



NEW JERSEY GOVERNOR'S COUNCIL FOR MEDICAL RESEARCH AND TREATMENT OF AUTISM

CLINICAL RESEARCH PROGRAM GUIDELINES

IMPORTANT DATES:

Publication of Notice of Grant Availability: December 5, 2011
Letter of Intent due date: February 17, 2012
Application due date: March 19, 2012
Notification date: June 1, 2012
Anticipated start date: June 15, 2012

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INTRODUCTION

Autism spectrum disorders (ASD) are complex neurodevelopmental disorders with early childhood onset. The prevalence of ASD may be increasing, and ASD is more common than previously thought. 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 that an average of 1 in 110 children in the United States has an ASD. As part of the same CDC study, the prevalence rate for the New Jersey sites was established at 1 in 94 children.

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 since 2000. As detailed in P.L. 2007, c. 168, the Council is to establish an Autism Center of Excellence in the State. The mission of the New Jersey Autism Center of Excellence (NJ ACE) is to research, apply and advance best practices in the understanding, prevention, evaluation and treatment of autism spectrum disorders, enhancing the lives of individuals across their lifespans.

As part of its enabling legislation, the Executive Director of the Council has the responsibility for establishing a Scientific Advisory Committee (SAC). The SAC will include 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 individuals with autism. The SAC will identify and make 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 and Senior Services (NJDHSS). The NJDHSS 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 NJDHSS guidelines.

PROGRAM OBJECTIVES

The Council is committed to advancing the current knowledge pool through clinical research that can lead to improvements in interventions that address the physical and behavioral health needs of children, adolescents and adults with ASD.

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. Council awards for this funding cycle are intended to promote clinical research, not to provide long-term support.

FUNDING PRIORITIES

The Council, through the NJDHSS, will fund a NJ ACE, consisting of several program sites and a coordinating center. The Program Sites will conduct clinical research projects that address the national priorities described in the Interagency Autism Coordinating Committee (IACC) Strategic Plan, available online at: <http://iacc.hhs.gov/strategic-plan/2012/index.shtml>. The applicant will state which short- or long-term objective is addressed by the proposed clinical research project. If applicable, the applicant should also reference the Healthy People 2020 objective (see MICH-29 in <http://healthypeople.gov/2020/topicsobjectives2020/pdfs/HP2020objectives.pdf>) addressed by the research project.

The NJ ACE Coordinating Center will provide common management and support functions to unify the NJ ACE Program Sites by serving as the voice of the NJ ACE and promoting the sharing of lessons learned and best practices in the conduct of clinical research.

Only clinical research projects, as defined by NIH, will be considered for funding the Program Sites. NIH defines human 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

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 affiliate with a New Jersey State 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 research entity, as described below.

NJ ACE Program Site applicants 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.

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.

Qualifying Entity

Public and private non-profit research entities in the State of New Jersey may apply for a Council grant under this program. A qualifying research 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 research. In no case can an individual be a qualifying research entity. The qualified research 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 in addition, for the Program Sites, procedures for the protection of human subjects as regulated by the NIH, and an Institutional Review Board (IRB) that will approve proposed research.

RESEARCH GRANTS AVAILABLE

The NJ ACE will consist of several program sites and a coordinating center. The NJ ACE Coordinating Center Grant Program (12-AUC-3) and the NJ ACE Program Sites Grant Program (12-AUC-4) are described in these guidelines. Applicants for one grant program are strongly advised to read the guidelines for the other to acquire a clear understanding of their expected contributions to the NJ ACE. Institutions interested in applying to be the NJ ACE Coordinating Center may apply under a separate application to be a NJ ACE Program Site, but only one of these grants could be awarded to a specific department or team within the same institution/organization. If separate teams or departments at a large institution wish to apply for and receive grants under both grant programs 12-AUC-3 and 12-AUC-4, there can be no overlap of personnel or duties between the proposed NJ ACE Coordinating Center and the proposed NJ ACE Program Site.

The Council reserves the right to distribute funds among the grants in the programs 12-AUC-3 and 12-AUC-4. The Council reserves the right not to fund any grant in either program to the maximum amount, or not to fund any grant in either program at all. A combined total of up to \$8,000,000 will be made available for a period of five years for programs 12-AUC-3 and 12-AUC-4.

NJ ACE Program Sites Grant Program (12-AUC-4)

The purpose of this grant program is to support up to three clinical research program sites capable of supporting the mission of the 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 disorders, enhancing the lives of individuals across their lifespans.

