



**New Jersey Department of Health
Governor's Council for Medical Research and Treatment of Autism
Meeting Minutes – March 4, 2013 6pm – 9pm (ratified)**

Council Members Present

Elizabeth K. Bell, BS, volunteer and independent contractor with Autism Speaks,
Autism Organization Representative

Matthew Cortland, BA, Instructor, Teach for America, Public Member

Caroline Eggerding, M.D., Healthcare Organization Representative and Chairperson of the
Governor's Council for Medical Research and Treatment of Autism

Susan P. Evans, Ed.D., Education Program Specialist for the Early Intervention Program,
Department of Health, Division of Family Health Services, Commissioner of Health Appointee

B. Madeleine Goldfarb, MA, Founder/Director of the Noah's Ark Children's Association,
Autism Organization Representative

Gary Weitzen, BA, Executive Director, Parents of Autistic Children (POAC) Autism Services,
Autism Organization Representative

Absent

Ketan Kansagra, M.D., FAAP, Children's Hospital of New Jersey at Newark Beth Israel Medical
Center, Academic Institution Representative

Judah Zeigler, Senate President Appointee

NJ Department of Health (DOH) Attendees

Martin T. Zanna M.D., MPH
Acting Executive Director
Governor's Council for Medical Research and Treatment of Autism

Linda N. Bocclair, M.Ed., MBA
Executive Assistant
Governor's Council for Medical Research and Treatment of Autism

Mary Ray, Contract Administrator 2
Governor's Council for Medical Research and Treatment of Autism
Commission on Brain Injury Research
Commission on Spinal Cord Research

Daphne Robinson, Ph.D., Consultant
Scientific Planning Consulting

Public Attendees

Michael Aquino, M.D.

I. Welcome - Council Chairperson, Dr. Caroline Eggerding called the meeting to order at 6:20 PM and welcomed everyone.

II. Public Meetings Act Announcement- Dr. Eggerding read the Public Meetings Act, followed by roll call.

III. Approval of the December 3, 2012 Council Meeting Minutes

Dr. Eggerding called for a motion to approve the minutes. MOTION by Ms. Bell to approve the minutes was seconded by Ms. Goldfarb.

MOTION to approve the minutes was passed with all in favor.

IV. Acting Executive Director's Report- Dr. Martin T. Zanna

Administrative Issues and Website

The following updates have been made to the website:

- The meeting calendar has been revised with the May 20, 2013 meeting added to enable the Council to discuss and vote for funding program sites and/or pilot projects resulting from the recent RFA. The June 3, 2013 meeting was removed from the website.
- A description of the NJ ACE grant program, including the Coordinating Center and Program Sites' grant abstracts have been added under "Current Grant Initiatives" and press releases have been added under "Reports/News/Meeting Minutes".
- 2012 progress reports from the 2010-2012 Basic and Clinical Sciences Research grantees will be added within the next month, replacing the 2011 progress reports. Nine of the ten grantees have been granted no cost extensions through June 2013.
- Once the current grant cycle is complete Council will be asked for suggestions on improving the website. Also policies and procedures are needed to address requests to post notices, fact sheets and other information on Council's website.

A Council member asked about the number of hits to the website. Dr. Zanna commented that the IT staff has provided that information and there had been a voluminous number of hits reported in 2012.

The Acting Executive Director of Autism NJ informed the Council staff that Dr. Linda Meyer no longer represents Autism NJ on Council. Autism NJ requested the appointment of an individual who has submitted an application to the Governor's office.

Report on RFA and Timeline

Thirty-two Letters of Intent have been received; six for Program Site grants and twenty-six for Pilot Project grants. The applications are due March 25, 2013 followed by review of the applications by members of the Scientific Merit Review Panel. Council can expect to receive access, through SAGE, to the applications and the critiques by the reviewers on May 6, 2013 in preparation for discussion and voting at the May 20, 2013 Council meeting.

In an effort to provide applicants with information that would be helpful as they plan their projects and write applications, the office staff worked with Dr. Gerard Costa and Dr. Daphne Robinson in designing an "RFA Information" webinar that was offered on February 1, 2013 to 22 potential applicants. The webinar provided an overview of the RFA including recommendations for addressing specific topics in the application that were identified as weaknesses in previous applications. Panel members, included Drs. Zanna, Robinson and Costa and Dr. Costa's staff, responded to questions from the potential applicants. Thanks to Dr. Costa for hosting the webinar at Montclair and a special thanks to Dr. Jerry Fails for working with the team in planning the webinar, providing technological expertise and follow-up with registrants.

