



**New Jersey Department of Health and Senior Services
Governor's Council for Medical Research and Treatment of Autism
Meeting Minutes – February 28, 2011 (ratified)
6pm – 9pm**

**Location: NJ Department of Health and Senior Services, Health & Agriculture Building,
369 South Warren Street, Trenton, NJ 08625-0360**

Council Members Present

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

Caroline Eggerding, MD, Vice President Clinical Services, Bancroft NeuroHealth,
Assembly Speaker Appointee and Chair of Governor's Council for Medical Research and
Treatment of Autism

Susan P. Evans, EdD, Education Program Specialist for Early Intervention Program,
Commissioner of Health and Senior Services Appointee

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

Linda S. Meyer, EdD, MPA, BCBA-D Executive Director of Autism New Jersey, Autism
Organization Representative

Grace M. Reilly, RN, MSN, APN-C, Adult Nurse Practitioner for Riverview Medical Center,
Individual with Autism or Family Member Representative

Kendell R. Sprott, MD, JD, Acting Director of Pediatrics, University of Medicine and Dentistry-
New Jersey Medical School, Academic Institution Representative

Barbie Zimmerman-Bier, MD, Appointment at Rutgers University, clinician at St. Peter's
University, Academic Institution Representative

Absent

Ketan Kansagra, MD, FAAP, Children's Hospital of New Jersey at Newark Beth Israel Medical
Center, Academic Institution Recommendation

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Judah Zeigler, Associate Vice President of Sharp's Retail and Consumer Marketing, Senate President Appointee

NJ Department of Health and Senior Services (DHSS) Attendees

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

Cynthia Kirchner, Senior Policy Advisor
Ethics Liaison for the DHSS

Linda N. Bocclair, 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

General Public Attendees

Susan Freedman, Regional Autism Center at Hunterdon Medical Center and Special Child Health Services Case Management

Audrey Mars, MD
Medical Director, Regional Autism Center at Hunterdon Medical Center

Tricia McGinley
Center for Neurological and Neurodevelopmental Health

Lisa Alberts
Center for Neurological and Neurodevelopmental Health

Yvette Janvier, MD
Children's Specialized Hospital

Fran Gallagher
NJ PCORE

Jill Harris, Ph.D.
Children's Specialized Hospital

AFM Haque, MD, MPH
Medical Director
Private Practitioner

Deborah Cohen, Ph.D.
Office of Autism
NJ Department of Human Services

Jonathan Sabin
Office of Autism
NJ Department of Human Services

Walter Zahorodny, Ph.D.
UMDNJ New Jersey Medical School

Barbara Wells
Autism New Jersey

I. Welcome and Introduction of Dr. Martin T. Zanna

Ms. Cynthia Kirchner, DHSS Senior Policy Advisor, welcomed everyone. She announced that Mr. John Crosbie was no longer with the Department, effective January 26, 2011. She indicated that Council business will move forward and if there are any question/concerns to contact her.

Ms. Kirchner welcomed Dr. Martin T. Zanna and introduced him as Acting Director of the Council, effective January 27, 2011. Dr.Zanna is a physician and Diplomat of the American Board of Preventive Medicine. He was designated the NJ LTC Acting Ombudsman on October 15, 2010 having served for many years at the NJ State Department of Health and Senior Services (DHSS) as well as the New Jersey Department of Human Services (DHS) in various positions as a public health physician and medical administrator. Dr. Zanna is a graduate of Harvard College (Cambridge, Mass), University of Minnesota Medical School, and the Harvard School of Public Health as well as a Fellow of the American College of Preventive Medicine.

Dr. Zanna will be working with the Council and Council staff as the Department recruits an Executive Director. The position is posted on the NJDHSS website and Ms. Kirchner encouraged Council to inform the autism staff of anyone who may be interested in the position. The Chairperson of the Council will be included in the selection process.