The NJ ACE Program Sites grant program grantees will develop and conduct clinical research projects that have the potential to improve the physical and/or behavioral health and well-being of individuals with ASDs. The clinical research project (as defined by NIH) will address a short- or long-term objective of in the Interagency Autism Coordinating Committee (IACC) Strategic Plan (<http://iacc.hhs.gov/strategic-plan/2012/index.shtml>). Each Program Site will receive up to \$450,000 per year for five years, including direct and indirect costs (15% maximum for indirect). The anticipated start date is June 15, 2012.

Applicants are encouraged to collaborate with clinical sites in New Jersey to ensure sufficient patient recruitment. Applicants are further encouraged to collaborate with other New Jersey-based researchers as well as with researchers located out-of-state, 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.

NJ ACE Coordinating Center Grant Program (12-AUC-3)

The NJ ACE Coordinating Center will provide common management and support functions to unify the NJ ACE Program Sites, increase efficiency and reduce costs. The Coordinating Center will receive up to \$300,000 per year for five years, including direct and indirect costs (15% maximum for indirect). The anticipated start date is June 15, 2012.

The Coordinating Center will unify the NJ ACE Program Sites by serving as the voice of the NJ ACE and promoting the sharing of best practices and lessons learned in the conduct of clinical research. The Coordinating Center will coordinate information and ensure regular communication among the Program Sites. Notably, this includes facilitating the streamlining of practices to increase efficiency for subject recruitment and retention and creating common, or similar, outreach materials. The Coordinating Center will work with the Council staff to facilitate new collaborations both among the Program Sites and with new entities. The Coordinating Center will also establish, manage and support a password protected web-based application to facilitate communications and document sharing among the Program Sites.

The NJ ACE Coordinating Center will also provide project assistance and training as needed. The Coordinating Center will identify recurring issues, and design ways to address them, for instance by directing Program Sites to relevant websites, developing standard operating procedures, and organizing trainings. Areas of support that the Coordinating Center is to provide include but are not limited to:

- Assist with IRB issues.
- Develop tools and standard operating procedures for use by the Program Sites for data entry, management and submission to the National Database for Autism Research (NDAR).
- Organize training sessions, as needed, for the use of clinical instruments such as the Autism Diagnostic Observation Schedule (ADOS), including yearly training refreshers to ensure inter-rater reliability.
- Provide biostatistics consultation services.
- Organize regular meetings of the Program Site Principal Investigators, including, but not limited to, conference calls and annual NJ ACE meetings to share research approaches, discuss lessons learned and identify potential areas of collaboration or expansion.

Finally, the Coordinating Center will conduct a multi-method, cross-site evaluation to assess context, implementation, participation, and achievement of the Program Sites' yearly project objectives. The Coordinating Center will monitor progress, collect lessons learned, and provide timely feedback and support to the Program Sites as needed. The Coordinating Center is required to submit a plan to the Executive Director, for subsequent review and approval by the Council, for evaluating the Program Sites. The plan must be submitted within six months of the Notice of Grant Awards. The evaluation plan will be reviewed by program evaluators and shared with the Council. The reviewers may suggest modifications that would be discussed with the Coordinating Center. Twice during the first year and yearly thereafter, the Coordinating Center will provide progress reports to Council, through the Executive Director, on its activities and its evaluation of the Program Sites, and, if necessary,

recommendations with respect to actions to improve the productivity of a Program Site. The Program Sites will be required to cooperate with the Coordinating Center by providing information when requested and sending staff to training workshops when appropriate.

Twice during the first year, and every year thereafter, the Coordinating Center will draft a questionnaire for its own self-evaluation. Following approval by the Council's Executive Director, the Coordinating Center will send these questionnaires to the Program Sites. The responses from the Program Sites will be sent to the Council's Executive Director, who will use this data as an adjunct to monitor the Coordinating Center's performance. A summary of the results will be provided to the Coordinating Center to ensure improved performance.

Under the management and leadership of the Principal Investigator the Coordinating Center will consist of a core team with expertise in coordinating multi-site research studies. The Coordinating Center will include personnel with expertise in ASD treatment as well as project management, project evaluation, IT data management and biostatistics. The Principal Investigator must be a manager who can provide evidence of strong administrative and academic leadership.

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 Program Site 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.

Consent language:

NDAR has developed and makes available sample language for inclusion in an informed consent: <http://ndar.nih.gov/ndarpublicweb/sharing.go#consent>. Two different versions of the language are available depending on whether the institution has a Certificate of Confidentiality.

