



Via FedEx

November 7, 2011

Brian Winklosky
MGH-Center for Child and Adolescent Health Policy
15th Floor-C100
100 Cambridge Street
Boston, MA 02114

Reference: ATN-AIR-11-03 Submission

Dear Mr. Winklosky:

Enclosed, please find the original signed application on behalf of Children's Hospital Los Angeles by Ms. Bonji Saliwan, Director of Financial Services, The Saban Research Institute.

Should you have any questions, or need additional information, please do not hesitate to contact me at the address below.

Thank you,

Naghma Ahmad
Sponsored Projects Analyst
The Saban Research Institute
Children's Hospital Los Angeles
4650 Sunset Boulevard, Mail Stop # 97
Los Angeles, CA 90027-6062
323/361-8560 Voice
323/361-7923 Fax
chlaawards@chla.usc.edu
nahmad@chla.usc.edu

cc: Kathryn Smith, Principal Investigator
Rosaura Diaz, Program Administrator

Enclosures



Autism Intervention Research Network on Physical Health

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AIR-P Network: Pilot Projects on Treatment Research Affecting Autism

PROPOSAL COVER PAGE

Response to RFA #: ATN-AIR-11-03

1. TITLE OF PROJECT

Use of Complementary and Alternative Medical Treatments in the ATN Population

2. PRINCIPAL INVESTIGATOR

SUPPORT REQUESTED: ☒ LEVEL 1 ☐ LEVEL 2

2a. NAME (Last, first, middle)

Smith, Kathryn A. Navarette

2b. DEGREE(S)

RN, DrPH

2c. POSITION TITLE

Senior Site Coordinator for the Children's Hospital, ATN site

2d. MAILING ADDRESS (Street, city, state, zip code)

4650 Sunset Blvd., Mailstop #30
Los Angeles, CA 90027

2e. DEPARTMENT

Boone Fetter Clinic

2f. TELEPHONE AND FAX

TEL: 323 361 8301

FAX: 323.361.8043

2g. E-MAIL ADDRESS:

Kasmith@chla.usc.edu

3. DATES OF PROPOSED PERIOD OF SUPPORT
(month, day, year—MM/DD/YY)

From

04/01/2012

Through

03/31/2013

4. COSTS REQUESTED FOR INITIAL BUDGET PERIOD

4a. Direct Costs (\$)

40,000

4b. Total Costs (\$)

64,000

5. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT

5a. Direct Costs (\$)

40,000

5b. Total Costs (\$)

64,000

6. ATN CENTER NAME/ADDRESS

Name

Children's Hospital Los Angeles

Address

4650 Sunset Blvd., Mailstop #30
Los Angeles, CA 90027

7. BUSINESS / ADMINISTRATIVE OFFICIAL (FOR SUBCONTRACT ARRANGEMENTS)

Name

Bonji Saliwan, Director, Financial Services
The Saban Research Institute

Title

Address

4650 Sunset Blvd., Mailstop #84 Los Angeles, CA 90027

Tel: 323.361.6463

FAX: 323.361.8054

E-Mail: swestcott@chla.usc.edu

SIGNATURE OF PRINCIPAL INVESTIGATOR

DATE

Kathryn A. Navarette

Bonji Saliwan Signature
Date 11/7/11
11/2/11

ABSTRACT

Autism is a neurodevelopmental disorder characterized by deficits in social interaction and language development, and restricted or stereotypical patterns of interests and activities (Weber and Newmark, 2007). Complementary and alternative medical (CAM) interventions are often used by parents of children with autism, alone or in conjunction with more traditional therapies. A 2006 report by Wong and Smith reported that 52% of children with ASD have tried a CAM at some point in their lives, compared to 28% of children without disabilities. A 2007 study by Hanson showed that 74% of families were using some type of alternative therapy.

This study seeks to characterize the prevalence of CAM use in the ATN Registry, and to examine predictors of its use. Expected benefits of the study include an increased understanding of the use of CAM. Data will be requested from the AIR-P Data Coordinating Center (DCC) of the entire sample of the ATN Registry (N=3580) for the dependent variables of traditional, complementary and alternative therapies, and independent variables of ethnicity, age of child, insurance type, region of country, parent educational level, language of household and child diagnosis. Aims of the study include the following:

Aim 1: Describe the use of CAM as well as traditional therapies in the ATN Registry population.

Aim 2: Explore predictors of CAM use in the ATN Registry population.

I. Introduction

Autism is a neurodevelopmental disorder characterized by deficits in social interaction, language development, and a restricted or stereotypical pattern of interests and activities (Weber and Newmark, 2007). The primary goals of treatment are to minimize the core features and associated deficits, maximize functional independence and quality of life, and alleviate family distress (Myers and Johnson, 2007). Treatments for autism can be considered traditional, focusing on therapies, educational interventions and standard medical treatments for comorbidities, or complementary and alternative.

Traditional treatments

Traditional goals to treat autism emphasize the development of social skills and social communication and the regulation of behavior. Goals are addressed through behavioral services, medications, social skills training and educational services that include disciplinary therapies. Among traditional treatments are: Applied Behavioral Analysis; TEACCH-sometimes called structured teaching; Discrete Trial Training; Developmental Individual Difference, Relationship-Based Approach (DIR/Floor Time); occupational therapy, including sensory integration intervention; speech therapy; social skills training and the use of augmentative and alternative communication modalities (Myers et al., 2007).

Complementary and alternative medical (CAM) treatments

CAM interventions are often used by parents of children with autism, alone or in conjunction with more traditional therapies. Levy et al. (2003) described the use of CAM in a sample of 284 children with suspected or recently diagnosed autism and found that 30% of the sample used some form of CAM, and that 9% were using potentially harmful CAM. Having an additional diagnosis was protective against its use, and being Latino was associated with the use of CAM. Harrington et al. (2006) reported on a survey of white middle to upper class families served in a private pediatric practice, and reported that 92% of autism spectrum disorder (ASD) patients had used CAM at some point. A 2006 report by Wong and Smith reported that 52% of children with ASD have tried a CAM at some point in their lives, compared to 28% of children without disabilities, and a 2007 study by Hanson showed that 74% of families were using some type of alternative therapy. Of note, in the studies by Wong et al. (2006) and Hanson et al. (2007), only 36% to 62% of caregivers who used CAM therapies for their children with ASDs had informed the child's primary care physician.

Despite the fact that CAM interventions are used with some frequency, there is little information about which therapies are used and their frequency of use, and which families are most inclined to use these therapies. This project proposes to answer these questions for the population of patients enrolled in the Autism Treatment Network.

There are several alternative approaches to treating individuals diagnosed with autism; some are controversial and have not been scientifically shown to be effective. Families may be using interventions that do not have conclusive evidence, peer reviewed research or evidenced based controlled studies (Jacobson et al., 2005; Weber and Newmark, 2007).

Complementary and alternative therapies include:

- a. Manipulative Therapies. This includes chiropractic and craniosacral therapies.
- b. Homeopathy, herbal therapies and floral therapies.
- c. Facilitated Communication. This approach uses a computer/typewriter device, with assistance from another person, for communication.
- d. Auditory Integration. This approach is based on the idea that certain sounds can cause emotional and behavioral difficulties and attempts to re-program the auditory system. The child listens to specifically modified music that is designed to have a corrective affect.
- e. Hormone Therapy. This approach uses two hormones, secretin and adrenocorticotropin which have been proposed as treatments for autism.
- f. Chelation Therapy. In this therapy, heavy metals, thought to be a cause of autism, are removed from the body, and hair analysis is often performed first to diagnose the presence of heavy metals.
- g. Immune Globulin Injections. This approach is used to treat an immune system damaged by exposure to mercury, believed by some as a cause of autism.
- h. Special Diets and Supplement Therapies. This includes modified diets, vitamins, minerals, probiotics, digestive enzymes, metabolic interventions and other nutritional supplements.
- i. Antibiotics and Antifungals. These are used to decrease gastrointestinal flora.
- j. Recreational Therapies. Equine, art, dance, music and dolphin therapies have been utilized.
- k. Other

This case (CAM) control (traditional treatments) study seeks to answer questions related to CAM, as well as traditional therapies, including types of CAM used, and potential predictors of CAM use in the ATN Registry population. This study will be conducted by a research team at Children's Hospital Los Angeles (CHLA), as part of their participation in the Autism Treatment Network. A description of the facilities and resources is attached.

