online form.

Proposal Abstract: State the application's long-term objectives and specific aim(s), referring to the project's relationship to autism, and describe concisely the methods for achieving these 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 basic research 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 publications.

Narrative:

A. **IACC objective:** State the IACC objective (see the subset of IACC objectives in the funding priorities section above) that is addressed by the proposed project and summarize the expected outcomes. (800 characters maximum)

B. **Significance:** Explain how this project has the potential to further understand cellular and molecular principles as well as circuits that influence brain and gut development and function and may be impacted in autism. How will scientific knowledge, clinical care or public health be advanced? (2,000 characters maximum)

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. Note that the relevance of the project to public health needs is more important than its innovation. (1,500 characters maximum)

D. **Approach, Experimental Design, and Capability:** Clearly state the purpose and nature of the research project including (1) your plan to develop hypothesis driven research, when appropriate, as well as specific aims, (2) background and significance, (3) preliminary data (optional), (4) experimental design and research methods, including data collection methods

and planned analyses potentially resulting in statistically sound conclusions for each specific aim. (48,000 characters maximum)

E. **ASD Knowledge:** 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. (1,500 characters maximum)

F. **Preliminary Data:** If applicable, discuss the PI's preliminary studies, data, and/or experience pertinent to this application. (3,000 characters maximum)

G. **Potential problems:** 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. (3,000 characters maximum)

H **Additional Funding:** Briefly describe any past or current funding for this or similar research studies and how this study will move the work forward. (2,000 characters maximum)

I. **Literature:** Literature cited (3,000 characters maximum)

J **Environment:** 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 laboratory facilities, equipment and other physical resources. Describe participating and affiliated units, patient populations, geographical distribution of space and personnel, and consultative resources, as appropriate. Describe the proposed structure and the relationships with collaborators and consultants as related to the scientific objectives and project needs. (3,000 characters maximum)
Note: Please attach a letter of support from a president, dean or other authority, as evidence of institutional support, labeled and attached as "Miscellaneous Attachments" in SAGE.

L **Key Personnel:** 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 "Miscellaneous Attachment" in SAGE. (3,000 characters maximum)

M. **Experience:** 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. (2,000 characters maximum)

N. **Resource Sharing Plan:** Describe your resource sharing plan; explain how data will be collected and how it will be shared, if the research design is compatible with the collection of

the data necessary for inclusion in NDAR. Refer to Appendix 3 for further information. (2,000 characters maximum)

O. **Yearly Project Objectives:** Describe the project's yearly objectives, the steps planned to accomplish these objectives and the methods and metrics used to evaluate successful completion (i.e. outcomes and deliverables) of yearly objectives. Provide benchmarks as needed. Yearly objectives will include but are not limited to process objectives such as hiring and training the necessary staff and obtaining IRB approval. Attach a realistic timeline for the entire project period showing key activities and responsible staff. Label charts and graphs and attach as "Miscellaneous Attachments "in SAGE. (3,000 characters maximum)

Appendix 4 – Abstracts and Narrative Questions – Postdoctoral and Graduate Student Fellowships (CAUT20AFP)

Abstract of Research Plan: State the plan's long-term objectives and specific aims, making reference to the autism relatedness of the project, and describe concisely 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. (4,000 characters maximum)

Lay Abstract of Research Plan: Describe your research project in simple, non-technical language that is understandable by a person not trained in science. This abstract is meant to serve as a public description of the proposed research and, should the award be made, it will be used in press releases and various NJGCA publications. (2,000 characters maximum)

Proposal Narrative (32,000 characters maximum):

A. **Specific Aims:** Describe the specific aims of the project.

B. **Significance:** Explain how this project has the potential to effect direct clinical 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, clinical care or public health be advanced? Briefly summarize how the project meets the definition for either clinical research. State the IACC objective (see the subset of IACC objectives in the funding priorities section above) that is addressed by the proposed project and summarize the expected outcomes.

C. **Preliminary Data:** If applicable, discuss any preliminary data, and experience pertinent to this application.

D. **Experimental Design:** Clearly state the purpose and nature of the research project including (1) your hypothesis (2) background and significance, (3) experimental design and research methods, including data collection methods and planned statistically sound analyses for each specific aim.

E. **Literature:** Literature cited

Appendix 5 – Review Criteria – Clinical and Basic Research Pilot Projects (CAUT20APL and CAUT20BSP)

Grant applications will be judged on scientific and technical merit, relevance to the IACC priorities, the NJ ACE 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 consider the significance, innovation, approach, feasibility, personnel, environment, and budget as listed below in order to judge the likelihood that the proposed research will have a 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.

Significance:

- Is the research proposal relevant to the selected IACC priority?
- Does the research proposal address an important problem?
- Will the proposed project advance the current knowledge pool in ways that may improve clinical practice for patients with ASD?
- How will the successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventive interventions for ASD?
- 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 responsive to the Clinical Research program, does the project meet the NIH definition of clinical research (see page 5)?

Innovation (not required):

- Is the proposed research innovative, including novel concepts, approaches, and/or methods?
- Does the application challenge and seek to shift current research or clinical practice paradigms?

Approach, Experimental Design and Capability:

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the proposed project?
- Does prior research and theory provide a rational basis for the proposed project?

- 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 the design have adequate methodological quality and power to increase the likelihood of producing statistically sound conclusions?

Environment, Key Personnel:

- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- If applicable, 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?
- Do the Investigators and key staff have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Research Subjects (for all Clinical Research Pilot Projects and applicable Basic Research Pilot Projects):

- Is the availability of subjects adequate?
- 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.
- 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?

Yearly project objectives:

- Are the objectives detailed and numerous enough to assess progress and identify emerging issues?
- Do the final objectives address the overarching goal of the project?

Resource Sharing Plans:

- Is the resource sharing plan acceptable?

Budget:

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

Appendix 6 – Review Criteria – Postdoctoral and Graduate Fellowship Research Program (CAUT20AFP)

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

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

The reviewers will consider the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial 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. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move the field forward.

Significance:

- Is the research proposal relevant to the selected IACC priority?
- Does the research proposal address an important problem?
- Will the proposed project advance the current knowledge in ways that may improve clinical practice for patients with ASD?
- How will the successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventive interventions for ASD?
- 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 responsive to the Clinical Research program, does the project meet the NIH definition of clinical research (see page 7)?

Innovation:

- Is the proposed research innovative, including novel concepts, approaches, and/or methods?
- Does the application challenge and seek to shift current research or clinical practice paradigms?

Approach, Experimental Design and Capability:

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the proposed project?
- Does prior research and theory provide a rational basis for the proposed project?
- 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 the design have adequate methodological quality and power to increase the likelihood of producing statistically sound conclusions?

Training:

- How do the training plan and mentorship from the advisor and two or more mentors align with the applicant's career goals?
- What is the likelihood of the applicant developing into an independent ASD researcher based on the training and mentoring plans and the proposed projects?

Environment:

- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigator adequate for the project proposed?

Research Subjects (if applicable):

- Is the availability of subjects adequate and system of education and protection of subjects appropriate?
- 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.
- Are the plans for inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Budget:

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