SHARING HUMAN DATA VIA THE NATIONAL DATABASE FOR AUTISM RESEARCH

To advance the goal of widespread data sharing among ASD researchers, investigators funded under the NJ ACE Program Sites grant program are expected to share those data via the NDAR (<http://ndar.nih.gov>). Fulfilling this expectation by the awardee will be among the terms and conditions of the award.

The NIH National Database for Autism Research (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 <http://ndar.nih.gov/ndarpublicweb/aboutNDAR.html>.

Minimal data Collection:

Patient data will be collected according to the guidelines of the NDAR, including the use of the NDAR Data Dictionary and Global User ID. All Program Site applications must include collection of data using the following forms or a justification of why the forms are not appropriate.

The minimal data collection requirements of an NJ ACE Program Site are:

- Medical History Form
(http://ndar.nih.gov/ndarpublicweb/Documents/CommonMeasures/CHARGE_Medical_History.pdf)
- Family History Form
(http://ndar.nih.gov/ndarpublicweb/Documents/CommonMeasures/CHARGE_Family_Characteristics_Questionnaire.pdf)
- Physical Examination Form
(http://ndar.nih.gov/ndarpublicweb/Documents/CommonMeasures/CHARGE_Physical_Exam.pdf)
- Genetic Testing Information Form
(<http://ndar.nih.gov/ndarpublicweb/Documents/CommonMeasures/Karyotype.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 technology. 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 provides two tools to help investigators develop appropriate strategies:

1) the NDAR Data Sharing Checklist (http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Data-Sharing_Checklist_10152009.pdf) – A list of critical steps in the data submission process, including informed consent language and GUID generation; and

2) the NDAR Data Submission Planning Cost and Effort Model (http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Data_Submission_Costs.xls) -- A customizable Excel worksheet that includes tasks and hours for the Principal Investigator and Data Manager.

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 (<http://ndar.nih.gov/ndarpublicweb/policies.go>) 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) what data and/or biospecimens will be made available for deposit in databases or in a repository accessible to the research community, (5) a timetable for deposition of the data and/or biomaterials, and a specified 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.

FUNDING AVAILABILITY, OBLIGATIONS AND DEADLINES

A combined total of up to \$8,000,000 will be made available for grant programs 12-AUC-3 and 12-AUC-4 for the five years of the programs. Awards will begin on or about June 15, 2012. Eligibility requirements are stated in the eligibility section. Successful applicants must abide by all programmatic and fiscal requirements of NJDHSS.

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. Please refer to the narrative questions listed below for specific requirements for the yearly project objectives.

Multi-year awards are made through one-year contracts. Each funding award within the multi-year period will be contingent upon the availability of funds. Support for the continuing years of all grants is contingent upon submission and approval of annual comprehensive progress reports. All 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 three months 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

Although a letter of intent is not required, 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.

A one-page letter of intent is highly recommended for all grant applications. Letters of intent must be filed with the Council office by February 17, 2012.

The letter of intent should include the following information:

- 1) Descriptive title of proposed research
- 2) Name, address, email and telephone number of the Principal Investigator
- 3) Participating institutions
- 4) Title of the funding opportunity-NJ ACE Coordinating Center (12-AUC-3) or NJ ACE Program Sites (12-AUC-4).

Please use the following address for all regular and overnight mail deliveries:

New Jersey Department of Health and Senior Services
New Jersey Governor's Council for Medical Research and Treatment of Autism
369 South Warren Street
Fifth Floor, Room #502
PO Box 360
Trenton, NJ 08625

APPLICATION SUBMISSION

During the application process, questions may be addressed to NJGCA@doh.state.nj.us. Until March 19, 2012, 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 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. Character limits are generous to allow for variability in responses to each question based on the needs of the applicant. Applicants should only use the number of characters needed to answer the questions. 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 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 5:00 PM on Monday, March 19, 2012. 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 5:00 PM on Wednesday, March 21, 2012. No exceptions will be made.

Please use the following address for all regular and overnight mail deliveries:

New Jersey Department of Health and Senior Services
New Jersey Governor's Council for Medical Research and Treatment of Autism
369 South Warren Street

Fifth Floor, Room #502
PO Box 360
Trenton, NJ 08625

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

Statement of Local Government Public Health Partnership - optional

Proposal Abstract: Refer to Coordinating Center and Program Sites Proposal Abstract listed below for specific information.

