New Jersey Governor's Council for Medical Research and Treatment of Autism

New Jersey Department of Health

The NJ Autism Center of Excellence (NJ ACE)

Request for Applications (RFA)

I. Clinical and Translational Research Pilot Projects

II. Postdoctoral Fellowship Research Program

IMPORTANT DATES:

Publication of Request for Applications: August 20, 2018
Letter of Intent due date (required): October 4, 2018
Application due date: November 19, 2018 (3 PM)
Notification date: May 1, 2019
Anticipated start date: June 1, 2019

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I. Clinical and Translational Research Pilot Projects

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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 27 clinical research grants, 4 basic science research grants and 5 autism medical homes grants.

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 following 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.

PROGRAM DESCRIPTION AND GUIDELINES

The purpose of this grant program is to support research capable of advancing the mission of the Council and offers funding for two initiatives: Clinical and Translational Research Pilot Projects and Postdoctoral Research Fellowships. Applicants for the Clinical and Translational 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 up

to $65,000 per year for a total of $130,000. A total of up to $1,500,000 will be awarded to both initiatives.

The awards for this funding cycle are intended to promote clinical and translational research and fellowships, 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 submit more than one application but may not apply for both a Postdoctoral Fellowship and a Clinical and Translational 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 and Translational Research Pilot Projects (CAUT19APL)

The Clinical and Translational Research Pilot Projects grantees will conduct research projects with the goal to improve the physical and/or behavioral health and well-being of individuals with ASD through the application of research findings. 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. Refer to Appendix 1 to select a short or long-term objective to address for research project.

If applicable, the applicant should also reference the Healthy People 2020 objective MICH-29 "Increase the proportion of young children with an autism spectrum disorder (ASD) and other developmental delays who are screened, evaluated, and enrolled in early intervention services in a timely manner". Please refer to the following site for additional information: http://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives.

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 and translational inter- and multidisciplinary teams. Preference will be given to projects that have been judged to have the potential for attracting grant support from federal or other organizations.

The Council will fund Clinical and Translational 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; and investigation of novel scientific ideas, model systems, tools, agents, targets and technologies that have the potential to substantially advance autism research.

Translational Research Pilot Projects are studies (1) that apply discoveries generated during research in the laboratory, and in preclinical translational studies, to the development of trials and (2) studies in humans on research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science. If the research project accelerates the application of findings across the levels (T1, T2, T3 and/or T4) of human research, it is considered translational research. For definitions of translational research (T1, T2, T3, T4) please refer to: http://catalyst.harvard.edu/pathfinder/t1detail.html and http://www.ctsi.ucla.edu/education/pages/ctsiworkshops "Building a Foundation in Research at UCLA" *Navigating the UCLA CTSI* Presentation (Slides #7-#12).

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

Postdoctoral Research Fellowships (CAUT19AFP)

The Council welcomes investigators with innovative approaches to examine the origins, pathophysiology and treatment of Autism Spectrum Disorders (ASD). The intent in funding fellowships is to encourage young researchers 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 that have been judge to have the potential for attracting grant support from federal or other organizations.

If applicable, the applicant should also reference the Healthy People 2020 objectives MICH-30 "Increase the proportion of children, including those with special health care needs, who have access to a medical home" and MICH-31 "Increase the proportion of children with special health care needs who receive their care in family-centered, comprehensive, and coordinated systems." Please refer to the following site for additional information: http://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives

The two-year Postdoctoral Fellowships 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. Institutions may supplement stipends, but not with other full-time fellowship awards.

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

A candidate may not apply for a NJGCA Postdoctoral Fellowship and a NJGCA Clinical and Translational Research grant in the same grant cycle. Non-research activities, such as teaching, may not occupy more than 10% of the fellow's time. Second year Postdoctoral Fellowship funding is contingent upon the availability of funds and upon the submission and successful review 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 NJGCA for continued funding.

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 State medical school, 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.

A. The Council supports compliance with NIH regulations, Office for Human Research Protections (OHRP) 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 OHRP, the IRB overseeing the research, the associated institution and the laboratory's senior scientist.

B. 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.

C. Grantees are encouraged to share data for studies in keeping with the Genomic Data Sharing Policy (https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing).

