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

Department of Health

The NJ Autism Center of Excellence (NJ ACE)

Request for Applications (RFA)

I. Clinical Research Pilot and Translational Research Pilot Projects
And
II. Autism Health Needs Medical Homes Pilot Projects

IMPORTANT DATES:

Publication of Request for Applications (RFA): September 9, 2015
Letter of Intent due date (required): November 12, 2015
Application due date: December 11, 2015 (3 PM)
Notification date: June 1, 2016
Anticipated start date: June 30, 2016

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TABLE OF CONTENTS

INTRODUCTION

Autism Spectrum Disorder (ASD) is a neurobiological disorder that becomes evident during early childhood. ASD impacts a person's social and communication skills. The prevalence of ASD may be increasing. The Centers for Disease Control and Prevention (CDC) estimates that an average of 1 in 68* children in the United States has ASD. The prevalence rate for the New Jersey sites was established at 1 in 45* children. ASD is more common than previously thought and there is presently no cure and only limited treatments. Generally ASD has lifelong effects.

The Governor's Council for Medical Research and Treatment of Autism (Council) was created by State appropriation in 1999 and has been issuing research, clinical and educational enhancement grants to public and private nonprofit entities since 2000. In 2012, the Council established the New Jersey Autism Center of Excellence (NJ ACE). The NJ ACE currently consists of (a) a Coordinating Center, (b) three Clinical Research Program Sites, (c) twenty-one Clinical and Translational Research Pilot Projects and (d) three Autism Health Needs Medical Homes Pilot Projects. 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.

As part of its enabling legislation, the Executive Director of the Council has the responsibility for establishing a Scientific Advisory Committee (SAC). The SAC includes three biomedical research scientists with demonstrated achievements in biomedical research relating to autism and two medical clinicians whose practice is primarily devoted to the treatment of people with autism. The SAC identifies and makes recommendations, through the Executive Director, to the Council regarding grants. These recommendations by the SAC are intended as guidance to the deliberations of the Council, which is responsible for decisions on funding of programs and grants.

As per P.L. 2007, c.174, monies from $1 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.
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.

*Reported in the MMWR Surveillance Summaries, March 28, 2014/63 (SS02; 1-21).

PROGRAM GOALS AND OBJECTIVES

The purpose of this grant program is to support pilot projects capable of advancing the mission of the New Jersey Autism Center of Excellence (NJ ACE). The mission of the NJ ACE is to "research, apply and advance best practices in the understanding, prevention, evaluation and treatment of autism spectrum disorder (ASD), enhancing the lives of individuals across their lifespans".

This grant program offers funding for two initiatives; Clinical and Translational Research Pilot Projects and Autism Health Needs Medical Homes Pilot Projects. Special consideration will be given to those applicants for the Autism Health Needs Medical Homes Pilot Projects who address the needs of adolescents and young adults.

Clinical and Translational Research Pilot Projects

The first initiative is the Clinical and Translational Research Pilot Projects (one or two year awards). The 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 short- or long-term objectives listed in Appendix 1 "Subset of IACC Objectives", which constitute a subset of the Interagency Autism Coordinating Committee (IACC) 2013 Strategic Plan Update.

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

Community engagement is encouraged and could foster collaborative research partnerships and enhance public trust in clinical and translational research. Community engagement is the bidirectional interaction between community stakeholders and research investigators. Investigators are encouraged to engage community in their research and build trust with the communities and populations being studied, as well as engage the community to contribute to the quality of study designs, methods and dissemination of findings. Organizations and agencies, including the CDC, National Institutes of Health (NIH) and Health Resources and Services Administration (HRSA) are becoming increasingly involved in supporting community engagement and community-engaged research and in promoting its use to solve some of the more challenging problems in healthcare and public health.

Council awards for this funding cycle are intended to promote clinical and translational research, 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 NIH and biomedical research foundations.

Autism Health Needs Medical Homes Pilot Projects

The second initiative is a grant program offering funding for Autism Health Needs Medical Homes Pilot Projects. Grantees that are successful in accomplishing the goals of the two-year project will be eligible to apply for three-year grants for expansion and continued implementation of their Autism Health Needs Medical Home, pending the availability of funds.

The goal of the Autism Health Needs Medical Homes Pilot Projects is to improve the overall health outcomes of people with autism, including but not limited to the physical health of children. Three projects were funded in the FY15 grant cycle, all addressing the needs of young children. In recognition of the need for autism medical homes for adolescents and young adults, special consideration will be given in this RFA to applicants addressing these populations. The Autism Health Needs Medical Homes Pilot Projects focus on reducing the unmet needs for specialty services for people with autism by bringing together primary care providers with specialists and ASD service providers to treat the whole person. The Autism Health Needs Medical Homes Pilot Projects' intent is to improve the quality of and access to services for children, adolescents and young adults and their families, including but not limited to: primary, sub-specialty, diagnostic, behavioral, cognitive, developmental, neurological, psychiatric and prevention/wellness care.

With the understanding that building relationships and integrating the principles of the medical home is an ongoing and complex process, a priority for this pilot project is in defining the roles of and coordination of services among project partners, specifically those providing diagnostic and/or treatment services.