II. Specific Aims/Hypothesis

The goal of this proposed research project is to examine ATN Registry data to compare the use of complementary and alternative medicine (CAM) with traditional therapies for children with autism by ethnicity/race, age, insurance status, region of the country, caregivers' educational level, whether English or Spanish is spoken at home, and child's diagnoses, in order to determine factors that influence the use of alternative and complementary therapies used alone, or in combination with traditional therapies. The hypothesis is that there are differences in the use of CAM compared to traditional therapies based on these factors. These differences will be explored in order to better inform providers about the use of CAM in the patients for whom they provide care. In addition, we will compare findings from the ATN Registry to findings in the literature.

The aims of the study are as follows:

Aim 1: Describe the use of CAM as well as traditional therapies in the ATN Registry population.

Aim 2: Explore predictors of CAM use in the ATN Registry population.

III. Background and Significance/Preliminary Studies

We will conduct an analysis of ATN Registry data using all available subjects (N= 3,580). Existing data available include the use of CAM and traditional therapies as collected on the ATN Parent Survey. Important covariate information, including ethnicity, age of child, type of insurance, region of the country in which the child was recruited for ATN participation, caregivers' educational level, whether English or Spanish speaking and the child's diagnosis, available from the ATN Demographics Form, the Lead Autism Specialist Assessment, and the Diagnosis List.

Expected benefits of the study include an increased understanding of the use of CAM, including who uses CAM, and what CAM therapies are used. This may help inform clinicians about the prevalence of use, and provide direction to researchers regarding which therapies should be studied further, and help prioritize efficacy studies based on prevalence of use. There are no negative effects expected as a result of this secondary data analysis. Strong positive findings among any of the independent variables may serve as the basis for future studies with larger populations of children.

IV. Research Design and Methods

This project will be carried out as a collaboration among members of the Children's Hospital Los Angeles (CHLA) ATN site team, including the following (see attached biosketches for qualifications):

Kathryn Smith, RN, DrPH- will serve as the project principal investigator, and is the senior ATN site coordinator and the nurse care manager of the Boone Fetter Autism Clinic at CHLA.

Larry Yin, MD, MSPH- will serve as a co-investigator and is the co-principal investigator and lead autism specialist for the CHLA ATN site.

Michele Kipke, PhD- will serve as a co-investigator and research mentor for the project, and is the CHLA site principal investigator for participation in the ATN.

Marie Poulsen, PhD- will serve as a co-investigator, and is the behavioral scientist for the CHLA ATN site.

Linda Randolph, MD- will serve as co-investigator and, and is the genetics-metabolics specialist for the CHLA ATN site.

Heather Volk, PhD- will serve as a co-investigator and assist with data analysis and advise the PI on statistical issues related to the study. Dr. Volk is an epidemiologist in the Departments of Preventive Medicine, Pediatrics, and Zilkha Neurogenetic Institute at the University of Southern California.

Erna Blanche, PhD- will serve as a co-investigator and data analysis consultant, and is an Associate Professor of Clinical Practice – Director, Clinical Doctorate Program, Division of Occupational Science and Occupational Therapy, University of Southern California.

Sharon Cermak, PhD- will serve as a co-investigator and will assist with data analysis and interpretation. She is a Professor of Occupational Science and Occupational Therapy, Division of Occupational Science and Occupational Therapy, University of Southern California.

Carolina Pena Ricardo, MD- will serve as a co- investigator and assist with data analysis. Dr. Pena Ricardo is a Developmental Behavioral Pediatrics fellow.

Aaron Tanner, MS, CCC-SLP- will assist with data analysis and is a speech and language pathologist who participates in autism assessments.

Sheree Schrager, PhD- will provide support to the project staff with all aspects of quantitative research methodology, data analysis and reporting.

Marcia Higareda- will serve as project coordinator and is ATN site coordinator for CHLA.

Data will be requested from the AIR-P Data Coordinating Center (DCC) of the entire sample of the ATN Registry (N=3580) for the following variables:

Dependent variables:

- a. Complementary and alternative medicine (CAM) interventions - from the Parent Survey
- b. Traditional therapies (behavioral, occupational, physical and speech therapy, social skills training and medications)- from the Parent Survey

Independent variables:

- a. Ethnicity of child- from the Demographics Form
- b. Age of child- calculated from date of birth on the Demographics Form
- c. Type of insurance of the child- from the Demographics Form
- d. Region of the country in which the family lives- from the ATN recruitment location, utilizing US Census Bureau categories as follows: Northeast, Midwest, South and West
- e. Caregivers' educational level- from the Demographics form
- f. English or Spanish spoken in the home- from the LAS Assessment
- g. Child's diagnoses- from the Diagnosis list

All members of the research team will meet on a biweekly basis throughout the project period to review project progress, oversee data analysis and interpret the data. In addition, all members will participate in developing dissemination materials, including peer reviewed journal articles, and presentations, both within their respective disciplines and for broader audiences.

AIR-P DCC staff will be available to answer data questions and Traci Clemons, AIR-P DCC Statistician will be available to consult regarding the statistical analyses and provide investigators access to the data requested above.

Data Analysis

This study seeks to characterize the prevalence of CAM in the ATN Registry and to examine predictors of CAM use. We will first create composite variables characterizing children as having received or not received CAM therapies. We will also attempt to refine this classification into children receiving CAM only, traditional therapies only, and CAM in addition to traditional therapies.

Aim 1: Demographics by CAM versus no CAM, and types of CAM will be summarized with descriptive statistics. For quantitative variables (e.g., age), summary statistics will include mean, standard deviation, median, minimum and maximum. For qualitative variables (e.g., education level) summary statistics will include number and percentage within each subgroup. The homogeneity of demographics and other characteristics between the two groups (CAM versus non CAM) will be tested using Fisher's exact test (dichotomous and nominal factors) and the t-test or Wilcoxon rank sum test (ordinal and continuous factors). Similar analytic techniques will be employed to examine contrasts within the three level group variable (CAM only, traditional therapy only, CAM and traditional therapy) should sample size be sufficient.

Aim 2: We will use logistic regression to examine the odds of CAM treatment vs. non-CAM treatment for participants in the ATN. Variables available from ATN registry data as described above will be included first in univariate analyses and subsequently in multivariate models to address potential confounding factors. We will also attempt to develop a multinomial logistic regression model to compare odds of CAM only, traditional therapy only, and CAM plus traditional therapy treatments. All analyses will explore the role of demographic (ex: gender), socioeconomic (ex: parental education), and regional variables (ex: recruitment center).

Power analysis

For the purposes of our power calculations, we assume 80% power and a type I Error of 0.05. Currently, there are 3,580 participants in the ATN Registry. If we assume CAM rates of 30-50% or greater, similar with previously published reports, then 1,074 or 1,709 children may have reported CAM use. While we will examine many predictor variables, Hispanic/Latino ethnicity has been previously associated with CAM use. In the ATN sample, approximately 10% reports Hispanic/Latino ethnicity. In our expected number of CAM cases, this translates to a minimum detectable odds ratio of 1.46 or 1.34, respectively. While we do not currently present power for other predictor variables, we expect to have ample power given the large ATN Registry sample size and the ability to detect a sizeable effect for an established predictor of CAM.