Proposal Lay Abstract: Refer to Coordinating Center and Program Sites Proposal Lay Abstract listed below for specific information.

Narrative: Refer to Coordinating Center and Program Sites Narratives listed below for specific questions.

Biographical Sketch: Education/Training (Institution, location, degree, year(s) and field of study); Position and Honors, Awards and Other Professional Activities, Selected Peer-reviewed Publications, Ongoing Research Support and Completed Projects.

Biographical Sketch Detail: : 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.

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: The NJ ACE is a multi-year project and applicants should prepare for expenditures for all five years. The first year budget request should be submitted with the application along with a

corresponding narrative justification. Additional yearly budgets can be submitted without the corresponding narrative justification if general descriptions of how funding will be used in years two through five are included in the program plan. Indirect costs cannot exceed 15% annually and are included in the maximum funding for the Coordinating Center and the Program Sites.

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 and, in addition, the Coordinating Center budget must include travel funds for Program Site personnel to attend necessary training sessions.

Funds and Program Income from Other Sources Related to this Application

Cost Summary

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

NJDHSS Required Attachments

Miscellaneous Attachments

NJ ACE Program Site Proposal 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. State the IACC short- or long-term objective that is addressed by the proposed project.
- B. Clearly state the purpose and nature of the clinical research project including specific aim(s) and hypothesis (if applicable), background and significance, innovation (if applicable), preliminary data (optional), experimental design and methods. Note that the relevance of the project to public health needs is more important than its innovation.
- C. Literature cited.
- D. Describe your plan for recruiting and retaining patients. Include, as a “Miscellaneous Attachment” in SAGE, a targeted/planned enrollment table.
- E. Describe your resource sharing plan; explain how data will be collected and shared. Refer to section on data sharing for further information.
- F. Describe the specific roles, responsibilities and expertise of key personnel, including clinical site managers, consultants and collaborators. Provide an organizational chart (“Required Attachment” in SAGE) for the entire Program Site. If the Program Site includes collaborations with individuals and/or clinical sites, provide a detailed description of each participating individual/site including the institution, departmental affiliations, resources (sites), and role in the overall research project(s). Include as “Miscellaneous Attachment” in SAGE pertinent letters of assurance and collaboration from all clinical sites involved in the research project.
- G. Briefly describe the overall environment – features of the institutional environment that are or would be relevant to the effective implementation of the proposed NJ ACE program. For Program Sites with multiple clinical sites, plans for interaction and cooperation should be addressed. As appropriate, describe available resources, such as clinical and laboratory facilities, participating and affiliated units, patient populations, geographical distribution of space and personnel, and consultative resources. 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.
- H. Describe the project’s yearly objectives, the steps planned to accomplish these objectives and the methods and metrics used to evaluate successful completion of yearly objectives. Yearly objectives will include, but are not limited to process objectives such as hiring and training the

necessary staff, obtaining IRB approval and submitting the manuscript(s). IRB approval by the end of the first year and submission of manuscript(s) by the end of the fifth year are required. 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. See “Note” under Budget Schedule A-C regarding general descriptions of funding in years two through five.

- I. Describe any experience with a web-based application for sharing documents and other information. Program Sites are expected to participate in a web-based application managed by the Coordinating Center.
- J. Describe how program continuity will be maintained if there is a change in the operational environment (e.g. staff turnover) to ensure stability over the five years of the project.

NJ ACE Coordinating Center Proposal Abstracts and Narrative Questions

Proposal Abstract: State your project’s goals and objectives 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.

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. Clearly state the purpose of the proposed project.
- B. Describe your experience in managing complex, multi-site programs. Applicants must provide evidence of ability to collaboratively manage a complex set of functions: bringing together several multi-site projects, evaluating ongoing activities, identifying areas of concern, working with program site(s) to develop potential solutions, and identifying and developing necessary training.
- C. Describe your experience in conducting clinical research, including but not limited to, experience with Institutional Review Board policies and procedures and subject recruitment and retention. Describe your expertise in ASD treatment and/or ASD clinical research.
- D. Describe your experience with project support and technical assistance, including but not limited to developing tools and standard operating procedures for data entry, data management

and data sharing, providing biostatistics consultations and managing a web-based application for document and information sharing.