II. Call to order, Roll call and Public Meetings Act Announcement

The meeting was called to order by Dr. Caroline Eggerding, Chairperson, at 6:15PM. Dr. Eggerding read the Public Meetings Act Announcement and announced that all votes will be recorded by roll call and recorded as Yes, No, Abstention or Recuse.

III. Election of the Chairperson

As stated in the Statute, the Council is to elect a Chairperson at the first meeting of the year. Dr. Eggerding called for nominations. MOTION by Dr. Barbie Zimmerman-Bier to postpone election of the Chair until ethics rules are defined and seconded by Dr. Linda Meyer.

Discussion focused on the need for feedback from the State Ethics Commission regarding issues raised at the December 6, 2010 Ethics Training presented by Ms. Margaret Cotoia. Issues include if individuals whose organizations receive funding from the Council can sit on Council and if organizations applying for grants funded by the Council can be represented on Council. Ms. Kirchner did follow up with Ms. Cotoia and is awaiting her response. Ms. Kirchner stated that the two Commissions that she oversees (Brain Injury and Spinal Cord Injury Commissions) do not permit grant recipients to serve on the Commissions. If a member's institution receives funding from the Commission, the member can serve on the Commission providing the member is not involved directly with the funded project. The member recuses from discussions and voting on funding issues for the institution. Ms. Kirchner emphasized the unique nature of the Autism Council with members receiving funding from the Council while serving on the Council. This is a major issue and one that is not easily resolved. The recusal process and the roles of the Council and of the grantees must be clear to ensure safeguards are in place while at the same time not decimating the Council of those institutions that need to be represented. A question was asked regarding the election as Chairperson of someone that everyone agrees can be nominated for the position. The motion was amended to include continuation of the current chair until a new chairperson can be elected.

The MOTION to postpone election of the Chair until ethics rules are defined and continuation of the current chair until a new chairperson can be elected passed with all in favor.

IV. Approval of December 6, 2010 Council Minutes

Dr. Eggerding asked for a motion to approve the minutes. MOTION by Dr. Zimmerman-Bier to approve the minutes was seconded by Ms. Bell. Questions and discussion: Why was the format of the minutes changed from specific quotes by members to general discussion points? Different people are recording the minutes since Family Health Services (FHS) is no longer responsible for recording the minutes. What happened to the meeting minutes from previous meetings that had been posted on the website? The meeting minutes prior to the September 2010 meeting have been archived since accessing minutes had become cumbersome with all minutes posted on the meeting calendar. In response to Council's request, the archived minutes will be retrieved and posted on the website under the "Reports/News" tab. It was noted that Council needs to receive the minutes within two to four weeks following a meeting. A comment was made that those members who did not attend the meeting should abstain from voting.

MOTION to approve the minutes as presented was passed with two abstentions.

MOTION by Dr. Zimmerman-Bier to distribute meeting minutes to Council within a target of four weeks after a meeting was seconded by Ms. Reilly. After a brief discussion of the need for flexibility the motion was AMENDED by Ms. Bell and seconded by Ms. Goldfarb to target four weeks but to allow for additional time for extenuating circumstances.

The MOTION to distribute meeting minutes to Council within a target date of four weeks but to allow for additional time for extenuating circumstances passed with all in favor.

V. Report of the Acting Executive Director

Dr. Eggerding called on Dr. Zanna to present his report. She requested that questions be held until the end of the report.

Administrative Issues

Dr. Lori Garg resigned to accept the position of Director, Newborn Screening Program, Family Health Services. She has been a tremendous asset to the Council. We are most appreciative of her willingness to assist the staff during the transition. Dr. Garg suggested that a public health nurse could monitor the grants, including review of quarterly reports and conducting site visits. Dr. Zanna commented that in the interim Dr. Danuta Buzdygan, a pediatric consultant employed part time by the DHSS, will assist with site visits.

Dr. Yvette Janvier resigned from her position on the Council, effective December 6, 2010. She will be missed by the Council but we are pleased to see her at the meeting tonight as a public member.

The Council's website has been updated with contacts, meeting calendar, funding opportunities and Center descriptions.