The success of the project is largely dependent upon the relationship established between the primary care provider, the patient and the family. Input from the families/caregivers is essential in identifying the various types of clinicians to be involved in the project, from general pediatricians to other primary care clinicians as relevant to the program to subspecialty providers and professionals providing diagnostic and/or treatment services for people with autism.

Applicants will describe their project's yearly objectives, the steps planned to accomplish the objectives, benchmarks and the methods and metrics used to evaluate successful completion (i.e. performance measures/outcomes and deliverables) of yearly objectives. The specific project requirements are listed in Appendix 6 and the abstract and narrative questions in Appendix 7.

The National Center for Medical Home Implementation (NCMHI) is a source of information for those interested in examples of medical home models and resources. A resource entitled "A Retrospective Look at Programs and Initiatives Toward a Family-Centered Medical Home for Every Child and Youth, 2008-2013" was recently published by the NCMHI and can be found at the NCMHI website: http://www.medicalhomeinfo.org/about/

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.
Applicants are advised to read the description of the NJ ACE Coordinating Center (see Appendix 2). Grantees will participate in the Center's services, as applicable.

FUNDING PRIORITIES

I. Clinical and Translational Research Pilot Projects

For purposes of this RFA, only projects defined by NIH as clinical research 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

If the clinical 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).

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.

II. Autism Health Needs Medical Homes Pilot Projects

Only applicants with Letters of Support from key partners demonstrating commitment to success will be considered for funding. Applicants are encouraged to review the NCMHI website at http://www.medicalhomeinfo.org/about/, as previously mentioned, for examples of medical home models and resources.

ELIGIBILITY

Qualifying Individuals

Individuals with the skills, knowledge, and resources necessary to carry out the proposed program as the Principal Investigator are invited to work with their organizations to develop an application. Applicants must be affiliated or become so with a New Jersey State medical school, academic institution, research organization or 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 submitting for the Clinical and/or Translational Research Pilot Projects are encouraged to collaborate with clinical sites in New Jersey to ensure sufficient patient recruitment. Applicants are further 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 academic institution, research organization, public or private non-profit entity, located in the State of New Jersey, 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.

For the Autism Health Needs Medical Homes Pilot Projects the applicant may be (1) a New Jersey non-profit organization comprised of primary care physicians and specialists who collaborate to improve the health of individuals with autism by providing quality services that are family-centered, accessible and comprehensive, within a coordinated system of care (2) a New Jersey non-profit organized as a legal

entity by interested parties for this RFA or (3) a single lead non-profit organization with multiple partner organizations.

Applicants cannot be in 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.

Clinical and Translational Pilot Projects – Additional Information

Applicants should indicate whether their project focuses on translational or clinical research. Applicants may apply for both a Clinical Research Pilot Project and a Translational Research Pilot Project grants; however, the same project cannot be funded twice. Given the competitive nature of these grants, applicants are encouraged to submit one well-developed and responsive application as opposed to multiple applications. It is anticipated that future funding opportunities will be made available through the Council. As described above, all research projects must meet the NIH definition of clinical research.

The Council will fund Clinical Research Pilot Grants with an emphasis on encouraging (1) experienced investigators to pursue a new direction 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.

The Council will fund Translational Research Pilot Projects with consideration for (1) studies that apply discoveries generated during research in the laboratory, and in preclinical 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.

Applicants for both the Translational and Clinical Research Pilot Projects 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.

Applicants for research projects are strongly advised to read the description of the NJ ACE Coordinating Center (see Appendix 2) to develop a clear understanding of their relationship to the Coordinating Center and expected contributions to the NJ ACE.

Sharing Human Data via the National Database for Autism Research (NDAR)

Submission of data to NDAR is strongly encouraged if compatible with the design of the pilot project. Please see Appendix 3 for details. Following the newly release 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 http://gds.nih.gov/03policy2.html

Protection of Human Subjects and Genomics Information

Compliance with NIH regulations for the protection of human subjects, and 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 newly released Genomic Data Sharing Policy (http://gds.nih.gov/03policy2.html)

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

FUNDING AVAILABILITY, OBLIGATIONS AND DEADLINES

A total of up to $6,000,000 will be made available for the Clinical Research, the Translational Research and the Autism Health Needs Medical Homes Pilot Projects. Applicants for the Clinical and Translational Research Projects may apply for a one-year or two-year award. Applicants for the Autism Health Needs Medical Homes Pilot Projects will apply for two-year awards. Maximum funding is up to $200,000 per year (total of $400,000 for two year grants), including direct and indirect costs (15% maximum for the latter). The anticipated start date is June 30, 2016.

Eligibility requirements are stated in the eligibility section above. Successful applicants must abide by all programmatic and fiscal requirements of the NJ Department of Health.

The application must present the detailed yearly project objectives that will demonstrate progress. 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 first year comprehensive progress report due by April 14, 2016. 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.

Applicants must comply with the following to qualify for a grant:

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 November 12, 2015. 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) For Clinical and Translational Research Projects, list the specific IACC question and objective (selected from the subset listed in Appendix 1) for the research project.
3) Name, address, email and telephone number of the Principal Investigator
4) Participating institutions and organizations
5) Title of the funding opportunity – Autism Pilot Projects 2016 (Clinical/Translational Research Pilot Projects) or Autism MED Pilot Projects 2016 (Autism Health Needs Medical Homes Pilot Project)
6) Overview of project (1-2 pages) - significance, aims and methods

The letter can be sent to NJGCA@doh.state.nj.us. 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.state.nj.us until December 1, 2015. 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).

