



## State of New Jersey

### DEPARTMENT OF HEALTH AND SENIOR SERVICES

DIVISION OF FAMILY HEALTH SERVICES

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JON S. CORZINE  
*Governor*

HEATHER HOWARD  
*Commissioner*

#### **New Jersey Department of Health & Senior Services Governor's Council for Medical Research and Treatment of Autism funding initiative: Basic Science and Clinical Research grant awards**

RFA Availability: April 6, 2009

Administered by: Governor's Council for Medical Research and Treatment of Autism

Application Receipt Date: July 23, 2009

Start Date: December 1, 2009

#### **WHAT IS AUTISM?**

Autism Spectrum Disorders (ASD) are a grouping of neurodevelopmental disorders that are characterized by communication and social impairments and deficits. ASDs are estimated to occur in as many as 1 in 150 children, with the incidence rate in New Jersey being estimated as high as 1 in 94 children. The onset of ASDs occurs before the age of 3, and although behavioral and pharmacological treatments can improve outcomes in some autistic individuals, there is currently no known reliable treatment or cure. Although Autism Spectrum Disorders occur in all ethnicities and across all socioeconomic groups, they occur four times more frequently in boys than girls.

#### **PURPOSE**

The New Jersey Department of Health & Senior Services, in collaboration with the Governor's Council for Medical Research and Treatment of Autism seeks to support all areas of basic science and clinical research that examine the origins, pathophysiology and treatment of Autism Spectrum Disorders (ASDs). The grant program is also intended to promote collaboration among researchers currently working on ASD-related projects and to encourage researchers in other fields to enter this compelling area of research. The data and preliminary results gained by using the Governor's Council funds will allow investigators from New Jersey to develop stronger proposals to biomedical research foundations and the National Institutes of Health. Preference will be given to projects that have been judged to have the potential for attracting grant support from federal or other organizations.

#### **TYPE OF RFA**

This is an open and competitive grant program that is based on a system of scientific review and which is available to all public and nonprofit private entities.

#### **RESEARCH SCOPE**

The Governor's Council for Medical Research and Treatment of Autism will support areas of research including, but not limited to: human behavior and social interaction, genetics, neurobiology (anatomy, development and neuroimaging), neurocognition, neuropathology, neurotoxicology, and studies based on model organisms. The Council also invites proposals in the areas of epidemiology, needs assessment, treatment modalities, population science, gastroenterology, and in translational research that applies the results from basic science and clinical research to the diagnosis and treatment of ASDs. Basic scientists and clinicians are encouraged to collaborate.

Grants are awarded for up to \$500,000 for up to 2 years (i.e., up to \$250,000/year for up to 2 years). The grants will fund research pertaining to basic mechanisms underlying ASDs, epidemiological and patient-oriented studies. **No indirect costs will be awarded to the grantee's organization.**

## REVIEW CRITERIA

Proposals received under this announcement will be reviewed for scientific and technical merit by a peer review panel consisting of established researchers from outside the State of New Jersey. Grant review panelists will be recruited by the Executive Director of the Governor's Council for Medical Research and Treatment of Autism. The Executive Director will also convene a panel to participate in a study section telephone conference meeting during which the grant applications will be discussed and ranked. The Executive Director will be responsible for assuring that the review and study section panels function in a fair and equitable manner in all of its deliberations and decisions.

In addition, the following criteria will be used to evaluate all proposals:

**Significance:** Does this study address an important problem within the field of Autism? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

**Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

**Investigator:** Is the PI and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Do the PI and investigative team bring complementary and integrated expertise to the project (if applicable)?

**Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

**Note:** An application does not need to be strong in all categories to be judged likely to have 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 a field forward.

### **Additional Review Criteria**

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

**Translational applications:** The likelihood that the research has clinical or translational applications.

**Potential for federal funding:** The likelihood that this line of research can receive further NIH funding.

**Protection of Human Subjects from Research Risk:** The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed.

**Inclusion of Women, Minorities and Children in Research:** The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated.

**Care and Use of Vertebrate Animals in Research:** If vertebrate animals are to be used in the project, the adequacy of the plans for their care and use will be assessed.

**Biohazards:** If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

### **Additional Review Considerations**

**Budget and Period of Support:** The reasonableness of the proposed budget and the appropriateness of the requested period of support in relation to the proposed research may be assessed by the reviewers. The priority score should not be affected by the evaluation of the budget.

**Data Sharing Plan:** The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

### REVIEW PROCEDURES

Each application will be assigned to a primary and to a secondary reviewer. Reviewers will be recruited by the Executive Director of the Council based on the topic areas represented in the grant applications. The initial reviews of the grants will be conducted via e-mail, and after assessing the assigned applications on the 5 review criteria, reviewers will rank the applications on a scale of 1 to 4 (with 1 representing an “excellent” application).

Once all grants have been assessed by a primary and secondary reviewer, a synopsis of each review will be prepared for the scoring committee meeting. A panel of 5 individuals (3 basic scientists and 2 clinicians), will then be assembled to rank order the applications. This scoring committee will be chaired by the nationally-renowned research selected by the Council. During the scoring committee meeting all applications will undergo a selection process in which only those applications deemed to have the highest scientific merit (generally the top half of applications under review), will be discussed and assigned a priority score. The scoring committee will then make recommendations to the Council with regard to which applications should receive Council funding.