Collaborative Database

The improved collaborative database was tested in late December and released to all six Centers during the week of January 24 after several months of working with the Centers, DHSS researchers, programmers and IRB staff to establish reporting requirements, timelines and obtain IRB approvals. Most Centers are entering data into the database or at least collecting data that will be entered into the database within the next month. The Centers are pleased with the improvements as compared to previous versions.

Grant Monitoring

Site Visits: Dr. Lori Garg and Ms. Linda Bocclair visited Hunterdon Medical Center on January 14 and reported that the Center is, at a minimum, meeting and often exceeding the requirement of their grant. The expertise of the staff and their commitment to serving their patients is impressive. A site visit to UMDNJ is scheduled for March 22 and four additional site visits will be scheduled for late March and April.

Center mid-year reports: The mid-year reports are summaries of Quarters 1 and 2 reports and are due on March 17. The reports will be forwarded to Council at least a week prior to the April 4th Council meeting. The same reporting format as the Year 2 Summary Report will be used with one additional question: "Were there any goals that you were not able to accomplish? If yes, why?" Quarter 3 reports are due April 29.

Conference call: The topics for the January 20 call with the Clinical Enhancement Centers' Principle Investigators included (1) the budget (expenditure reports and no cost extensions), (2) sustainability of services after June 30, 2011, (3) differences between current funding vs. new RFAs, (4) collaborative database updates and (5) Center presentations to Council. The next conference call is scheduled for March 24.

Quarterly Reports: Dr.Lori Garg has been reviewing quarterly reports with Ms. Boclair and most recently with Dr. Zanna. While it appears that the Centers are meeting or exceeding grant requirements Dr. Zanna and Ms. Boclair will review and summarize the reports.

Center presentations: Dr. Audrey Mars, Hunterdon Medical Center and Dr. Mark Mintz, CNNH will present highlights of their respective Centers at the April 4 Council meeting.

Basic Science Research Grants

Final reports have been received from all eleven of the 2007-2009 basic science grantees. Dr. Zanna has read several of the reports and is impressed with the work of the grantees. The reports will not be released without written permission from the grantees since several may be in process of submission or awaiting the final results of the peer review process. The list is included in Council's packet. Please note that one report outstanding on the list was received on Friday, as expected.

Also all eleven of the current grantees (2010-2012) progress reports have been received and will be sent to Council. Summaries of the reports will be included in Council's 2010 Annual Report.

We anticipate that the 2007-2009 grantees will participate in the Autism New Jersey's October 13-14, 2011 conference in Atlantic City. Dr. Meyer will comment during the discussion of this report.

Ethics Training Follow-up

Members who have not completed the Ethics Training and/or signed forms indicating receipt of the documents distributed at the training meeting have been notified. Forms are available tonight for those who have not signed. Copies of the Conflict of Interest Forms (COI) are also available. Please send your CVs to Ms. Boclair if you have not done so.

RFAs -Autism Center of Excellence (ACE)

A timeline for the RFAs is included in Council's packet. Two members of the Council and one outside reviewer, Dr. Clara Lajonchere, Vice President of Clinical Programs at Autism Speaks, are reviewing the RFAs. The Notices of Grant Availability (NOGA) were published on February 9 in the 2012 issue of the NJDHSS Grant Directory. The NOGA presents brief descriptions of the RFAs.

Rutgers University

The timeline for the Memorandum of Agreement (MOA) with Rutgers University is included in Council's packet. Dr. Dorothy Gabado is conducting the needs assessment.

Dr. Zanna thanked Council for their attention and Dr. Eggerding asked Council for comments and questions.

Discussion following Dr. Zanna's report:

NOGAs: Notices of Grant Availability (NOGA) for the two RFAs (Coordinating Center and Program Sites) were published in the NJDHSS Department Directory on February 9. The purpose of the NOGA is to alert the public to the availability of funding in FY12. NOGA information is limited to general descriptions and duration of the projects and the level of funding.