There will be no recruitment and enrollment of subjects outside of the ATN. The group that receives traditional therapies will serve as the control group. All ATN study sites have assured the protection of human subjects through approval of ATN Registry participation by the Institutional Review Board, and ATN Registry participants include children and minorities. Because there is no primary data collection for this study, and the desired data are available from the ATN, it is expected that the study can be completed within the required one-year time frame.

Study Timeline

Study Phase	Activities	Timeline
Post award and study start up (April 1 to May 31, 2012)	Participate in the development of the Central Protocol package	April 1 until complete
	Finalize study roster	By May 1
	Finalize data request and send to the EMMES team	By May 31
	Agree upon timeline for interim analysis between project team and DCC	By May 31
Study maintenance (June 1, 2012 to March 31, 2013)	Conduct analyses of data	June 1 to March 31
	Update study roster as needed	Ongoing
	Convene biweekly meetings of project team to explore relationships between study variables	June 1 to completion of project
Study closeout (March 31-May 31, 2013)	Conduct final analysis and summarize results	March 31 to May 31
	Prepare products for dissemination	March 31 to May 31
	Prepare final reports for funder	May 1 to May 31

IRB Acknowledgement

The Principal Investigator and all Co-Investigators are aware and understand the requirements for institutional IRB review of this proposal. The PI has carefully considered the timing of the protocol review and fully understands the staff time needed to coordinate the effort as well as potential obstacles/delays. If funded, the proposal will be submitted for review to the Institutional Review Board at CHLA (Committee on Clinical Investigation).

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM 04/01/2012	THROUGH 03/30/13
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List PERSONNEL (*Applicant organization only*)

Use Cal, Acad, or Summer to Enter Months Devoted to Project

Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mths	Acad. Mths	Summer Mths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Kathryn Smith	PD/PI	.30			133,368	3,334	1,054	4,388
Larry Yin	Co-I	.30			199,700	0	0	0
Michele Kipke	Co-I	.30			199,700	0	0	0
Marie Poulsen	Co-I	.30			199,700	0	0	0
Heather Volk	Co-I	.30			199,700	0	0	0
Erna Blanche	Co-I	.30			199,700	0	0	0
Carolina Pena Ricardo	Co-I	.30			199,700	0	0	0
SUBTOTALS →								

CONSULTANT COSTS

EQUIPMENT (*Itemize*)SUPPLIES (*Itemize by category*)

TRAVEL

INPATIENT CARE COSTS

OUTPATIENT CARE COSTS

ALTERATIONS AND RENOVATIONS (*Itemize by category*)OTHER EXPENSES (*Itemize by category*)

CONSORTIUM/CONTRACTUAL COSTS

DIRECT COSTS

SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (*Item 7a, Face Page*)

\$

CONSORTIUM/CONTRACTUAL COSTS

FACILITIES AND ADMINISTRATIVE COSTS

TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD

\$

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY						FROM 04/01/2012	THROUGH 03/30/13	
List PERSONNEL (Applicant organization only) Use Cal, Acad, or Summer to Enter Months Devoted to Project Enter Dollar Amounts Requested (omit cents) for Salary Requested and Fringe Benefits								
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Sharon A. Cermak	Co-I	.30			199,700	0	0	0
Linda Randolph	Co-I	.30			199,700	0	0	0
Aaron Tanner	Co-I	.30			199,700	0	0	0
Sheree Schrager	Biostatistician	1.20			87,220	8,722	1,823	10,545
Marcia Higareda	Research Coordinator	.30			53,756	18,814	3,932	22,746
SUBTOTALS →						30,871	6,889	37,679
CONSULTANT COSTS								
EQUIPMENT (Itemize)								
SUPPLIES (Itemize by category) General Supplies								2,321
TRAVEL								
INPATIENT CARE COSTS								
OUTPATIENT CARE COSTS								
ALTERATIONS AND RENOVATIONS (Itemize by category)								
OTHER EXPENSES (Itemize by category)								
CONSORTIUM/CONTRACTUAL COSTS					DIRECT COSTS			
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page)							\$	40,000
CONSORTIUM/CONTRACTUAL COSTS					FACILITIES AND ADMINISTRATIVE COSTS			
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD							\$	40,000

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY**

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD <i>(from Form Page 4)</i>	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
PERSONNEL: <i>Salary and fringe benefits. Applicant organization only.</i>	37,679				
CONSULTANT COSTS					
EQUIPMENT					
SUPPLIES	2,321				
TRAVEL					
INPATIENT CARE COSTS					
OUTPATIENT CARE COSTS					
ALTERATIONS AND RENOVATIONS					
OTHER EXPENSES					
DIRECT CONSORTIUM/ CONTRACTUAL COSTS					
SUBTOTAL DIRECT COSTS <i>(Sum = Item 8a, Face Page)</i>	40,000				
F&A CONSORTIUM/ CONTRACTUAL COSTS					
TOTAL DIRECT COSTS	40,000				
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD					\$ 40,000

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

Children's Hospital Los Angeles

Budget Justification

Personnel

PRINCIPAL- INVESTIGATOR (Kathryn Navarette Smith, DrPH, RN Senior Site Coordinator for the Children's Hospital, ATN site. Budgeted at .30 person months in Cal. Year 1):

Qualifications: Dr. Smith has over 35 years of experience caring for children with special health care needs. She serves as Associate Director for Administration at the University of Southern California (USC) University Center for Excellence in Developmental Disabilities (UCEDD) and Senior Site Coordinator for ATN at Children's Hospital Los Angeles (CHLA). Her current clinical activities include nurse care manager of the Boone Fetter Clinic for children with autism and other neurodevelopmental disabilities, co-director of the Spina Bifida Center, and co-director of the Rett Clinic at CHLA. Dr. Smith leads the policy concentration in the Leadership Education in Neurodevelopmental Disabilities (LEND) training program at USC UCEDD, focusing on child health related issues. She co-teaches a graduate course in the School of Public Health at the University of California Los Angeles (UCLA), Children with Special Health Care Needs: A Systems Perspective and teaches child health related courses in the Public Health Program at USC. Dr. Smith's research interests include the areas of autism, spina bifida, transition and Rett syndrome. Her current research projects are principal investigator of a CDC National Spina Bifida Registry.

Job description:

Dr. Smith will serve as the project principal investigator and will be responsible for managing protocol implementation. She will supervise and support the Biostatistician and Site Coordinator and meet regularly with Co-Investigators, Biostatistician and Project Coordinator to achieve project goals. She will participate in dissemination of project results.

Fringe rate: 31.6%

Cost of Living Increase: 4%

CO-INVESTIGATOR (Larry Yin, MD, MSPH, Co-Principal Investigator and Lead Autism Specialist for the Children's Hospital Los Angeles ATN site)

Qualifications: Dr. Yin is an Assistant Professor, Clinical Pediatrics, Keck School of Medicine, University of Southern California and Director of Clinical Services, USC University Center of Excellence in Developmental Disabilities, CHLA. He is a board certified Developmental/Behavioral Pediatrician and serves as the medical director of the Boone Fetter clinic. He has over 18 years experiencing providing care for children with neurodevelopmental disorders and other special health care needs and also serves as the medical consultant to the San Gabriel Pomona Regional Center.