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. In addition to completing the text boxes in SAGE, it is recommended to attach the full proposal (abstracts and narrative) as a Word document with tables, charts and illustrations as a "Miscellaneous Attachment".

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

The deadline for the electronically submitted grant applications is **3:00 PM on Friday December 11, 2015**. In addition, the Council must receive from the applicant **two hard copies of the application** (one being a signed original) at the Council's office by 3:00 PM on Wednesday December 16, 2015. 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

APPLICATION FORMS IN SAGE

The following forms are included in the SAGE application. Grant applications that do not include all of the required information will be returned to the applicant without further consideration.

DHSS Organization Information Review Page

Application Summary-Select Cost reimbursement for Preferred Payment Plan

Project Location

Research Assurance Information

Written Response to Reviewers' Critiques: Applicants who are reapplying for a grant are required to complete this section by addressing the critiques of the original application.

Proposal Abstract

Proposal Lay Abstract

Narrative: Projects narrative questions are listed in **Appendix 4 (Clinical and Translational Research Pilot Projects and Appendix 7 (Autism Health Need Medical Homes Pilot Projects**

Biographical Sketch: For each of the key personnel list: (1) Education/Training (Institution, location, degree, year(s) and field of study); (2) Position and Honors, Awards and Other Professional Activities, (3) Selected Peer-reviewed Publications, (4) Ongoing Research Support and (5) Completed Projects.

Other Support: For each of the key personnel list (1) active support, (2) applications and proposals pending review or funding, (3) applications and proposals planned or being prepared for submission. See the SAGE for specific information required for each category.

Resources and Environment

Collaborative Arrangements: If applicable, describe the involvement of collaborators in the proposed project. Attach copies of letters from the collaborators, including time commitments and agreed upon responsibilities.

Budget Schedules A – C: Full and part-time personnel costs, personnel costs with no fringe, consultant services cost and other cost categories. For each schedule entered and saved a justification must be completed. Refer to "Related Forms" at the bottom of the pages.

Note: If applying for a one year grant (an option for Clinical and Translational Research Pilot Projects) only the one year will be entered in SAGE. Applicants for two year grants should prepare for expenditures for two years. The first year budget request should be submitted with the application along with a corresponding narrative justification. The second year budgets can be submitted without the corresponding narrative justification if general descriptions of how funding will be used in year two

is included in the program plan. Indirect costs cannot exceed 15% annually and are included in the maximum funding.

The first year budget request should include, at a minimum, with corresponding narrative justification, (1) salary and justification for the Principal Investigator and other staff needed to meet the first-year responsibilities; (2) information about any sub-awards; (3) expenses related to communications, supplies, equipment; (4) travel funds for key personnel to attend an annual meeting to share research approaches, discuss lessons learned and identify potential areas of collaboration.

Cost Summary

Statement of Local Government Public Health Partnership

Schedule D: Officers and Director's List

Certification of Human Subjects & the Containment of Recombinant DNA Research

Certification of Equipment Needs: Equipment description and justification (include number and manufacturer)

Certifications Regarding Institutional Responsibilities

Schedule G: Certification Regarding Debarment and Suspension

Schedule H: Certification Regarding Lobbying

Schedule I: Certification Sheet indicating that the official (name and title) certifying for the agency agrees with all requirements and conditions of the application.

Schedule J: Agency Minority profile

Schedule K- Certification Regarding Environmental Tobacco Smoke

NJDOH Required Attachments

Note: A Valid Tax Clearance Certificate is due with submission of the **a**pplication. Failure to include this will make your application non-responsive. For the Business Assistance Tax Clearance Application and Fee ($75.00 or $200.00) information please refer to
http://www.state.nj.us/treasury/taxation/busasst.shtml

Additionally, a Statement of Gross Revenue or Annual Audit Report is required. Refer to the Cost Controlling Initiatives on your grant application in SAGE under "Terms and Conditions". This is required to maintain compliance with the Commissioner's Cost Controlling Initiatives.

Miscellaneous Attachments – See narrative questions for required attachments. Also attach the full proposal (narrative and abstracts) as a Word document with tables, charts and illustrations as a "Miscellaneous Attachment".

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.

The Clinical and Translational Research applications will also be reviewed for relevance to ensure that they:

- address one or more of the IACC objectives listed in the "Funding priorities" section,
- constitute clinical or translational research, according to the definitions listed above.

In the event the Council office determines that an application does not meet the administrative review and/or the relevancy review 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 and Translational Research grant applications. The Panel(s) will judge the applications on the criteria listed in Appendix 5.

A panel with expertise in health services research will judge the Autism Health Needs Medical Homes Pilot Projects on the applicant's proposal and its compliance with RFA requirements, its organizational capacity to perform the work as presented in its proposal, readiness to implement an Autism Health Needs Medical Home and the cost proposal.

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 panel(s) 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 his/her application at the conclusion of the selection process, anticipated to be no later than June1, 2016. At that time, formal notification will be made to the institutions of successful applicants and contracts will be initiated shortly thereafter by the Council.