Site visits: Dr. Zanna addressed the questions of site visit protocols and indicated that both he and Dr. Buzdygan (pediatric consultant) have previous experience with conducting site visits. He briefly described the protocol that will be used for the two upcoming site visits and those to be scheduled in March and April.

Program monitoring and implementation: Concern was expressed by Council regarding the lack of information on the progress made by the Clinical Enhancement Centers since the beginning of Year 3 of the grant. Council approved noncompetitive funding for Year 3 based on increased accountability and adherence to a monitoring policy proposed by the Executive Director. At that time Council was assured that monitoring would follow the policy but it was never clear who was doing what and to this date, that information has not been provided to Council. Since there appeared to be significant monitoring of the Child Evaluation Centers by Family Health Services (FHS), Council accepted the assurance that similar monitoring would be implemented for the Clinical Enhancement Centers. As of October 2010 the collaborative database was still not operational and there had been no site visits. Two and one-half years into the grant and not all sites have received IRB approvals.

It was noted that as of December 2010, five of the six Centers have IRB approval and, in response to the question, yes, funding is being withheld for the Center without IRB approval. It was noted that in his report to Council Dr. Zanna described the implementation of the collaborative database and the program monitoring activities that have occurred since October. There is a need for the Department to define what it considers appropriate oversight and determine what information Council needs to satisfy the need for accountability. After a review of the proposed grant monitoring system, it was noted that we need to be realistic in our expectations considering the resources available at the State. There are fewer employees at the State, representing not only a reduction in numbers but also in the loss of a tremendous amount of experience.

What resources are available to monitor the Centers? The Department is recruiting a public health nurse consultant to assume responsibility for grant monitoring including review of quarterly reports and conducting site visits. The number of required site visits per year was discussed with disagreement as to the number or if a specific number had been agreed upon since Centers with problems may need more frequent sites versus those meeting all grant requirements. All seemed to be in agreement that there needs to be a grant monitoring protocol for evaluating Centers – what needs to be done and how often. The Council's Annual Report should include Center's accomplishments. The 2009 Report was incomplete.

Council meetings: In response to a question by Council regarding the location of Council meetings, Ms. Kirchner announced that all meetings will be held in Trenton unless otherwise notified, in conformity with the Public Meetings Act Announcement.

Hiring staff: While hiring staff during a transition period is difficult, consulting services can be contracted to provide grant monitoring services. Family Health Services (FHS) was monitoring the grants when the Council was moved into the Commissioner's Office. FHS is no longer responsible for the Council's grants. While Council has the funds to hire personnel it is unlikely that a new position would be approved considering the financial constraints at the State. The Department will move forward with hiring a consultant for monitoring.

Timeline for RFA: One member commented that it was encouraging to see a lot of work being done to move the RFAs forward and that it is best to take six months to do it right. Letters of Intent are required for both RFAs and will be added to the timeline. The purpose of the Letter of Intent was clarified. The Letter is used as a means of determining the number of potential applicants and to plan for processing the applications. The Letter will be due 30 days prior to the application due date. Applicants are not screened or eliminated as a result of the Letter. This needs to be explained in the RFA since some RFAs require Letters as a means of screening applications and inviting only select applicants to submit proposals. There are pros and cons to requiring Letters of Intent. While it is helpful for staff in planning work schedules, if an organization sees the RFA after the due date for the Letter that organization would be unable to apply. The selection of a grant review committee may be a challenge considering all that needs to be done, in addition to the RFAs, during Dr. Zanna's tenure as Acting Executive Director. Another challenge could be the expertise required – both clinical and research. Concerns were expressed regarding conflict of interest and possible relationships between applicants and panel members. The Department makes every effort to vet potential reviewers and out of State reviewers are always selected to review grants.