Job Description: Dr. Yin will serve as a co-investigator and will work closely with the Principal Investigator and other project staff to ensure that all research procedures and protocols are followed. Dr. Yin will also assist in data analysis, and prepare written reports and make oral presentations on findings and policy relevance to professional audiences and for publication in peer-review journals.

Fringe rate: 31.6%

Cost of Living Increase: 4%

CO-INVESTIGATOR (Michele Kipke, PhD, Principal Investigator for the Children's Hospital Los Angeles ATN site)

Qualifications: Dr. Kipke is a Professor of Pediatrics and Preventive Medicine at Keck School of Medicine at the University of Southern California and Vice Chair of Research in Pediatrics of

The Saban Research Institute of Children's Hospital Los Angeles. She is a nationally known researcher and policy expert on children and families. Dr. Kipke is Director of the Community, Health Outcomes, and Intervention Research at CHLA. In addition, she is the recent recipient of a \$5 million endowment that will support research focused on early diagnosis and intervention of autism and autism spectrum disorder. Dr. Kipke will provide project guidance and consultation in all element of the Registry.

Job Description: Dr. Kipke will serve as co-investigator and research mentor for the project. She will work closely with the Principal Investigator and other project staff to ensure that all research procedures and protocols are followed.

Fringe rate: 31.6%

Cost of Living Increase: 4%

CO-INVESTIGATOR (Marie Poulsen, PhD, Behavioral Scientist for the Children's Hospital Los Angeles ATN site)

Qualifications: Dr. Poulsen is a licensed psychologist and Professor of Pediatrics, USC Keck School of Medicine. She participated in the development of the Institute for the Developing Mind, Boone-Fetter Clinic for children with autistic spectrum disorder, and currently serves on the assessment team. She has worked with young children with autism and their families for over 30 years, including consultation with state child care and preschools, as well as regional and national Head Start programs. She has a Governor's appointment to the California Interagency Coordinating Council on Early Intervention where she serves on the Executive Committee and is Chair of the Quality Service Delivery System Committee. Dr. Poulsen has been a principal investigator or co-investigator of several research projects relating to children with special health care needs.

Job Description: Dr. Poulsen will serve a Co-Investigator and will work closely with the Principal Investigator and other project staff to ensure that all research procedures and protocols are followed and will assist with data analysis. Dr. Poulsen will also prepare written reports and make oral presentations on findings and policy relevance to professional audiences and for publication in peer-review journals.

Fringe rate: 31.6%

Cost of Living Increase: 4%

CO-INVESTIGATOR (Heather Volk, PhD, MPH, Epidemiologist, Department of Preventive Medicine, Pediatrics, and Zilkha Neurogenetic Institute at the University of Southern California.)

Qualifications: Dr. Volk is a clinical researcher both dually appointed at CHLA and USC. Dr. Volk, is an Assistant Professor in the Department of Preventive Medicine and Pediatrics and the Zilkha Neurogenetic Institute. She is an epidemiologist and has conducted research in psychiatric, genetic, and environmental epidemiology. Dr. Volk brings expertise in study design and data analysis allowing for understanding of registry and repository data to be incorporated into its design and direction.

Job Description: Dr. Volk will serve a Co-Investigator and assist with data analysis and advise the Principal Investigator on statistical issues related to the study. Dr. Volk will also prepare written reports and make oral presentations on findings and policy relevance to professional audiences and for publication in peer-review journals.

Fringe rate: 31.6%

Cost of Living Increase: 4%

CO-INVESTIGATOR (Erna Blanche, PhD, Associate Professor of Clinical Practice Director, Clinical Doctorate Program, Division of Occupational Science and Occupational Therapy, University of Southern California.)

Children's Hospital Los Angeles

Budget Justification

Personnel

PRINCIPAL- INVESTIGATOR (Kathryn Navarette Smith, DrPH, RN Senior Site Coordinator for the Children's Hospital, ATN site. Budgeted at .30 person months in Cal. Year 1):

Qualifications: Dr. Smith has over 35 years of experience caring for children with special health care needs. She serves as Associate Director for Administration at the University of Southern California (USC) University Center for Excellence in Developmental Disabilities (UCEDD) and Senior Site Coordinator for ATN at Children's Hospital Los Angeles (CHLA). Her current clinical activities include nurse care manager of the Boone Fetter Clinic for children with autism and other neurodevelopmental disabilities, co-director of the Spina Bifida Center, and co-director of the Rett Clinic at CHLA. Dr. Smith leads the policy concentration in the Leadership Education in Neurodevelopmental Disabilities (LEND) training program at USC UCEDD, focusing on child health related issues. She co-teaches a graduate course in the School of Public Health at the University of California Los Angeles (UCLA), Children with Special Health Care Needs: A Systems Perspective and teaches child health related courses in the Public Health Program at USC. Dr. Smith's research interests include the areas of autism, spina bifida, transition and Rett syndrome. Her current research projects are principal investigator of a CDC National Spina Bifida Registry.

Job description:

Dr. Smith will serve as the project principal investigator and will be responsible for managing protocol implementation. She will supervise and support the Biostatistician and Site Coordinator and meet regularly with Co-Investigators, Biostatistician and Project Coordinator to achieve project goals. She will participate in dissemination of project results.

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Cost of Living Increase: 4%

CO-INVESTIGATOR (Larry Yin, MD, MSPH, Co-Principal Investigator and Lead Autism Specialist for the Children's Hospital Los Angeles ATN site)

Qualifications: Dr. Yin is an Assistant Professor, Clinical Pediatrics, Keck School of Medicine, University of Southern California and Director of Clinical Services, USC University Center of Excellence in Developmental Disabilities, CHLA. He is a board certified Developmental/Behavioral Pediatrician and serves as the medical director of the Boone Fetter clinic. He has over 18 years experiencing providing care for children with neurodevelopmental disorders and other special health care needs and also serves as the medical consultant to the San Gabriel Pomona Regional Center.

Job Description: Dr. Yin will serve as a co-investigator and will work closely with the Principal Investigator and other project staff to ensure that all research procedures and protocols are followed. Dr. Yin will also assist in data analysis, and prepare written reports and make oral presentations on findings and policy relevance to professional audiences and for publication in peer-review journals.

Fringe rate: 31.6%

Cost of Living Increase: 4%

CO-INVESTIGATOR (Michele Kipke, PhD, Principal Investigator for the Children's Hospital Los Angeles ATN site)

Qualifications: Dr. Kipke is a Professor of Pediatrics and Preventive Medicine at Keck School of Medicine at the University of Southern California and Vice Chair of Research in Pediatrics of

The Saban Research Institute of Children's Hospital Los Angeles. She is a nationally known researcher and policy expert on children and families. Dr. Kipke is Director of the Community, Health Outcomes, and Intervention Research at CHLA. In addition, she is the recent recipient of a \$5 million endowment that will support research focused on early diagnosis and intervention of autism and autism spectrum disorder. Dr. Kipke will provide project guidance and consultation in all element of the Registry.

Job Description: Dr. Kipke will serve as co-investigator and research mentor for the project. She will work closely with the Principal Investigator and other project staff to ensure that all research procedures and protocols are followed.

Fringe rate: 31.6%

Cost of Living Increase: 4%

CO-INVESTIGATOR (Marie Poulsen, PhD, Behavioral Scientist for the Children's Hospital Los Angeles ATN site)

Qualifications: Dr. Poulsen is a licensed psychologist and Professor of Pediatrics, USC Keck School of Medicine. She participated in the development of the Institute for the Developing Mind, Boone-Fetter Clinic for children with autistic spectrum disorder, and currently serves on the assessment team. She has worked with young children with autism and their families for over 30 years, including consultation with state child care and preschools, as well as regional and national Head Start programs. She has a Governor's appointment to the California Interagency Coordinating Council on Early Intervention where she serves on the Executive Committee and is Chair of the Quality Service Delivery System Committee. Dr. Poulsen has been a principal investigator or co-investigator of several research projects relating to children with special health care needs.