Blinded reviews will be provided to both funded and non-funded applicants; no further information shall be provided.

Non-funded applicants also will be notified.

APPENDIX 1
Subset of IACC objectives

Question 1: When should I be concerned?

Short-Term Objectives

A. Adapt with existing tools, at least one efficient diagnostic instrument (i.e., briefer, less time intensive) that is valid in diverse populations for use in large-scale studies.

B. Validate and improve the sensitivity and specificity of new or existing screening and diagnostic tools, including comparative studies of general developmental screening versus autism-specific screening tools, in both high-risk and population-based samples, including those from resource-poor international settings and those that are diverse in terms of age, socio-economic status, race, ethnicity, gender, characteristics of ASD, and general level of functioning.

C. Conduct at least three studies to identify reasons for the health disparities in accessing early screening and diagnosis services, including identification of barriers to implementation of and access to screening, diagnosis, referral, and early intervention services among diverse populations, as defined by socioeconomic status, race, ethnicity, and gender of the child.

D. Conduct at least two studies to understand the impact of early diagnosis on choice of intervention and outcomes.

E. Conduct at least one study to determine the positive predictive value and clinical utility (e.g., prediction of co-occurring conditions, family planning) of chromosomal microarray genetic testing for detecting genetic diagnoses for ASD in a clinical setting.

Long-Term Objectives

F. Identify behavioral and biological markers that separately, or in combination, accurately identify, before age 2, one or more subtypes of children at risk for developing ASD, and evaluate whether these risk markers or profiles can improve early identification through heightened developmental monitoring and screening.

B. Develop at least five measures of behavioral and/or biological heterogeneity in children or adults with ASD, beyond variation in intellectual disability, that clearly relate to etiology and risk, treatment response, and/or outcome.

C. Identify and develop measures to assess at least three "continuous dimensions" (e.g., social reciprocity, communication disorders, and repetitive/restrictive behaviors) of ASD symptoms and severity that can be used by practitioners and/or families to assess response to intervention for people with ASD across the lifespan.

Question 2: How Can I Understand What Is Happening?

Short-Term Objectives

A. Support at least four research projects to identify mechanisms of fever, metabolic and/or immune system interactions with the central nervous system that may influence ASD during prenatal-postnatal life.

B. Launch three studies that specifically focus on the neurodevelopment of females with ASD, spanning basic to clinical research on sex differences.

C. Launch three studies that target improved understanding of the underlying biological pathways of genetic conditions related to autism (e.g., fragile X, Rett syndrome, tuberous sclerosis complex) and how these conditions inform risk assessment and individualized intervention.

D. Launch three studies that target the underlying biological mechanisms of co-occurring conditions with autism, including seizures/epilepsy, sleep disorders, wandering/elopement behavior, and familial autoimmune disorders.

E. Launch two studies that focus on prospective characterization of children with reported regression to investigate potential risk factors.

F. Support five studies that associate specific genotypes with functional or structural phenotypes, including behavioral and medical phenotypes (e.g., nonverbal individuals with ASD and those with cognitive impairments).

Long-Term Objectives

A. Launch at least three studies that evaluate the applicability of ASD phenotype and/or biological signature findings for performing diagnosis, risk assessment, or clinical intervention.

Question 3: What Caused This To Happen And Can This Be Prevented?

Short-Term Objectives

A. Enhance existing case-control studies to enroll racially and ethnically diverse populations affected by ASD.

B. Support at least two studies to determine if there are subpopulations that are more susceptible to environmental exposures (e.g., immune challenges related to infections, vaccinations, or underlying autoimmune problems).

C. Initiate studies on at least 10 environmental factors identified in the recommendations from the 2007 IOM report "Autism and the Environment: Challenges and Opportunities for Research" as potential causes of ASD.

D. Support at least two studies that examine potential differences in the microbiome of individuals with ASD versus comparison groups.

E. Support at least three studies that focus on the role of epigenetics in the etiology of ASD, including studies that include assays to measure DNA methylations and histone modifications and those exploring how exposures may act on maternal or paternal genomes via epigenetic mechanisms to alter gene expression.

Long-Term Objectives

A. Conduct a multi-site study of the subsequent pregnancies of 1,000 women with a child with ASD to assess the impact of environmental factors in a period most relevant to the progression of ASD.

B. Determine the effect of at least five environmental factors on the risk for subtypes of ASD in the prenatal and early postnatal period of development.

Question 4: Which Treatments and Interventions will Help?

Short-Term Objectives

A. Test safety and efficacy of at least five widely used interventions (e.g., nutrition, medications, assisted technologies, sensory integration and medical procedures) that have not been rigorously studied for use in ASD.

B. Complete two multi-site randomized controlled trials of comprehensive early intervention that address core symptoms, family functioning and community involvement.

C. Launch randomized controlled trials of interventions including biological signatures and other measures to predict response, and monitor quality of life and functional outcomes in each of the following groups:

- Five trials in infants and toddlers.
- Three trials in school-aged children and/or adolescents.
- Three trials in adults.