Research Funding and the October 13-14 Autism New Jersey Conference: Since there have been a number of research projects funded in the past, Council asked if the researchers are obligated or required to present the results of their research to the Council and/or at a conference? Dr. Meyer enthusiastically expressed interest in researchers presenting poster sessions at the Autism New Jersey 29th Annual Conference on October 13-14, 2011 in Atlantic City. She described the conference as "bigger and better" this year and a good opportunity to highlight the work of the Council funded research. The National Organization of Autism Research is sponsoring a track at the conference to promote science in autism. Ms. Barbara Wells is the conference director and will follow-up with additional information as it becomes available. While it is unlikely that researchers who have completed their grants are obligated to present at the conference, they may see it as an opportunity and should be invited. Dr. Zanna read several of the 2007-2009 Grant Reports and found them to be impressive. Following a discussion of past and current research and the potential to showcase the work funded by the Council, a MOTION was made by Ms. Goldfarb to create a sub-committee to explore and provide an update of all old Council funded research (emphasizing outcomes of such research) and seconded by Dr. Zimmerman-Bier. Ms. Goldfarb agreed to work with Dr. Zanna to convene a subcommittee.

Discussion of the Council's role with the Autism New Jersey Conference continued with options available to participate in the Conference. It was decided that Council would encourage 2007-2009 grantees to present at a poster session. There will be no cost to Council and space and display boards will be provided at no cost to the researchers. Researchers will pay a \$100 registration fee. Autism New Jersey does not receive funding from Council. Council will be responsible for recruiting the researchers and coordinating all arrangements, setting up the posters, hosting the poster session and directing conference participants to the displays. It was suggested that lay abstracts from the 2007-2009 researchers be posted on the Council's website by the end of June. Dr. Zanna agreed to reach out to the researchers to personally invite them to participate. He will reach out to Council to assist him, as needed. MOTION by Dr. Evans to coordinate through Autism New Jersey and participate in a poster session inviting research and Clinical Enhancement Center grantees to present at the Autism New Jersey conference in October and seconded by Ms. Goldfarb.

MOTION to create a sub-committee to explore and update all old Council funded research to determine the outcomes of the research passed with seven in favor and one recusal.

MOTION to coordinate through Autism New Jersey and participate in a poster session inviting research and Clinical Enhancement Center grantees to present at the Autism New Jersey conference in October passed with seven in favor and one recusal.

In reference to the needs assessment being conducted by Rutgers University for the Council, a comment was made about the possibility of Rutgers setting up a booth to interview families. Since the Council is funding the Rutgers project but not directing the project, it might be appropriate to recommend or alert Dr. Dorothy Gaboda of the opportunity for a booth.

Status of the Clinical Enhancement Centers' reports: Council was reminded of the discussion with Mr. Crosbie, previous Executive Director. At that time there was agreement that the quarterly reports were too lengthy and the raw data was not helpful in assessing Centers since the goals and objectives differed among the Centers. The intent was to summarize the data and distribute to Council. Ms. Boclair commented that Center reports due on March 17 summarizing Quarters 1 and 2 will be distributed to Council. A comment was made that Council needed to see the third year grants that Dr. Garg approved since the goals and objectives were included in the grants. Ms. Boclair commented that the goals and objectives for each Center are listed in their respective mid-year reports along with the activities/methods and evaluation.

Conference calls with Clinical Enhancement Centers' Principles Investigators: The question was asked if Council can participate in the Principle Investigator's calls. Yes, but participation must be limited to less than a quorum since more than a quorum of Council members requires public notification of the calls. Council will be notified via email of the agenda and call in information for the March 24 call.

VI. Proposed Additions to the Rules of Order

Dr. Eggerding noted that "Additions to the Rules of Order" had been distributed for comments and is now up for a vote. The document focuses on the duties of an active council member.

MOTION by Dr. Sprott to approve the “Additions to the Rules of Order” was seconded by Ms. Goldfarb. Discussion: The premise is good but the document needs a lot of work. There is overlap between the responsibilities as listed in the Rules of Order. Specific comments:

#2 “Exercise duties in a manner consistent with the best interests of the mission of the Council”. Does this supersede or replace statements in the Rules of Order? A comment was made that the original statement remains unless there are objections.