Job Description: Dr. Poulsen will serve a Co-Investigator and will work closely with the Principal Investigator and other project staff to ensure that all research procedures and protocols are followed and will assist with data analysis. Dr. Poulsen will also prepare written reports and make oral presentations on findings and policy relevance to professional audiences and for publication in peer-review journals.

Fringe rate: 31.6%

Cost of Living Increase: 4%

CO-INVESTIGATOR (Heather Volk, PhD, MPH, Epidemiologist, Department of Preventive Medicine, Pediatrics, and Zilkha Neurogenetic Institute at the University of Southern California.)

Qualifications: Dr. Volk is a clinical researcher both dually appointed at CHLA and USC. Dr. Volk, is an Assistant Professor in the Department of Preventive Medicine and Pediatrics and the Zilkha Neurogenetic Institute. She is an epidemiologist and has conducted research in psychiatric, genetic, and environmental epidemiology. Dr. Volk brings expertise in study design and data analysis allowing for understanding of registry and repository data to be incorporated into its design and direction.

Job Description: Dr. Volk will serve a Co-Investigator and assist with data analysis and advise the Principal Investigator on statistical issues related to the study. Dr. Volk will also prepare written reports and make oral presentations on findings and policy relevance to professional audiences and for publication in peer-review journals.

Fringe rate: 31.6%

Cost of Living Increase: 4%

CO-INVESTIGATOR (Erna Blanche, PhD, Associate Professor of Clinical Practice Director, Clinical Doctorate Program, Division of Occupational Science and Occupational Therapy, University of Southern California.)

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Smith, Kathryn A. Navarette		POSITION TITLE Principal Investigator	
eRA COMMONS USER NAME KATSMITH			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of California Los Angeles, School of Public Health	Dr.P.H	2011	Health Services
University of California Los Angeles (UCLA)	M.N.	1978	Nursing
California State University Long Beach	B.S.N.	1977	Nursing

A. Personal Statement

Dr. Smith has over 35 years experience caring for children with special health care needs, including those with neurodevelopmental disabilities. At Children's Hospital Los Angeles (CHLA), she serves as the senior Autism Treatment Network site coordinator, nurse care manager in the Boone Fetter autism clinic, co-director of the Spina Bifida Center, associate director for administration at the University Center for Excellence in Developmental Disabilities at CHLA, and policy concentration leader within the Leadership Education in Neurodevelopmental Disabilities (LEND) training program at the UCEDD. She has a strong interest in child health policy, quality improvement and research in these areas.

B. Positions and Honors.**Positions and Employment****Academic Appointments**

2006-Present Assistant Professor of Clinical Pediatrics, Keck School of Medicine, University of Southern California (USC)

1986-Present Assistant Clinical Professor, University of California, Los Angeles (UCLA), School of Nursing, Los Angeles, CA

Professional Experience and Appointments

1976-1985 Staff Nurse/Charge Nurse – Pediatrics, ICU/CCU, Newborn Nursery, Emergency Department, Memorial Hospital of Gardena, Gardena, CA

1978-1979 Lecturer – California State University, Long Beach, CA

1980 Remedial Tutor – Pediatric Nursing, University of California, Los Angeles, CA

1979-1988 Clinical Nurse Specialist, Pediatrics – Orthopaedic Hospital, Los Angeles, CA

1988-1990 Public Health Nurse Specialist/Community Care Coordinator – Los Angeles County, California Children Services, Automated Case Management System/Community Based Care Coordination Project, Los Angeles, CA

1990-1992 Project Director – Early Intervention Management Information Systems Development Project, Los Angeles, CA

1990-1993 Co-Director, National Center for Case Management and Automation

1993-1998 Co-Director, ACCESS-MCH: Automation and Care Coordination Enhancing Services Systems in Maternal and Child Health

- 1996-2001 Director, Establishing a Community Based Interagency Services System for Children with Special Health Care Needs in Los Angeles County
- 1998-Present Associate Nursing Director, University of Southern California, University Center of Excellence in Developmental Disabilities, Childrens Hospital Los Angeles
- 1998-2004 Director, An Integrated Medical Home Training Program for Providers and Families of Children with Special Health Care Needs
- 2000-2003 Director, Building Medical Homes for Children with Special Health Care Needs
- 2001-2004 Director, The California Medical Home Project
- 2004-Present Assistant Director, MCH Training Program, UCLA Center for Healthier Children, Families and Communities
- 2006-Present Associate Director for Administration, University of Southern California, University Center of Excellence in Developmental Disabilities, Childrens Hospital Los Angeles
- 2008-Present Director, Rett Clinic, University Center of Excellence in Developmental Disabilities, Childrens Hospital Los Angeles
- 2008-Present Nurse Care Manager, Boone Fetter Autism Clinic, Childrens Hospital Los Angeles
- 2009-Present Co-Director, Spina Bifida Center, Childrens Hospital Los Angeles
- 2010-Present Senior Site Coordinator, Autism Treatment Network, Children's Hospital Los Angeles

Other Experience and Professional Memberships

- 1994-Present March of Dimes Birth Defects Foundation, Southern California Chapter. Education Committee, 1994-1997; Board of Directors 1997-1998; Executive Committee 1997-1998; Chair 1997-1998; Professional Education Committee 1997-2002; Chair, Professional Education Committee 1998-2002; Program Services Committee 1998-Present; Chair, Program Services Committee 2002-2004
- 2000-Present Chair, Los Angeles County California Children Services Workgroup

Honors

- 1997 Sigma Theta Tau
- 1990 March of Dimes, Southern California Chapter Outstanding Program Contribution

B. Selected peer-reviewed publications (in chronological order)

1. Greenberg C, Smith K. Anticipatory guidance for the employed breastfeeding mother. *Journal of Pediatric Health Care*, 1991; 5:204-209.
2. Smith K, Gabard D, Dale D, Drucker A. Parental opinions about attending parent support groups. *Children's Health Care*, 1994; 23(2):127-138.
3. Smith K, Layne M, Garell D. The impact of care coordination on children with special health care needs. *Children's Health Care*, 1994; 23(4):251-266.
4. Smith K, Wheeler B, Parker T, Pilecki P. The role of the pediatric nurse practitioner in educating teens with mental retardation about sex. *Journal of Pediatric Health Care*, 1995; 9:59-66.
5. Smith K. Care Coordination in CSHCN Agencies: Report of a National Survey. 1995. ACCESS-MCH, Los Angeles.
6. Monahan C, Szpur M, Manago R, Smith K. Database management systems for case management programs. In Albrecht G (Ed.), *Advances in Medical Sociology*, 1995; Greenwich, CT: JAI Press, Inc.