D. Support at least five studies on interventions for nonverbal individuals with ASD. Such studies may include:

- Projects examining service-provision models that enhance access to augmentative and alternative communication (AAC) supports in both classroom and adult service-provision settings, such as residential service-provision and the impact of such access on quality of life, communication, and behavior;

- Studies of novel treatment approaches that facilitate communication skills in individuals who are nonverbal, including the components of effective AAC approaches for specific subpopulations of people with ASD; and

- Studies assessing access and use of AAC for children and adults with ASD who have limited or partially limited speech and the impact on functional outcomes and quality of life.

E. Support at least two studies that focus on research on health promotion and prevention of secondary conditions in people with ASD. Secondary conditions of interest include weight issues and obesity, injury, and co-occurring psychiatric and medical conditions.

Long-Term Objectives

A. Complete at least three randomized controlled trials on medications targeting core symptoms in people with ASD of all ages.

B. Develop interventions for siblings of people with ASD with the goal of reducing the risk of recurrence by at least 30%.

C. Conduct at least one study to evaluate the safety and effectiveness of medications commonly used in the treatment of co-occurring conditions or specific behavioral issues in people with ASD.

D. Support at least five community-based studies that assess the effectiveness of interventions and services in broader community settings. Such studies may include comparative effectiveness research studies that assess the relative effectiveness of:

- Different and/or combined medical, pharmacological, nutritional, behavioral, service-provision, and parent- or caregiver-implemented treatments;

- Scalable early intervention programs for implementation in underserved, low-resource, and low-literacy populations; and

- Studies of widely used community intervention models for which extensive published data are not available.

Outcome measures should include assessment of potential harm as a result of autism treatments, as well as positive outcomes.

Question 5: Where Can I Turn for Services?

Short-Term Objectives

A. Support two studies that assess how variations in and access to services affect family functioning in diverse populations, including underserved populations.

B. Conduct one study to examine how self-directed community-based services and supports impact children, youth, and adults with ASD across the spectrum.

C. Implement and evaluate five models of policy and practice-level coordination among State and local agencies to provide integrated and comprehensive community-based supports and services that enhance access to services and supports, self-determination, economic self-sufficiency, and quality of life for people with ASD across the spectrum and their families, (which may include access to augmentative and alternative communication [AAC] technology), with at least one project aimed at the needs of transitioning youth and at least one study to evaluate a model of policy and practice-level coordination among State and local mental health agencies serving people with ASD.

Long-Term Objectives

A. Test four methods to improve dissemination, implementation, and sustainability of evidence-based interventions, services, and supports in diverse community settings.

B. Test the efficacy and cost-effectiveness of at least four evidence-based services and supports for people with ASD across the spectrum and of all ages living in community settings.

C. Evaluate new and existing pre-service and in-service training to increase skill levels in service providers, including direct support workers, parents and legal guardians, education staff, and public service workers, to benefit the spectrum of people with ASD to and promote interdisciplinary practice.

Question 6: What Does the Future Hold, Particularly for Adults?

Short-Term Objectives

A. Launch at least two studies to assess and characterize variation in the quality of life for adults on the ASD spectrum as it relates to characteristics of the service delivery system (e.g., safety, integrated employment, post-secondary educational opportunities, community inclusion, self-determination, relationships, and access to health services and community-based services) and determine best practices.

B. Evaluate at least one model, at the State and local level, in which existing programs to assist people with disabilities (e.g., Social Security Administration, Rehabilitation Services Administration) meet the needs of transitioning youth and adults with ASD.

C. Conduct at least one study to measure and improve the quality of lifelong supports being delivered in community settings to adults across the spectrum with ASD through provision of specialized training for direct care staff, parents, and legal guardians, including assessment and development of ASD-specific training, if necessary.

Long-Term Objectives

A. Develop at least two individualized community-based interventions that improve quality-of-life or health outcomes for the spectrum of adults with ASD.

B. Conduct one study that builds on carefully characterized cohorts of children and youth with ASD to determine how interventions, services, and supports delivered during childhood impact adult health and quality of life outcomes.

C. Conduct comparative effectiveness research that includes a cost-effectiveness component to examine community-based interventions, services, and supports to improve health outcomes and quality of life for adults on the ASD spectrum over age 21. Topics should include:

- Community housing for people with ASD;
- Successful life transitions for people with ASD, including from post-secondary education to adult services, employment, sibling relationships, and day programs; and
- Meeting the service and support needs of older adults with ASD.

APPENDIX 2

NJ ACE Coordinating Center at Montclair State University

The NJ ACE Coordinating Center provides common management and support functions to unify the NJ ACE grantees, increase efficiency and reduce costs. The five year Coordinating Center grant was awarded to Montclair State University in 2012.

As applicable, the Coordinating Center at Montclair State University (CC-MSU):

1. Promotes the sharing among grantees of best practices and lessons learned in the conduct of clinical research.
2. Coordinates information and ensures regular communication among the grantees.
3. Identifies recurring issues, and designs ways to address them, for example by directing grantees to relevant websites, developing standard operating procedures, and organizing trainings.
4. Engages grantees in reflective practice – a way of supporting the practice of action research.
5. Works with the Council staff to facilitate new collaborations both among the grantees and with new entities.
6. Supports a password protected web-based application to facilitate communications and document sharing among the grantees.
7. Provides grantees with support in all aspects of research implementation and practice including, but not limited to:
    - Institutional Review Board (IRB) issues
    - Project evaluation
    - IT data management
    - National Database for Autism Research (NDAR) issues
    - Biostatistics consultation services.