To offer additional support to potential applicants who did not receive awards during the last grant cycle, notes from the meeting of the Scientific Merit Review Panel were sent to each of the applicants. Applicants were offered the opportunity to address questions, concerning their critiques, to the reviewers. Previously, the only interface with applicants was through posted "Frequently Asked Questions" as well as inquiries by e-mail and phone. It is anticipated that this additional support will increase the chances of improved quality of the applications that would achieve scores within a fundable range. This process represents more active engagement with potential applicants.

Report on NJ ACE Grantees

Progress reports from the NJ ACE Coordinating Center and Rutgers University grantees are due April 5, 2013 and will be sent to Council by May 6, 2013 for review in preparation for voting for continuation funding at the May 20, 2013 meeting.

Status of FY 14 Research Funding Ad hoc Committee

As mentioned at the December Council meeting, the current RFA process and funding decisions will inform the work of the ad hoc committee and can be included in decisions for funding in FY

14. Dr. Eggerding anticipates that the ad hoc Committee will reconvene shortly after the May 20, 2013 Council meeting with recommendations due to Council at the Sept. 9, 2013 meeting. An RFA will be posted in December 2013 for funding by June 2014. Dr. Zanna thanked those who participated in the ad hoc committee and looks forward to their continuing work.

National Autism Awareness Month

April is National Autism Awareness Month. Dr. Zanna requested that members send any activities planned during the month to Linda Bocclair so that she can compile a list to refer to as needed. Dr. Evans commented that the Department of Health staff are considering activities in recognition of National Autism Awareness Month and the Governor will issue a proclamation.

V. Update-NJ ACE Coordinating Center, Montclair State University (MSU) - Dr. Gerard Costa

Dr. Costa, the Principal Investigator for the NJ ACE Coordinating Center (CC) grant, presented a report on the CC plan, including an overview of the CC responsibilities and team members, the status of the selection of Clinical Research Program Sites and a review of the CC's past and current activities. In consultation with the Governor's Council staff, the decision was made to amend the original timeline of objectives and activities, with limiting activities and delaying hiring of additional staff, until final selections were made of all program sites and pilot projects. Activities to date include: (1) development and dissemination of a draft of the initial "Site Needs Survey" in anticipation of the full launch of the CC when all program sites and pilot projects are chosen; (2) revision of CC objectives and timeline in response to new program sites and pilot projects funding plan; (3) submission of the RDF (Research Determination Form) to IRB at MSU; (4) Letter of Support for Rutgers project in subject recruitment and data analysis; (5) site visit with CC-MSU and Rutgers team members to Hunterdon Medical Center to meet with Dr. Audrey Mars and team to review NDAR database and NJ ACE; (6) development and coordination of February 1, 2013 web-based information session for all entities interested in the RFA process; (7) job posting for project coordinator and; (8) CC website under development, purchase of dedicated server (expected URL is <http://www.njace-cc.montclair.edu>) with launch expected in April, 2013.

Discussion:

One responsibility of the CC is to provide specific training, as identified through a needs survey, for grantees. A Council member asked if ADOS/ADI and perhaps other training could be available to non-grantees. Dr. Eggerding commented that the ad hoc committee could make a recommendation to provide funding for such training throughout the state. Ms. Goldfarb commented on her experiences in providing ADOS training at UMDNJ, specifically the practicum component of the training, as a consideration in planning. The question was asked if there is a shift in ADOS/ADI training as a result of the DSM-5. No one was aware of changes although it was suggested that Dr. Catherine Lord, an expert in this area, could be contacted, as needed.

The question was asked of Dr. Costa if the CC team members were "autism people" before they became involved in the CC. Dr. Costa commented that team members are content specialists in their respective areas, including information technology and biostatistics. The team has experience in multi-site organizations, an important consideration in convening the team. One member who did have autism experience, in addition to Dr. Costa himself, was the medical

director Dr. Charles Cartwright; however, Dr. Cartwright found it necessary to withdraw due to other responsibilities. Dr. Costa is recruiting an autism content specialist to serve as medical director for the CC.