7. Smith K. Children with Special Health Care Needs and Care Coordination in the Context of Managed Care, 1997, ACCESS-MCH, Los Angeles.
8. Smith K. Health promotion through community care. In Bowden V, Dickey S, and Greenberg D. (Eds.), Children and their families: The continuum of care, 1998, Philadelphia, PA: W.B. Saunders.
9. Smith K. Outcome Measures Workgroup. Care Coordination Outcomes for Children with Special Health Care Needs, 1998, ACCESS-MCH, Los Angeles.
10. Smith K. Special populations: Children in the community. In Smith CM, and Maurer FA (Eds.), Community health nursing: Theory and practice, 2000, Philadelphia, PA: W.B. Saunders.
11. Inkelas M, Smith KA, Kuo AA, Rudolph L, Igdaloff S. Health care access for children with special health care needs in California. Maternal and Child Health Journal, 2005; 9S(2):109-116.
12. Betz, CL, Ruccione, K, Meeske, K, Smith, K, and Chang, N. Health literacy: a pediatric nursing concern. Journal of Pediatric Nursing 2008;34(3):231-239.
13. Smith, K, Mizokawa, S, Neville-Jan, A, and Macias, K.. Urinary Continence across the Life Course. Pediatric Clinics of North America, 2010; 57 (4):997-1011.
14. Smith, K, Freeman, KA, Neville-Jan, A, Mizokawa, S, and Adams, E. Cultural Considerations in the Care of Children with Spina Bifida. Pediatric Clinics of North America, 2010; 57(4):1027-1040.
15. Betz, CL, Smith, K, and Macias, K. Testing the Transition Preparation Training Program: A Randomized Controlled Trial. International Journal of Child and Adolescent Health: Special Issue on: Youth Health Care Transition, 2010; 3(4).
16. Smith, K. Health promotion through community care. In: Children and their Families: The Continuum of Care (2nd edition, Bowden, V. and Greenberg, C. [editors]). Wolters Kluwer Health/ Lippincott Williams and Wilkins, Philadelphia, PA, pp 62-74, 2010.
17. Smith, K. and Savage, T.A.: Policies, legislation and ethical/legal issues. In: Nursing Care for Individuals with Intellectual and Developmental Disabilities: An Integrated Approach (1st edition, Betz, C.L. and Nehring, W.M., [editors].) Brookes Publishing, Baltimore, MD, pp 355-370, 2010.

C. Research Support

Ongoing Research Support

1 U01 DD000386-01

Smith (PI)

9/30/2008 – 8/31/2011

CDC

Spina Bifida Patient Registry Project

The purpose of the project is to test the feasibility of utilizing a standardized registry toll for collecting data on patients with spina bifida in order to learn more about the population and to improve care.

Role: PI/Project Director

SBA

Smith (PI)

1/15/2011- 8/15/2012

Spina Bifida Electronic Medical Record (EMR) Beta Test

The aim of this project is to pilot the feasibility of utilizing a standardized Spina Bifida Electronic Medical Record in spina bifida clinic, to improve patient care including coordination of care, process improvement, tracking, preparation for transition, patient monitoring for follow-up, and patient safety.

Role: PI/Project Director

Completed Research Support

1R21NR009415

Betz (PI)

7/1/2002 – 3/31/2009

NIH/NINR

Testing of the Transition Preparation Training Program

The purpose of the project is to investigate the processes involved in the transition of racially and ethnically diverse ASHCN to adult health care, particularly the role of state health systems in facilitating or hindering their transitions.

Role: Project Director

2005-5/6-03

Jacobs (PI)

10/01/05 - 9/30/09

CDC AUCD

The Effectiveness of Bowel and Bladder Techniques on Children with Spina Bifida

The purpose of this project is to improve the health and well-being of children with spina bifida at an early age by identifying the most effective intervention strategies for preventing and/or managing associated urinary and bowel problems.

Role: Project Director

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Larry Yin		POSITION TITLE Asst. Professor, Clinical Pediatrics	
eRA COMMONS USER NAME larryin			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of California, Riverside	B.S.	1986	P Biology
University of California, Los Angeles	M.S.P.H.	1988	Nutritional Sciences
St. Louis University	M.D.	1993	Medicine
Childrens Hospital Los Angeles	Internship	1993-1994	General Pediatrics
Childrens Hospital Los Angeles	Residency	1994-1996	General Pediatrics
Childrens Hospital Los Angeles	Chief Resident	1996-1997	General Pediatrics

A. Personal Statement

Dr. Larry Yin is an Assistant Professor of Clinical Pediatrics at the Keck School of Medicine of the University of Southern California, Director of Community and Clinical Services at the USC University Center of Excellence in Developmental Disabilities, and Medical Director of the Boone Fetter Clinic at Childrens Hospital Los Angeles. He is dually boarded in general pediatrics and developmental-behavioral pediatrics. Dr. Yin has over 13 years providing care for children with neurodevelopmental disorders and special health care needs. He has extensive experience in medical education and provides leadership in curriculum development for medical students, pediatric residents, developmental-behavioral pediatric fellows, and the Leadership Education in Neurodevelopmental and Related Disorders fellows. Dr. Yin has seen first-hand the rise in autism incidence and the challenges families confront through his role at the San Gabriel/Pomona Regional Center, and has been extensively involved in the planning and design of services offered through the Boone Fetter Clinic. He is the medical director of the USC UCEDD Rett Syndrome Clinic, providing interdisciplinary care to children from the Southern California region and overseeing community-based services. Other relevant work includes technical consultation for the Developmental Disabilities Resources for Health Care Providers (www.DDHealthInfo.org) on various medical topics related to neurodevelopmental disorders. As medical director of the Child Health Works Project, a five-year, five million dollar grant-funded initiative funded by First Five Los Angeles, he worked collaboratively with community agencies to provide a health screening program for at-risk preschoolers. Through those efforts, lasting change in screening methodologies was realized and awareness on the health risks of obesity in preschoolers elucidated.

B. PROFESSIONAL EXPERIENCE (Selected)**Academic**

2002-Present Assistant Professor of Clinical Pediatrics, USC Keck School of Medicine.
2000-2002 Director, Medical Student Clerkship in Pediatrics, Loma Linda University School of Medicine

1998-2002 Assistant Professor of Pediatrics, Loma Linda University School of Medicine.
1996-1997 Clinical Instructor, USC School of Medicine.

Clinical

2009 American Board of Pediatrics, Developmental Behavioral Pediatrics
1998-Present Associate, Childrens Hospital Los Angeles.
2004-Present Director, Community Pediatrics, Childrens Hospital Los Angeles
2007-Present Director, Community and Clinical Services, USC University Center of Excellence in Developmental Disabilities.
2008-Present Medical Director, Boone-Fetter Clinic. Childrens Hospital Los Angeles
2008-Present Medical Director, USC UCEDD Rett Syndrome Clinic
2002-2008 Medical Director, Child Health Works.
1997-2002 Director, Growing Fit Clinic, Loma Linda University Health Care.
1997 American Board of Pediatrics, General Pediatrics
1997-1998 Clinical Instructor in Pediatrics, Loma Linda University School of Medicine.

HONORS/AWARDS

2000 John Mace Award-Pediatric Faculty Award of Excellence, Department of Pediatrics, LLU School of Medicine.
1998 Clinical Faculty Award of Excellence, Department of Pediatrics, LLU School of Medicine.
1997 Francis Nunnally Intern Award-Intern of the Year, 1997.
1996 Barbara Korsch Award for Medical Education-Medical Cases on CD-ROM.
1989 St. Louis University Summer Research Fellowship.
1986-88 UCLA School of Public Health Traineeship Award.