Consent language:

The National Database for Autism Research (NDAR) has developed and makes available sample language for inclusion in an informed consent:
http://ndar.nih.gov/contribute_informed_consent.html

Sharing human data via NDAR:

Submission of data to NDAR is strongly encouraged if compatible with the design of the pilot project. Please see Appendix 2 (Sharing Human Data via National Database for Autism Research (NDAR) for details. Following the NIH Genomic Data Sharing (GDS) policy, sharing of genomic information is encouraged, as applicable, for studies with 100 or more subjects. For additional information please refer to https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing.

FUNDING AVAILABILITY, OBLIGATIONS AND DEADLINES

A total of up to $1,500,000 will be made available for the Clinical and Translational Research Pilot Projects and the Postdoctoral Research Fellowships. For the Clinical and Translational Research Pilot Projects, maximum funding is up to $200,000 per year including direct costs and 15% maximum for indirect costs. For the two-year Postdoctoral Research Fellowships, maximum funding is up to $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 anticipated start date is July 1, 2019. Eligibility requirements are stated in the eligibility section above. In some cases, the Office of the Executive Director may suggest modifications to the yearly project objectives or require additional objectives before awarding the grant.

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 comprehensive progress report due by February 14, 2020. 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 a review panel, convened by the Office of the

Executive Director, and recommended to the Council for continued funding. If grantees meet some but not all yearly project objectives, Council reserves the right to bring in outside reviewers to assess whether progress is adequate and, as may be necessary, to design a remediation plan. 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 one-page Letter of Intent is required and is due by October 4, 2018. 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
2) The specific IACC question and objective being addressed (selected from those in Appendix 1).
3) Name, address, email and telephone number of the Principal Investigator
4) Participating institutions and organizations
5) Title of the funding opportunity – Clinical and Translational Research Pilot Project (APL); OR Postdoctoral Fellowship (AFP)
6) Overview of project (1 page) – Significance, aims and approach

The letter can be sent 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 toNJGCA@doh.nj.gov until November 7, 2018. The answers to questions from applicants will be posted weekly on the Council website at www.nj.gov/health/autism under “Grant Opportunities/FAQs”.

The Council will only accept for review applications submitted electronically through the New Jersey System for Administering Grants Electronically (SAGE) at www.sage.nj.gov . The Council will not accept grant applications sent by telefacsimile.

After an applicant logs on to the SAGE, the applicant's Authorized Official must authorize the 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). The full list of required SAGE forms is on the Council's website at www.nj.gov/health/autism under "Grant Opportunities/SAGE".

For the grant applications, character limits for the proposal abstract, proposal lay abstract and proposal narrative are included in SAGE. To ensure equity among applications, character limits cannot be exceeded. Applicants should be cautious while utilizing the cut and paste function of most word processing programs to transfer text into narrative boxes within the SAGE application. The SAGE will not recognize certain formatting, including tables, graphs, photographs, bullets, certain scientific notations and tabs. 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.

The deadline for the electronically submitted grant applications is November 19, 2018 (3 PM). In addition, the Council must receive from the applicant **one signed hard copy of the application** at the Council's office by November 21, 2018. No exceptions will be made.

Please use the following address for all regular and overnight mail deliveries:
New Jersey Department of Health
New Jersey Governor's Council for Medical Research and Treatment of Autism
225 East State Street
Second Floor-West
PO Box 360
Trenton, NJ 08608

GRANT 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 relevant Clinical, Translational and Postdoctoral Fellowship Research grant applications. The Panel(s) will judge the applications on the criteria listed in Appendix 5 for Clinical and Translational Research Pilot Projects and Appendix 6 for Postdoctoral Fellowship Research. The Council will make the final funding recommendations, considering the mission of the Council and the potential impact of the grant on the understanding, prevention, evaluation and treatment of ASD.

The panels will assign scores to each application. 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. 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 organizations/institutions will be formally notified of the outcome of their application at the end of the selection process, anticipated to be no later than May 1, 2019. At that time, formal notification will be made to the institutions of successful applicants and contracts will be initiated shortly thereafter by the Council. Non-funded applicants also will be notified. There is no appeals process.