A question was asked about plans for the website. Dr. Costa commented that the website is under development and is open to ideas. He sees the website as an opportunity to help translate into everyday language the implications of the research occurring in New Jersey. The grantees will send information to the CC that can be shared with the public. The website will also be used to help in recruitment of subjects given that one of the responsibilities of the CC is to serve as a clearing house for the recruitment process. Dr. Costa envisions the website to have links to other resource systems but also developing resources for families that can be downloaded. The grantees will have a link where they can share information with each other and learn from each other with the goal of forming a unified community of autism researchers. The website provides a real opportunity to create much more synergy among all the various sites.

A member suggested providing a vehicle for input from parents and commented that a website is a great place to start the process. Perhaps this could be accomplished through Council contacts as the CC staff work with the grantees. Parents can provide invaluable information that otherwise may not be considered in discussions among the grantees. Dr. Costa agreed and commented that input from autism organizations will be solicited and inclusion of a parent link on the website would serve as an invaluable resource.

A member commented that it was her understanding that the Council delegated to the CC the responsibility to serve as a central location for training materials and best practices that exist in past and current research but are not centralized and available for viewing. Dr. Costa commented that some of that is being planned but there is a need to look at what exists with the possibility of geomapping of services, so practitioners and parents can know about the range of services close to their residences. With regard to the CC's role as a repository of best practices/materials, Dr. Costa will review the CC budget and assigned responsibilities. The large range of materials in the field are quite diverse and not held within the CC's archives or holdings, but the CC should be able to provide lists and links to where most, if not all, materials can be obtained.

Dr. Eggerding suggested working with Dr. Zanna as the website is developed to ensure synergy between the CC and the Council's website.

During the third year of the grant the CC plans to host a state-wide summit on autism to include every conceivable group including researchers, families, educators, clinicians, funders and others. International experts will be invited to speak, raising the opportunity to think outside the box. The CC team is committed to promoting a multidisciplinary approach, by looking at issues through many different lenses and generating a lot of discussion. The summit is a wonderful opportunity to do just that.

Review of Legislation and Needs Assessment

Dr. Eggerding suggested that at some point Council set aside time to review the legislation (P.L. 2007, c.168) and the "Needs Assessment to Inform the Development of a Strategic Plan for the Governor's Council for Medical Research and Treatment of Autism" conducted by Rutgers Center for State Health Policy and compare them to the current progress to ensure that Council is addressing the issues identified by the needs assessment and continues to align with the intent of the legislation. A member commented that perhaps this could be accomplished through the work of the ad hoc committee.

VI. Report on the March 23, 2012 Scientific Meeting of Basic and Clinical Sciences Research Grantees-B. Madeleine Goldfarb, M.A.

Council member Ms. B. Madeleine Goldfarb presented a report on the March 23, 2012 Scientific Meeting of Council funded basic and clinical science researchers. Ms. Goldfarb proposed the idea of a meeting to Council in 2011. Having worked with researchers throughout her career, she understood the importance of collaboration among researchers while recognizing the limited opportunities available for such collaborations.

It is anticipated that Ms. Goldfarb's report will serve to inform the ad hoc committee of Council. The ad hoc committee is charged with recommending funding priorities for FY14. It was also suggested that the three-fold increase in the number of Letters of Intent received for the current RFA cycle, as compared to the previous cycle was due, in part, to the collaborations among the researchers at the March 2012 meeting

Ms. Goldfarb's report included an overview of the agenda: (1) Opening Remarks by Council's Acting Executive Director Martin T. Zanna M.D., MPH; (2) Welcome by Ms. Goldfarb; (3) "Autism Research: Strengths and Needs in New Jersey" presented by Dorothy Gaboda, M.S.W., Ph.D., Rutgers Center for State Health Policy; (4) a report of the Council's activities by Dr. Zanna; (5) overview of Interdisciplinary Discussion Groups by Michael Lewis, Ph.D.; and (6) three discussion groups and reports of recommendations led by: Emanuel DiCicco-Bloom, M.D. (Group 1), Dennis Carmody, Ph.D. (Group 2) and Yvette Janvier, M.D. (Group 3).