C. PUBLICATIONS (Partial List)

- Yin L, Wills H, Clarke N, Shacks J, Bottrell CL, Poulsen MK. Cardiovascular Risk in Preschool Children. *Infant, Child, Adolescent Nutrition*. 1:197-204. 2009. ICAN: DOI: 10.1177/1941406409341077
- Yin L, Bottrell C, Clarke N, Shacks J, Poulsen MK. Otoacoustic emissions: a valid, efficient first-line hearing screen for preschool children (p147-152) Published Online: 2009 DOI:10.1111/j.1746-1561.2009.00383.x
- Yin L, Bottrell C, Clarke N, Shacks J, Poulsen MK. Otoacoustic emissions: a valid, efficient first-line hearing screen for preschool children. *J Sch Health*. 2009 Apr;79(4):147-52. PubMed PMID: 19292846.
- Clarke N, Shacks J, Kerr AR, Bottrell CL, Poulsen MK, Yin L. Use of a Non-cycloplegic Autorefractor to Perform Vision Screening in Preschools. *The Journal of School Nursing*. 24: 158-163. 2008.
- Sheehan NC, Yin L. Childhood obesity: nursing policy implications. *J Pediatr Nurs*. 21(4):308-310; 2006.
- James SF, Yin L. (1989). Diet induced DNA damage. Altered nucleotide metabolism in methyl donor deficient rats. *Carcinogenesis*, 10(7):1209-1214.
- James SF, Yin L, Swendseid MA. (1989). DNA strand breaks, thymidylate synthesis and NAD levels in methyl donor deficient rats. *J Nutrition*, 119:661-664.
- Yin L, Terasaki PI. (1988). A rapid quantitated viability test for transplanted kidneys – Ready for human trial. *Clinical Transplantation*, 2:295-298.
- Takiff H, Novak M, Yin L, Iwaki Y, Terasaki PI. (1987). Examination of the clonal deletion hypotheses following transfusions in rat cardiac transplants. *Transplantation Proc.*, 12(1):1452-1454.
- Takiff H, Calabria R, Yin L, Stabile BE. (1985). Mesenteric cysts and intra-abdominal cystic lymphangiomas. *Arch. Surg.*, 120:1266-1269.

D. RESEARCH SUPPORT

ACTIVE

R01 MH089474-01/ H43606 (Yin) 9/30/2009 – 8/31/2011
NIH-NIMH via University of Southern California
Autism In Urban Context: Linking Heterogeneity with Health & Service Disparities

This is a two-year urban, multi-method ethnographic study that examines the health and service disparities in Autism Spectrum Disorders diagnosis of African American children living in Los Angeles. A combination of urban ethnography and social network analysis, follows a cohort of 16 African American children diagnosed with ASDs, their primary caregivers and the practitioners who serve them and documents the children's pathways to an ASD diagnosis and services.

Role: Co-Investigator

T- 73MC00008-17 (Baer) 7/1/2006 – 6/30/2012
DHHS/HRSA/MCHB
Leadership Education in Neurodevelopmental Disabilities (LEND)

The purpose of this study is to recruit and train annually long-term and short-term disciplines representing culturally, racially and linguistically diverse communities, to meet the LEND competencies in the interdisciplinary, family-centered, culturally competent care of children, with or at risk for neurodevelopmental and related disabilities with special emphasis on ASD.

Role: Co-Investigator

90DD0602/03 (Jacobs) 7/1/2007 – 6/30/2012
DHHS/HRSA/ACF/Administration on Developmental Disabilities
Administration on Developmental Disabilities "CORE"

To achieve the goals and targeted outcomes of Early Intervention, Special Education, Health/Mental Health, Prevention and Treatment of Abuse Neglect and Victimization, Reducing Racial, Cultural, and Linguistic Disparities in Access to Services, Family Support, Self-Advocacy, Civic Engagement, Parent/Consumer Leadership through four core functions: Pre-Service Training and Continuing Education, Exemplary Clinical and Community Service, Community Education and Information Dissemination, and Research, Evaluation and Policy.

Role: Co-Investigator

PENDING

NIH-NICHD via USC (Solomon) 7/1/2010 - 6/30/2014
Social Engagement in Autism and Typical Development
and its Physiological Correlates During Human-Animal Interaction

The purpose of this study is to build an empirical research base on how autistic children perceive, relate to and think about animals; how pets in the home impact children's social and emotional development and health (e.g. allergies, the immune system, asthma, mitigation of obesity); and whether and under what conditions therapeutic uses of animals is safe and effective.

Role: Co-Investigator

COMPLETED

00214 (Jacobs)

7/01/2002 – 02/29/2008

First Five LA

Child Health-Works (First Five LA)

The purpose of this study was to build community capacity and partnerships to provide health and mental health screening to at-risk preschoolers living in underserved areas of Los Angeles.

Role: Medical Director

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Michele D. Kipke, Ph.D.	POSITION TITLE Professor		
eRA COMMONS USER NAME mkipke			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
New York University, New York, NY	B.A.	06/84	Psychology
Albert Einstein College of Medicine/Yeshiva University Bronx, NY	Ph.D.	12/90	Experimental/Health Psychology
University of Southern California, Los Angeles, CA			Spatial Analysis/ Geographic Information Sciences; Functional Magnetic Resonance Imaging

A. Personal Statement

Dr. Michele Kipke is a Professor of Pediatrics at the Keck School of Medicine of the University of Southern California (USC), Vice Chair of Research within the Department of Pediatrics at Children's Hospital Los Angeles, and Co-Director of the Southern California Clinical and Translational Science Institute. A nationally known researcher and policy expert on children and families, Dr. Kipke is also Director of the Community, Health Outcomes & Intervention Research (CHOIR) Program of The Saban Research Institute and head of the Division of Research on Children, Youth & Families in the Department of Pediatrics at Children's Hospital Los Angeles. In 2008 she launched the Children's Hospital Boone Fetter Clinic, its new Diagnostic, Clinical, and Research Center for Autism and Other Neurodevelopmental Disorders. From 1997-2001 she served as the Director of the Institute of Medicine's and National Research Council's Board on Children, Youth and Families in Washington, DC.

Dr. Kipke received her Ph.D. in Experimental/Health Psychology in 1990 from the Albert Einstein College of Medicine at Yeshiva University. Since that time, she has engaged in an array of research activities to better understand child and adolescent development, health, and well-being. Dr. Kipke is widely published on topics that examine individual, familial, peer, and social network influences on youths' involvement in risky behaviors (e.g., alcohol and other drug use, unintended pregnancies, HIV infection and other sexually transmitted diseases, violence). Additionally, she has conducted research on the causes and consequences of homelessness among youth in Los Angeles, and the factors that drive young people in Los Angeles to own and carry weapons.

Dr. Kipke remains active in conducting her own research. She is currently the Principal Investigator for several studies, including research focused on: (a) community-level risk factors associated with poor health outcomes among children, including overweight and obesity; (b) strategies to ensure the effective transition from pediatric to adult healthcare services; (c) HIV risk among high-risk youth groups, including an NIH-funded longitudinal study with a large and ethnically diverse cohort of young men; and (d) new intervention research focused on HIV prevention among African American and Asian young men. In addition, she is the recent recipient of a \$5 million endowment that will support research focused on early diagnosis and intervention of autism and autism spectrum disorders, and has invested the past three years to developing a robust clinical, translational and community-partnered research infrastructure to support autism research at Children's Hospital Los Angeles.