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. Strengthen the evidence base for the benefits of early detection of ASD.
2. Reduce disparities in early detection and access to services.
3. 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.
4. 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 – Sharing Human Data via the National Database for Autism Research (NDAR)

To advance the goal of widespread data sharing among ASD researchers, investigators funded under the NJ ACE Pilot Project grant program are strongly encouraged to share those data via the NIH NDAR (http://ndar.nih.gov), if compatible with the design of the pilot project. Established by the NIH, NDAR is a secure bioinformatics platform for scientific collaboration and data sharing that enables the effective communication of detailed research data, tools, and supporting documentation. NDAR houses research data of all types (genetic, imaging, clinical assessment, etc.) from human subjects involved in ASD studies, and is currently on track to receive data from tens of thousands of such subjects. NDAR's first data release occurred in November 2010, making mostly clinical assessment data from over 10,000 research subjects available to qualified investigators. It is expected that in the next several years, ASD data from more than 90% of new investigations will be available in or through NDAR.

NDAR links data across research projects through its Global Unique Identifier (GUID) and Data Dictionary. Investigators funded under these Grant Programs will be able to use these technologies to submit data to NDAR. Patient data will be collected according to the NDAR standards, including the use of the NDAR Data Dictionary and Global User ID (see https://ndar.nih.gov/standards.html). To accomplish this objective, it will be important to formulate a) an enrollment strategy that will obtain the information necessary to generate a GUID for each participant, and b) a budget strategy that will cover the costs of data submission. The NDAR web site (https://ndar.nih.gov/contribute.html) provides tools to help investigators develop appropriate strategies, including: a list of critical steps in the data submission process, including informed consent language and GUID generation; and a customizable Excel worksheet to estimate cost. The NDAR Data Sharing Policy (https://ndar.nih.gov/policies.html) is available for review on the NDAR web site. NDAR staff will work with investigators to help them submit data types other than phenotypic, genetic, or imaging. For answers to frequently asked questions and how to contact the NDAR Manager, please see: http://ndar.nih.gov.

Appendix 3 – Abstracts and Narrative Questions – NJ ACE Clinical and Translational Research Pilot Projects (CAUT19APL)

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 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 Selected IACC Objectives in Appendix 1 that is addressed by the proposed project and summarize the expected outcomes. If applicable, explain how the research is relevant to Healthy People 2020 objective MICH-29 "Increase the proportion of young children with an autism spectrum disorder (ASD) and other developmental delays who are screened, evaluated, and enrolled in early intervention services in a timely manner". (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 for either clinical research or translational 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)

P. **Web-based applications:** Briefly describe any experience with a web-based application for sharing documents and other information. (1,500 characters maximum)

Q. **Translational Nature:** If applicable, include a brief paragraph on the translational aspects of your application. If applicable, briefly describe the cost-effectiveness of the clinical approach being tested. (2,000 characters maximum)

Appendix 4 – Abstracts and Narrative Questions – Postdoctoral Fellowship Research Program (CAUT19AFP)

Abstract of Research Plan: State the plan's long-term objectives and specific aims, referring 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 or translational 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. If applicable, explain how the research is relevant to Healthy People 2020 objective MICH-29 "Increase the proportion of young children with an autism spectrum disorder (ASD) and other developmental delays who are screened, evaluated, and enrolled in early intervention services in a timely manner".

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 – Criteria for Independent Scientific Review – Clinical and Translational Research Pilot Projects (CAUT19APL)

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:

- 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 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, the mission of NJ ACE, and if applicable, to Healthy People 2020 objective MICH-29?
- 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?
- Does the project meet the NIH definition of clinical research (see page 5)?

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?

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:

- Is the availability of subjects adequate and system of education and protection of subjects appropriate?
- For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the Scientific Merit Review Panel (Panel) will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 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.
- For research in one of the six categories that are exempt under 45 CFR Part 46, the Panel will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.
- 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?

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 NJ ACE?

Resource Sharing Plans:

- Are the plans to share data and other resources, or the rationale for not sharing, reasonable?

Translational Research:

- If applicable, comment on the potential of the project to impact human health or take a positive step in the pathway to such an impact.

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 – Criteria for Independent Scientific Review – Postdoctoral Fellowship Research Program (CAUT19AFP)

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 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, the mission of NJ ACE, and if applicable, to Healthy People 2020 objective MICH-29?
- 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?
- Does the project meet the NIH definition of clinical research (see page 5)?

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?
- For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the Scientific Merit Review Panel (Panel) will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 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.
- For research in one of the six categories that are exempt under 45 CFR Part 46, the Panel will evaluate: 1) the justification for the exemption, 2) human subjects' involvement and characteristics, and 3) sources of materials.
- 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?