The recommendations of the scoring committee and the ranking of the grant applications will then be presented to the Governor’s Council by the Scoring Committee Chair. During this presentation Council members will only see ranking and field of study information for the grants, and not any identifying information about the specific grants or investigators. The Council will then vote to determine the number of applications it will fund.

Please note that the following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review.
- Availability of funds.
- Relevance of program priorities.

### ELIGIBILITY

Grant applications may be submitted by New Jersey-based public and private nonprofit organizations, such as universities, colleges, hospitals, laboratories and units of State and local governments. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Other entities, companies, consortia and organizations may partner with eligible institutions for support under this program. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for support.

Nonprofit organizations are defined as any college/university or an organization that is owned and operated exclusively for scientific or educational purposes, and for which no part of the net earnings benefits any private shareholder or individual.

Institutions must appoint a principal investigator to be the individual designated by the applicant institution to direct the project that is supported by the grant. The Principal Investigator/Project Director is responsible and accountable to applicant institution officials for the proper conduct of the project.

Eligible applicants must comply with the terms and conditions for the administration of grants, general and specific grant compliance requirements issued by the granting agency, and applicable federal cost principles relating to the applicant.

#### TYPE OF FUNDING

Under this program, a total of \$5 million is available for up to 10 awards of no more than \$500,000 in total costs. These monies are to be used for basic research, clinical and translational research projects. General operational costs, new construction, renovation expenses for existing laboratories or shared resources that are already being supported by the institution or another outside agency will not be allowed. Funds requested must be based on the requirements of the project and fully justified.

While there is no restriction on the number of applications submitted by an institution or agency, the Governor's Council, in partnership with the DHSS, reserves the right to consider other contributing factors such as programmatic and relevancy factors in making decisions among applications that have comparable scientific merit based upon review panel recommendations. Administrative and general operational costs must be specifically and directly related to the project, necessary for the project's completion, and adequately justified. Accordingly, support for the following will not be allowed in the application:

- Greater than 20% of the Principal Investigator's salary (**thus, up to 20% is allowable**)
- Administrative salaries
- Secretarial, office expenses and telephone services
- Clinical care or treatment services not directly related to the project or shared resource
- General IT and computer services not related to the project
- Facility leasing or rentals
- Equipment
- Library services including the purchasing and binding of books and periodicals
- Furniture for laboratories and office equipment and supplies
- Dues for membership and registration fees in scientific societies or at professional meetings
- Recruitment and relocation expenses
- Facility construction, building maintenance or major alterations

Upon acceptance of a grant award, the applicant's organization assumes legal and financial responsibility for awarded funds and the conduct of supported activities. It is the responsibility of the applicant's institution and principal investigator to assure the accuracy and validity of all fiscal, scientific and administrative information pertaining to the awarded grant and the retention of the data.

#### SCIENTIFIC AND BUDGETARY OVERLAPS

The Governor's Council does not fund studies that have scientific or budgetary overlap with grants supported by other agencies. Accurate and complete information on actively funded, pending and planned proposals for each professional must be provided on the application form entitled "Other Support." Please indicate the percent of time and effort dedicated to each activity. It is important to note that the sum of all the percentages must not exceed 100 percent. When applicable, a letter assuring that duplicate funding sources will not be accepted by the principal

investigator must be included in the proposal. Should funding be accepted from another agency, it is the responsibility of the principal investigator to notify the Governor's Council immediately. The Governor's Council is in communication with other funding agencies and reserves the right to investigate any possible overlaps.

APPLICATION FORMAT

Application forms for this RFA can be downloaded from the "Forms" section of our website <http://www.nj.gov/health/autism/>.

DEADLINES

<u>Hard Copy and E-mailed Copy</u>	<u>Due Date</u>	<u>Activation Date</u>
Letter of Intent	June 29, 2009	
Application	July 23, 2009	December 1, 2009

Letter of Intent:

In order to be eligible to submit a grant application for the Governor's Council's Basic Science and Clinical Research grant initiative, applicants are **required** to submit a letter of intent by 4:00 PM on June 29, 2009. The letter of intent needs to include a descriptive title of the project, and the name, address, phone number and email address of the Principal Investigator, a 1 to 2 page description of the project, its purpose, and a statement outlining how the proposed project will significantly advance the understanding and treatment of ASDs.

Letters of intent must be delivered to the Governor's Council's office by 4:00 PM on June 29, 2009. No late letters of intent will be accepted. An applicant must submit a letter of intent by 4:00 PM on June 29, 2009 to be eligible to submit a full application for this grant program.

Full grant application:

***The original of the full grant application, 5 hard copies and an e-mail copy of the application must be received in the Governor's Council's office no later than 4:00 p.m. on the application due date of July 23, 2009.***

**Late applications will not be accepted.**

The letter of intent and hard copies of the proposal are to be sent to:

Mail Delivery

Governor's Council for Medical Research and Treatment of Autism  
Department of Health and Senior Services  
Division of Family Health Services  
PO Box 364  
Trenton, NJ 08625-0364

Hand Delivery

Governor's Council for Medical Research and Treatment of Autism  
Department of Health and Senior Services  
Division of Family Health Services, 6<sup>th</sup> Floor  
50 East State Street  
Trenton, NJ 08625-0364

The e-mail version of the full grant application is to be mailed to:  
[mike.gallo@doh.state.nj.us](mailto:mike.gallo@doh.state.nj.us)