The Coordinating Center provides quarterly progress reports to Council, through the Executive Director, on its activities and its evaluation of the grantees, and, if necessary, recommendations with respect to actions to improve the productivity of a grantee. The grantees are expected to cooperate with the Center by providing information when requested and attending monthly conference calls and quarterly and annual meetings as well as training workshops when appropriate.

The Center, under the management and leadership of the Dr. Gerard Costa, consists of a core team with expertise in coordinating multi-site research studies and includes personnel with expertise in ASD research and treatment as well as project management, project evaluation, clinical research, IT data management and biostatistics.

APPENDIX 3

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.

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 will function as a data repository for all NJ ACE clinical research projects. Coordination of data acquisition across the clinical sites and local data management for data cleaning and entry will be the responsibility of the NJ ACE Program Site. NDAR provides extensive tutorials and directions on its website. The NJ ACE Coordinating Center will provide assistance to the Program Sites by providing biostatistical consulting and developing tools and standard operating procedures for data entry, data management and submission of data to NDAR. For more information on NDAR, visit https://ndar.nih.gov/about.html .

Minimal data Collection:
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).

NJ ACE Program Sites are required to collect the following data to share via NDAR. NJ ACE Pilot Projects are encouraged to collect the same data, if scientifically appropriate. The minimal data collection requirements of an NJ ACE Program Site are:

- Medical History Form: http://ndar.nih.gov/ndarpublicweb/Documents/CommonMeasures/ACE%20Subject%20Medical%20History%20Form.pdf
- Family History Form: http://ndar.nih.gov/ndarpublicweb/Documents/CommonMeasures/ACE%20Family%20Medical%20History%20Form.pdf
- Physical Examination Form: http://ndar.nih.gov/ndarpublicweb/Documents/CommonMeasures/ACE%20Subject%20Physical%20Exam%20Form.pdf

- Genetic Testing Information Form: http://ndar.nih.gov/ndarpublicweb/Documents/Genetic_Tests.pdf
- Autism Diagnostic Interview-Revised (ADI-R) and the Autism Diagnostic Observation Schedule (ADOS), for use according to their published manuals
- Vineland Adaptive Behavior Scales, Second Edition
- An IQ or developmental assessment measure, that includes both nonverbal and verbal components and results in standardized scores for both.

Sharing via NDAR:
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 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.

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 NJ ACE CC can provide assistance and training in NDAR submission. Data submission remains the responsibility of each project team. Investigators are expected to certify the quality of all data generated by grants funded under this Grant Program prior to submission to the repository and to review their data for accuracy after submission.

Submission of descriptive data is expected semi-annually (every January 15 and July 15); submission of all other experimental data is expected after the primary objectives of the grant have been met (the primary objectives of a grant will be determined in consultation with the Principal Investigator and NJDHSS Council staff prior to award).

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 .

Resource sharing plan:
It is expected that the investigator's data sharing plan will specify the following elements: (1) description of what data 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 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.

The deposition of data is encouraged to occur at intervals throughout the period of the award and not be detained until the end of the award period. Similarly, the proprietary period for data release is encouraged to be short to facilitate rapid data release. Adherence to shortened time intervals for data deposition and release is highly desirable. This is expected to result in all data being released to the scientific community no later than the end of the award period. Requests for exemptions or extensions will require compelling justification and will be fully evaluated through peer review and by Council staff.

APPENDIX 4

NJ ACE Clinical Research Pilot Projects and Translational Research Pilot Projects

Abstracts and Narrative Questions

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.

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.

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. 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**

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. **2000 Characters**

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. **1500 Characters**

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**

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. **1500 Characters**

F. **Preliminary Data:** If applicable, discuss the PI's preliminary studies, data, and/or experience pertinent to this application. **3000 Characters**

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. **3000 Characters**

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. **2000 Characters**

I. **Literature:** Literature cited **3000 Characters**

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. 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". **3000 Characters**

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**.

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. **3000 Characters**

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. **2000 Characters**

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. **2000 Characters**

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. **3000 Characters**

P. **Web-based applications:** Briefly describe any experience with a web-based application for sharing documents and other information. Grantees are expected to participate in a web-based application managed by the NJ ACE Coordinating Center. **1500 Characters**

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. 2000 Characters

APPENDIX 5

Criteria For Independent Scientific Review

Clinical and Translational Research Pilot Projects

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 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 priorities and the mission of NJ ACE?
- Does the research proposal address an important problem?
- Is the research proposal relevant, if applicable, to Healthy People 2020 objective MICH-29?
- Will the proposed project advance the current knowledge pool in ways that can 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?

- Does the project meet the definition of clinical or translational research?

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?
- Will the proposed pilot project lead to an intervention that can be adopted and implemented in community settings should it prove effective?

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?
- 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—Note: May not be applicable to pilot projects.

- Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Genome Wide Association Studies (GWAS).

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

Autism Health Need Medical Homes Pilot Project

Project Requirements

1. Project Charter: The Project Charter serves as a focal point throughout the project. For example, it is a baseline that can be used in team meetings and in change control meetings to assist with scope management.