#3 “Establish as a high priority attendance and participation in all regular Council meetings and conference calls”. Does this supersede Rules of Order? A comment was made that the statement is intended to reinforce best practices. Three years ago Council met every other month, then more frequently and now back to six per year.

#5. “Support the decisions of the Council and the DHSS...” This implies that Council must refrain from publically expressing opinions that may conflict with those of Council and/or DHSS even when members need to be critical when serving in another role, such as a member of a catholic institution and not as a representative of Council.

Discussion continued with the following comments: It is premature to pass the “Additions to the Rules of Order”. They are somewhat redundant and confusing. A subcommittee should be appointed to ensure the “Additions to the Rules of Order” are consistent with language of the legislation and clearly stated.

Council members need information so that they can be knowledgeable and the information is not provided when a member receives notice of appointment from the Governor’s Office. It is often not clear what is expected of the member. It is advisable to give information such as ethical and other responsibilities before an applicant is appointed to the Council. A comment was made to consider including the information on the Council’s website.

Concern was expressed over rescheduling meetings. Dr. Eggerding explained that the reason for the change in the February 7 meeting was due to the fact that, not only was she unavailable, but that Mr. Crosbie was no longer with the Department.

Ms. Kirchner commented that the Council is moving in a positive direction but that the necessary changes will not occur all at once. She referred to her experiences with the Brain Injury Commission over the past ten years and how members faced problems similar to those of the Council. The Commission is now fully operational with ethical issues resolved, members clearly understanding their roles and responsibilities and policies and procedures in place to accomplish the Mission of the Commission. Ms. Kirchner encouraged Council members to continue in the positive direction and they will accomplish what they set out to do as a Council.

The MOTION to approve the “Additions to the Rules of Order” failed with three in favor and five opposed.

The question was asked if there should be a motion to address the issue of the “Additions to the Rules of Order” It was suggested that members with suggestions should talk to Dr. Evans so that Council will be prepared to vote at the next meeting.

VII. Report of Revenue and Expenditures

Ms. Ray commented that the Report lists Revenue and Expenditures through December 2010. Expenditures for new construction listed on pages 2 and 3 will be corrected to read information processing equipment. The note at the end of the pages refers to an adjustment that will be made at the end of the year. Council will be charged for one-third of the Executive Director's salary, one third of the contract administrator's salary and full salary for the Executive Assistant. Conferences include food at meetings, peer reviewers for grants (honorariums, lodging, and travel) and site visits. Council can be reimbursed for travel to attend meetings. Mary will send the forms. Whatever is not spent at the end of the fiscal year rolls over to next fiscal year. Mary will look into consultant costs for program monitoring. Cost for the year must be under \$39,000. Once an hourly rate is determined, the total number of hours available can be determined.

VIII. Comments by public member attendees

Dr. Jill Harris from Children's Specialized Hospital provided an overview of the agenda for the March 18 Autism symposium to be held at the Pines Manor in Edison. The program includes presentations by several nationally known autism experts and workshops for parents and professionals. The symposium is funded in part by the Council.

Ms. Tricia McGinley announced a Community Education Workshop Series for families and Professionals, offered by the Center for Neurological and Neurodevelopmental Health at the new CNNH facility in Gibbsboro. The series runs from March through December with weekly workshops during the month of April. The series is funded in part by the Council

AFM Haque, MD,MPH introduced himself and thanked the Council for all they're doing for the children with autism. His child is autistic and he cares for autistic children in his practice. He struggles every day when parents come to him hoping that he can fix the problem but he cannot. More must be done to help address autism and he encourages the State to go to the level where real meaningful research and treatment options can be explored and best practices implemented. He offered his assistance to help in anyway.

IX. Adjournment

Dr. Eggerding thanked the public for their comments and called for a motion to adjourn. MOTION by Dr. Evans to adjourn the meeting and seconded by Ms. Goldfarb.

MOTION passed with seven in favor and one opposed. The meeting was adjourned at 8:50 PM.