Following is a summary of opportunities from the "Autism Research: Strengths and Needs in New Jersey" presentation:

- Study prevalence, diagnosis, and treatment of ASDs in underrepresented and underserved groups.
- There is a big gap in information about adults with autism, a relatively new priority area for autism research and one that is expected to expand.
- The influence of environmental risk factors on ASDs has received attention in NJ.
- Improve early identification of ASDs in very young children. New tools are being developed for use with very young children.
- Develop a NJ cohort of baby siblings of children with autism, similar to the EARLI study.
- Build on recent findings about the developmental plasticity of teens with ASD.
- More evidence regarding effective treatment approaches is needed for medical conditions which are frequently comorbid with autism.

- Increase the number of studies using brain imaging in connection with other approaches, e.g., linking brain function and behaviors.

Ms. Goldfarb thought it would be interesting to compare the areas of opportunities with the Letters of Intent received for the current RFA cycle to determine if there was any correlation with the meeting of the researchers.

The discussion groups addressed the following questions: Group 1: What are ways of identifying early onset of ASD? Who identifies the children and how? How can basic science research advance our understanding of this topic? Group 2: What do we know a child with ASD can and cannot do and how do we know it (i.e. the nature of deficits and strengths)? How can basic science research advance our understanding of this topic? Group 3: What do we do to help (i.e. the when and how of interventions)? How can basic science research advance our understanding of this topic?

Recommendations from the discussion groups included, but not limited to, the following:

- Funding fellowships would increase capacity ensuring a stable future for autism research in New Jersey with investigators initiating and following through with studies.
- Provide resources to allow clinical and basic scientists to collaborate on pilot and exploratory/collaborative grants, including translational research.
- An idea worthy of consideration is the creation of a biological materials resource center that would archive blood samples collected at birth to be used for biological testing and research.
- It was suggested that consideration be given to bringing clinical research expertise to New Jersey by funding a Chair in autism, someone with successful NIH clinical autism research and in creating human populations for genetic studies.
- Allow multiple principal investigators on grant applications rather than just one principal investigator. That would allow collaboration not only across disciplines but across institutions within the state such that both get credit and then can perhaps combine two particular grants into one with have a wider base.
- Given all the very different models of analysis, something that basic research can contribute is a framework for starting to link these ideas together.

Ms. Goldfarb ended her presentation with a summary of participants' comments with an overwhelmingly positive response to the meeting.

Discussion

Dr. Costa commented that one item of particular importance was the question of “what do we know that children with autism can and cannot do and how do we know it”. The question speaks to an understanding of what the core deficits are in autism. The more there is cross fertilization among the sites with different perspectives the more the researchers will think in broader terms.

Ms. Goldfarb commented that she is hopeful that the meeting proceedings will be published and distributed in the near future to inform stakeholders of the important work of the New Jersey autism researchers and possibilities for the future. Dr. Zanna commented that the document will be submitted, if possible, for approval by the next Council meeting. Dr. Evans suggested that the report to be sent to the Governor’s office and legislators be formatted in easily digestible pieces such as presented in the PowerPoint. The public will also need the report in a similar format.

Dr. Eggerding commented on CHOP’s Center for Autism Research model that illustrates how to integrate basic research, clinical translational research and both professional and family-based education. Perhaps a few members of Council (and Dr. Costa) could visit CHOP to understand how they structure and coordinate the model. It is very impressive in that they provide opportunities on many different levels and they are very good at public relations. Although Council is doing something more complex (i.e. a statewide version) seeing the CHOP model may give the state ideas for a framework.

Ms. Goldfarb commented that she was disappointed that at the end of funding in 2011 for the six Clinical Enhancement Centers the respective institutions did not, for the most part, support the continuation of the services that had been funded by the Council. She is hopeful that there will somehow be a way to match support from Council with institutional support so as to confirm commitment by the institutions for sustaining services.

Q&A-RFA Review Process

Q. In the review process, if we want bench scientists and clinicians to collaborate and focus on clinical impact, how can the review process reflect the need to provide flexibility and avoid the extremely critical critiques of applications that are the norm in the more basic science oriented applications?