The grantee will develop and document the following Project Charter components required for the family-centered medical home.

A. Project Summary
B. Project Objectives
C. Constraints
D. Activities schedule and project milestones
E. Governance Structure-see note below
F. Project team-people working on this project and their roles and responsibilities
G. Quality measurement and improvement approach
H. Change Management: process to track changes in this project
I. Points of Contact if other than the Prinicpal Investigator
J. Signatories
K. Appendices with any additional, relevant information

Note: The Governance Structure must be documented and implemented by April 15, 2016 to qualify for continuation funding for year two of the project. Governance Structure refers to the mechanisms, processes and relations by which the project is controlled and directed. The document will identify the distribution of rights and responsibilities among different participants in the project and the rules and procedures for making decisions. Governance mechanisms include monitoring the actions, policies and decisions of the project.

Deliverable 1: Project Charter

2. HIT (Health Information Technology) System Assessment: The grantee must understand its HIT landscape to leverage the data needed for the medical home interventions. A reliable, timely, user-friendly data system will depend on access to a common language and aggregated data from multiple sources. Recognizing the important role that HIT can play in the pediatric family-centered medical home, the American Academy of Pediatrics (AAP) supports development and universal implementation of a comprehensive electronic infrastructure. For information about the use of HIT in the medical homes model see http://www.medicalhomeinfo.org/about/newsletter/spotlight_issues/HIT.aspx

The grantee will assess its electronic infrastructure used to communicate and transfer patient information between physicians and other professionals, patients, programs, and service agencies. This will involve an assessment of the use of computer applications to record, store, protect, retrieve, and transfer clinical, administrative, and financial information electronically within health care settings.

Specifically, the assessment will include:

A. Core Clinical Systems: applications that handle electronic health records, patient health records, documentation, order entry, medication management, results review from labs or radiology, drug reference information, drug interaction databases, order-set content, alerts and alerts configuring tools, business intelligence tools and dashboards, internal and external registries, health risk assessment tools, charge capture, billing, scheduling, and contact directories.
B. Hardware/Software: the number of workstations/terminals, handheld/portable devices, and printers per bed/exam room, per clinician; the age of these devices and the software/operating version of these devices; the reliability and speed (as perceived by the users) of these devices.
C. Network Connectivity: number and proportion of computers connected to internet and high-speed internal communications.
D. Wireless/Remote Systems: number and use of wireless devices (alphanumeric pager, smart phones, tablets, laptops); telemedicine infrastructure (remote monitoring or data gathering from patients at home via machines that measure blood pressure or blood sugar); remote access to information systems by clinicians.
E. Integration Among Clinical Systems: number of different terminals/workstations/windows required to access the full portfolio of applicable applications.

Deliverable 2: HIT System Assessment

3. Workflow Mapping: The grantee's capacity to document, understand, and improve how care delivery activities are carried out in the Autism Health Needs Medical Home are essential for a successful system. Clinical workflows include care steps performed at different points in time by different people/members, including patients and their caregivers, in the medical home. These workflows can be sequential or simultaneous. There are workflows for an individual provider (or patient), for the care team, and the Autism Health Needs Medical Home as a whole.

The grantee must develop:

A. Workflows of its current environment for providing healthcare ("as is" workflow)

B. Workflows for its proposed medical homes environment for providing healthcare ("to be" workflow)

Deliverable 3: "As Is" Workflow and "To Be" Workflow

4. Action Plan: The grantee should use the mapped workflows to build a shared understanding about the related decision support needs and opportunities for the medical home. The grantee must develop and implement an Action Plan that provides logistical detail about the interventions in the medical home that includes:

A. Where these interventions fit in the mapped workflow.

B. How these interventions drive performance on the measures set forth in accomplshing the objectives as defined by the grantee.

C. How each partner in the medical home contributes to the different intervention choices available, depending on the partner's role.

D. A process for recognizing patient patterns for specific care action, such as using data-triggered alerts, smart patient assessment worksheets, data summaries, or predictive analytics.

E. A process for intervention selection once a pattern is recognized.

F. An approach to continuously communicate and validate the Action Plan and results with stakeholdersto enhance effectiveness of the medical home.

G. An approach to assessing and monitoring progress on the Action Plan and continuously improving upon it so that the grantee's Goals and Objectives are met.

H. An approach for deploying and continuously improving the Autism Health Needs Medical Home beyond the grant period.

Deliverable 4: Action Plan

5. System Tools: To help ensure that Autism Health Needs Medical Home plans are executed correctly and completely after the grantee has implemented its workflow and action plan, the grantee must identify and develop/leverage the medical home's automation capabilities. The grantee must provide a report of the automated tools that it has developed/leveraged that are relevant to the goals of the project. These tools must be available for use/transfer to other medical homes. The tools can include:

A. Parameter Guidance Tools: to help clinicians apprioriately order interventions when the patient has additional constraints that affect therapy.

B. Order Sets and Care Plan Tools: to help ensure that the correct medication are ordered and administered in the correct doses and frequencies.

C. Critiques and Warnings: to help catch potential errors such as drug allergy or drug-drug interaction, duplicate or inapproriate tests, or failure to order appropriate durg levels.

D. Smart Documentation Forms: to help encourage complete process execution to ensure that clincians address every element in the care plan.