- E. Describe your experience with organizing and evaluating training programs, convening and documenting meetings and providing logistical support for conferences.
- F. Describe your experience with project evaluation and present a sample evaluation plan for an autism clinical research project that addresses one of the IACC objectives. Include a sample logic model and potential metrics, labeled and attached as “Miscellaneous Attachments” in SAGE.
- G. Describe the project’s yearly objectives, the steps planned to accomplish these objectives and the methods and metrics used to evaluate successful completion of the yearly objectives. Yearly objectives will include, but are not limited to, process objectives such as fully staffing the project, sharing documents and other information between all Program Sites through a web-based application and submitting a plan to evaluate the Program Sites for approval by the Council’s Executive Director. The web-based application must be completely operational within three months and the evaluation plan submitted within six months. Attach a realistic time line for the entire project period (graph or chart) showing key activities and responsible staff. Label charts and graphs and attach as “Miscellaneous Attachments” in SAGE. See “Note” under Budget Schedule A-C regarding general descriptions of funding in years two through five.
- H. Describe the functions of key personnel, consultants and collaborators. The Coordinating Center staff must include individuals with expertise in clinical research, project management, project evaluation, ASD treatment, IT data management and biostatistics. Include an organizational chart for the entire Coordinating Center showing the relationship among key personnel, collaborators, consultants and support staff. Label the chart and attach as “Miscellaneous Attachments in SAGE”.
- I. Briefly describe the features of the institutional environment that are or would be relevant to the effective implementation of the proposed NJ ACE program. As appropriate, describe available resources, geographical distribution of space and personnel, and consultative resources. For a Coordinating Center that consists of multiple sites/organizations, plans for interaction, cooperation and decision-making should be addressed. Provide evidence of institutional support including a letter of support from a president, dean or other authority labeled and attached as “Miscellaneous Attachments” in SAGE.
- J. Describe how program continuity will be maintained if there is a change in the operational environment (e.g., staff turnover) to ensure stability over the five years of the project.

GRANT REVIEW PROCESS

All research proposals will be reviewed in accordance with the Grant Review Process set forth herein. For both Grant Programs, 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 Program Site applications will also be reviewed for relevance to ensure that they:

- address an IACC objective, and
- constitute clinical research, according to the NIH definition.

In the event the Council office determines that an application does not meet those relevancy 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 will convene to evaluate all relevant grant applications. The Panel will judge the applications on the criteria described below. The panel will assign scores to each application and make funding recommendations. If it is determined that ad hoc expertise is needed, additional scientific referees may be used. The Independent Scientific Merit Review Panel will forward its recommendations for funding to the Council, through the Executive Director, for final review and action.

Grants triaged by either Administrative Review and/or the Independent Scientific Merit Review Panel will not be forwarded to the Council, and will not be funded. The authority to authorize or not authorize grants is fully vested in the Council according to New Jersey statute P.L. 2007, c.168 (NJSA C.30:6D-60).

CRITERIA FOR INDEPENDENT SCIENTIFIC REVIEW

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, final scoring, and ranking of all proposals. The panel will also recommend a cut-off point for funding.

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.

The following topics will be addressed during the review of the NJ ACE Program Sites:

Significance:

- Is the research proposal relevant to IACC priorities and the mission of NJ ACE?
- 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 ASDs?

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?

Experimental Design and Capability:

- Does prior research and theory provide a rational basis for the proposed research?
- 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?
- 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:

- 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).

Budget:

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

The following topics will be addressed during the review of the NJ ACE Coordinating Center:

Management capabilities:

- Does the staff have experience managing large multi-site projects?
- Are the planned structure and functioning of the Coordinating Center consistent with efficient management of complex projects?

Project support capabilities:

- Does the staff have experience in supporting a project?
- Are the planned structure and functioning of the Coordinating Center consistent with timely and efficient assistance to the Program Sites?

Project evaluation capabilities:

- Does the application exhibit adequate experience with project evaluation?
- Does the sample evaluation plan reflect an excellent understanding of project evaluation and clinical research?

Knowledge of clinical research and of ASD treatment:

- Does the staff include individuals with experience managing clinical research?
- Does the staff include a clinician experienced in treating patients with ASDs?

Environment, key personnel:

- Is the environment supportive of the application?
- Are the collaborations and organizational plans conducive to a collaborative, multi-disciplinary and efficient functioning?
- Does the key personnel have the required expertise, including IT staff with knowledge of data management?

Yearly project objectives:

- Are the objectives detailed and numerous enough to assess progress and identify emerging issues?

Budget:

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

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 June 1, 2012. 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. No reviews will be generated for triaged proposals.

Non-funded applicants also will be notified. There is no appeal process.