A. Council wants to fund projects that will provide something useful at the end and the reviewers want to recommend projects that are likely to succeed. The question is “how can we make the process better while keeping proper standards?” We’re going to clarify some processes but not change the fundamental elements of the review. Before the reviewers see the applications we’re going to have an orientation session to make some fundamental points and emphasize that the potential clinical impact (significance) of a project is very important to the Council. First, these are a milestone based projects and in that sense they are not like NIH projects. If a grantee is not performing the Council can vote to discontinue funding. Second, we have a Coordinating Center, but not the way NIH thinks about Coordinating Centers. During the orientation session we will detail what the Coordinating Center can do to support grantees. For example, the Coordinating Center can help with ADOS training and provide biostatistical consultations. They

are not going to do the data analysis for the grantees but if the grantee needs help at some point the Coordinating Center is there to help. They can also help with subject recruitment and submission to NDAR. Applicants for the pilot projects don't have to have it all figured out when they apply. Third, the reviewers are allowed to suggest funding an application if specific revisions or actions are enacted. As an example, the reviewer can recommend funding only Aim 1 of a project or only if the applicant does something specific (ex. hire a person to address a specific need). If the applicant doesn't agree or is not capable of implementing the recommendation they will not be funded. These are the major areas that we are addressing while adhering to the same standards and not changing the fundamental process.

Member's comment: We want something good for the funding and we're setting the parameters and giving some flexibility. Saying what we are looking for is positive.

Q&A – Follow-up to March 23, 2012 Meeting of the Basic and Clinical Science Researchers

Q. Are we having discussions about the next meeting of the researchers considering the success of the 2012 meeting and the need to keep the up momentum?

A. Dr. Costa commented that the CC is planning a statewide summit of autism researchers to be offered during the third year of project (2015). Dr. Costa's current focus is on realigning priorities as a result of the delay in funding a full complement of program sites. He is getting to know the two current grantees and anticipates the need to bring many more grantees into the "fold" in June as result of the current RFA cycle. The group that will plan the Summit is critically important and before providing specifics he will need to know who the players are and decide how to best proceed. Building relationships among all concerned is critical to the success of the Summit and to the future of the NJ ACE.

Comment from a member: We should consider offering a meeting of researchers similar to the 2012 meeting but not as comprehensive as the statewide summit to be offered by the CC. To differentiate the types of meetings it was suggested that the March 2012 meeting described by Ms. Goldfarb, was an internal/"family of programs" gathering and the summit was a larger "external" venue.

Dr. Eggerding proposed that by autism awareness month next year (April 2014) that there be a follow-up to the 2012 meeting. A task of the ad hoc committee could be to plan a meeting as its next step. If the focus is on translational research planning the meeting could be one part of that process. It was suggested that a meeting be held biannually to bring researchers together to continue the conversations and report on the state of the autism research in NJ. Members agreed to add to ad hoc committee agenda a 2014 meeting and include Dr. Costa on committee discussions, as appropriate. Dr. Costa agreed with the recommendation to host the internal/"family gathering" meeting at Montclair State University and welcomed the opportunity to be involved in the planning of the meeting.

VII. Report of Revenues and Expenditures

Ms. Ray presented the Revenue and Expenditures Report (July 1, 2012 – June 30, 2013). There were no comments or questions from Council.

Mary commented that revenue was slightly lower for November and December, most likely due to the storm (Sandy) and the holidays.

VIII. Election of the Chairperson

Dr. Zanna called for nominations. Ms. Goldfarb nominated Dr. Eggerding. Ballots were distributed; members voted and unanimously elected Dr. Eggerding as Chairperson for 2013. Dr. Eggerding thanked the members.

IX. Public Comments

Dr. Aquino commented that it was a great meeting. He is a gastroendocrinologist and has two children on the spectrum. He has been following the Council proceedings and acknowledges the great work done by Council and wished to show his appreciation. Dr. Aquino is a former Board President for Autism New Jersey (2005). When a member encouraged Dr. Aquino to submit his application for membership on the Council, he commented that he had submitted an application and resume through the Governor's office.

Dr. Eggerding thanked Dr. Aquino for his comments and his interest in the Council.

X. Adjournment

Dr. Eggerding called for a motion to adjourn. MOTION by to adjourn by Dr. Evans was seconded by Mr. Weitzen.

MOTION passed with all in favor. The meeting was adjourned at 8:20 PM.