E. Filtered reference information: to support correct care plan execution by providing information as needed.

F. Patient Dashboard Portal: To track referral for self management and to engage patients' families in monitoring and managing autism.

G. Data Display and Summary Tools: to present large amounts of patient information in a user-friendly, workflow friendly way that is viewable on mobile devices and is browser agnostic so clincians see the right information at the right time.

H. Event and Time Alert Tools: to help clincians spot unusual events that may indicate a need to change the care plan or to help ensure that an ordered test has occurred.

I. Retrospective Analytics: to help the Grantee look at performance over a period of time and detect variances from desired outcome so the Autism Health Needs Medical Home can be continously improved.

Deliverable 5: Report of Automation Tools Implemented

6. Performance Deployment, Monitoring, and Measurement: The grantee must deploy its Action Plan and monitor the effectiveness of the interventions, as well as the workflow impacts for its providers. The grantee must provide a Post-Deployment Report, detailing its successes, lessons learned, and tips for other providers to consider when assessing the viability of an Autism Health Needs Medical Home.

The grantee must develop a plan for identifying, tracking, measuring, and addressing intended and unintended intervention effects and include these elements in its Quarterly Monitoring Report. As part of monitoring, the grantee may find it necessary to re-tool its Autism Health Needs Medical Home because of a negative impact on response time, the intervention did not function as planned, or there were unanticipated problems with workflow.

The grantee must develop a process for capturing and reporting measures as defined in its Charter for accomplishing its objectives through June 30, 2017 to the Council and the DOH. The grantee must report on a quarterly basis, through SAGE, on each of the objectives by the 10th business day following the close of the quarter. Site visits will be conducted during the first three months of the project and require

more frequent reporting through SAGE if problems are identified that may result in the inability of the grantee to fulfill the requirements of the grant.

Deliverables 6A: Post-Deployment Report, 6B Quarterly Monitoring Report and 6C Quarterly reporting of Performance Measures

APPENDIX 7

Autism Health Need Medical Homes Pilot Project

Abstracts and Narrative Questions

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.

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.

Narrative:

Note: Questions A-H relate to the deliverables. General information about the applicant's institution (history, current practices and accomplishments) and plans for the proposed medical home should be included in Question K.

A. Project Charter (Deliverable 1): Describe the approach and plans for developing and documenting each component, as listed in Appendix 6, of the Project Charter. Refer to Appendix 6 for the specific requirements for component E (Governance Structure). **9,000 Characters**

B. HIT System Assessment (Deliverable 2): Describe the approach and plans for assessing the electronic infrastructure including core clinical systems, hardware/software, network connectivity, wireless/remote systems and integration among clinical systems. **6,000 Characters**

C. "As Is" Workflow and "To Be" Workflow (Deliverable 3): Describe the approach and plans for developing the workflow of the current environment for providing healthcare ("as is" workflow) and the workflow for the proposed medical homes environment for providing healthcare ("to be" workflow). **2,000 Characters**

D. Action Plan (Deliverable 4): Describe the approach and plans for using the mapped workflows to develop and implement an Action Plan addressing each component of the Action Plan as defined in the RFA. **2,000 Characters**

E. Report of Automation Tools Implemented (Deliverable 5): Describe the approach and plans for identifying/leveraging the medical home's automated tools that are relevant to the goals of the project. Examples of tools are listed in the RFA. **2,000 Characters**

F. Post-Deployment Report (Deliverable 6A): Describe the approach and plans for detailing the successes, challenges and lessons learned in the deployment of the Action Plan including the effectiveness of the interventions, as well as workflow impacts for its providers. Provide tips for other providers to consider when assessing the viability of an Autism Health Needs Medical Home. **2,000 Characters**

G. Quarterly Monitoring Report (Deliverable 6B): Describe the approach for developing a plan for identifying, tracking, measuring and addressing intended and unintended intervention effects and include these elements in the Quarterly Monitoring Reports. As part of the monitoring it may be necessary to re-tool the Autism Health Needs medical Home because of a negative impact on response time, the intervention did not work as planned or there were unanticipated problems with workflow. **2,000 Characters**

H. Quarterly Reporting of Performance Measures (Deliverable 6C): Describe the approach for developing a process for capturing and reporting measures as defined in the Charter for accomplishing project objectives. Reporting through SAGE, the state's electronic grants management system is described in the RFA. **2,000 Characters**

I. Describe the project's yearly objectives, the steps planned to accomplish the objectives, the methods and the performance measures used to evaluate successful completion (i.e. outcomes and deliverables) of yearly objectives. Attach a timeline for the entire project period showing key activities, responsible staff and deliverables. **4,000 Characters**

J. Describe the patient population including plans for recruiting and retaining patients and the age range of the patients. Note: While all applications will be evaluated, applications addressing the needs of adolescents and young adults are of particular interest and will be given preference for funding. **2,000 Characters**

K. Describe the organization's capacity to achieve the goals, objectives and deliverables including the expertise of the project manager and key staff, the overall environment that will be relevant to the effective implementation of the project and any contractual organizations that will have significant roles in meeting the deliverables. **20,000 Characters**

L. Describe the organization's readiness to design, develop, implement and measure performance as required by the RFA. **4,000 Characters**