B. Positions and Honors (Selected)**Positions and Employment**

2010 -	Vice Chair of Research, Department of Pediatrics, Children's Hospital Los Angeles
2007 –	Associate Director, Southern California Clinical and Translational Science Institute & Director, Office of Community Engagement, University of Southern California,
2007 – 2010	Member, Board on Children, Youth, and Families, National Research Council/Institute of Medicine, National Academy of Sciences, Washington, DC
2007 –	Scientific Advisory Board, Parent Resource Center, Partnership for a Drug Free America
2004 -	Member, Cancer Control Research Program, USC/Norris Comprehensive Cancer Center, Keck School of Medicine, University of Southern California
2001 –	Director, Community, Health Outcomes, and Intervention Research (CHOIR) Program, The Saban Research Institute, Children's Hospital Los Angeles
2001 -	Professor, Departments of Pediatrics (primary) and Preventive Medicine (secondary), Keck School of Medicine, University of Southern California
2001 – 2010	Associate Director, The Saban Research Institute, Children's Hospital Los Angeles
2001 – 2006	Standing Committee Member, NIH Review Committee, Behavioral and Social Sciences and Public Health, National Institutes of Health, Washington, DC
1997 – 2001	Director, Board on Children, Youth, and Families, Institute of Medicine and National Research Council, National Academy of Sciences
1993 - 1997	Associate Professor, Department of Pediatrics, University of Southern California School of Medicine & Childrens Hospital Los Angeles; Associate Director, Division of Adolescent Medicine
1990 – 1993	Clinical Assistant Professor, Department of Pediatrics, University of Southern California School of Medicine & Childrens Hospital Los Angeles; Associate Director, Division of Adolescent Medicine

C. PUBLICATIONS (Selected from 51 peer reviewed publications)

1. Schrager SM, Wong CF, Weiss G, Kipke MD. HIV Testing and Risk Behaviors Among Young Men who have Sex with Men in Los Angeles County. American Journal of Health Promotion, 2011; 25(4), 244-247.
2. Wolfson JA, Schrager SM, Coates TC, Kipke MD. Sickle Cell Disease in California: a population-based description of emergency department utilization. Pediatric Blood and Cancer, 2011; 56:413–419.
3. Wolfson J A, Schrager SM, Khanna R, Coates T, Kipke MD. Sickle-cell disease in California: Sociodemographic Predictors of Emergency Department Utilization. Pediatric Blood and Cancer (online), 2011.
4. Epstein D, Wong CF, Khemani RG, Moromisato DY, Waters K, Kipke MD, Markovitz BP. Race/ethnicity is not associated with mortality in the pediatric intensive care unit (PICU). Pediatrics (on line). 2010.
5. Kubicek K, McDavitt B, Carpineto J, Weiss G, Kipke MD. Use and Perceptions of the Internet for Sexual Information and Partners: A Study of Young Men who Have Sex with Men. Archives of Sexual Behavior. On-line August 31, 2010.
6. Wong CF, Kipke MD, Weiss G. Risk factors for alcohol use, frequent use, and binge drinking among young men who have sex with men. Addictive Behaviors, 33(8), 1012-1020, 2008.
7. Kubicek K, Carpineto J, McDavitt B, Weiss G, Iverson E, Au C-W, Kerrone D, Martinez M, Kipke MD. Integrating professional and folk models of HIV risk: YMSM's perceptions of high-risk sex. AIDS Education and Prevention, 20(3), 220-238, 2008.
8. Kipke MD, Weiss G, Ramirez M, Dorey F, Ritt-Olson A, Iverson E, Ford W. Club drug use among young men who have sex with men in Los Angeles. Substance Use and Misuse, 42 (11), 1723-1743, 2007.
9. Kipke MD, Weiss G, Wong CF. Residential status as a risk factor for drug use and HIV risk among young men who have sex with men. AIDS and Behavior, Special Supplement on Housing and HIV/AIDS 2007.

10. Kipke MD, Kubicek K, Weiss G, Wong CF, Lopez D, Iverson E, Ford W. The health and health behaviors of young men who have sex with men. *Journal of Adolescent Health*, 2007, 40(4): 342-350.
11. Kipke MD, Iverson E, Moore D, Booker C, Ruelas V, Peters AL, Kaufman F. Neighborhood food and park environments: Risks for childhood obesity in East Los Angeles. *Journal of Adolescent Health*, 2007, 40(4): 325-333.
12. Limbos M, Chan LS, Warf C, Schneir A, Iverson E, Shekelle P, Kipke MD. Effectiveness of interventions to prevent youth violence – a systematic review. *American Journal of Preventative Medicine*, 2007, 33(1):65-74.
13. Kipke MD, Iverson E, Booker C. Community-level risks for obesity. *Obesity Research*, 13, A7, 2005.
14. Chan LS, Kipke MD, Schneir A, Iverson E, Warf C, Limbos MA, Shekelle P. Preventing violence and related health-risking social behaviors in adolescents. Evidence Report/Technology (Prepared by the Southern California Evidence-based Practice Center under Contract No. 290-02-2003. AHRQ Publication No. 0X-E00X-2. Rockville, MD: Agency for Healthcare Research and Quality. August, 2004.
15. Weiker R, Edgington R, Kipke MD. A collaborative evaluation of needle exchange for youth. *Health Education and Behavior*, 1999, 26(2): 213-224.

D. Research Support

Ongoing Research Support

ACTIVE

1KL2RR031991-01 (Buchanan)

07/01/10 – 6/30/15

4.80 calendar

(Kipke – subaward PI)

USC/NIH (NCRR)

Los Angeles Basin Clinical and Translational Science Institute

The purpose of this project is to establish an infrastructure for research to be translated from bench to bedside to the community.

Role: Director/Center for Community Translation

8040644.2 (Kipke/Yin)

01/04/11-12/31/13

1.80 calendar

Autism Speaks

CHLA Autism Network

Partner with Autism Speaks and its ATN to develop effective strategies to identify, manage and treat the physical health conditions of children with ASD.

Role: Center Principal Investigator

R01 DA-022968-01 (Kipke),

04/01/08-03/31/12

3.60 calendar

National Institute for Drug Abuse (NIDA)

African American Young Men's Study

The purpose of this study is to conduct mixed-methods research to understand and characterize: 1) the structural, social, and cultural characteristics of the Ball and House communities in Los Angeles; 2) Ball and House members' use of illicit drugs, involvement in HIV risk and protective behaviors, and their social and sexual networks; and 3) the role that rejection, discrimination and internalized homophobia play with respect to encouraging drug use and HIV risk, and hence might be targets for intervention.

Role: Principal Investigator

Completed Research Support

1R21HD065289-01 (Levit)
NIH/NIDA

09/30/09-08/31/11

*In kind

The MET Signaling k, Autism and Gastrointestinal Dysfunction

This research is investigating the genetic associations between signaling system variation and gastrointestinal dysfunction in children with conditions with autism spectrum disorders (ASDs). The study combines modern genetic, biological and high quality clinical characterization data of a group of ASD patients who have co-morbid gastrointestinal dysfunction.

Role: Site-Investigator

R21DA024588-01 (Kipke)
NIDA, NIH

02/15/08-01/31/11

1.40 calendar

Young Men's Adult Identity Mentoring

The purpose of this study is to: 1) adapt an effective, evidence-based intervention called Project AIM (Adult Identity Mentoring) so that it is developmentally appropriate and culturally relevant for use with African-American (AA) young men who have sex with men (YMSM) in Los Angeles; 2) pilot test the feasibility and acceptability of the new intervention that we will call Young Men's AIM (YM-AIM); and 3) identify barriers and facilitators with respect to implementing YM-AIM in community settings.

Role: Principal Investigator

1 R03 DA024976-01A1
NIH/NIDA

09/15/08-08/31/10

.30 calendar

Drugs, Sexual Impulsivity, HIV: Psychosocial and Cognitive Risk Factors of YMSM

The specific aims of this study are to: 1) To empirically validate Social Action Theory, a theory of behavioral change, to determine if it addresses the interaction of individual, contextual, and social correlates of sexual and drug risk taking outcomes among YMSM; and 2) To compare and incorporate the relationships depicted in Social Action Theory with conflicting findings from the research literature to develop a comprehensive theory of the psychosocial and cognitive risk factors for drug use, sexual impulsivity, and HIV among YMSM.

Role: Co-Investigator

GCRC M01 (M01-RR000043) (Kipke) Los Angeles Basin Clinical and Translational Science Institute
Pilot and Feasibility Grant

Community-Based Research to Reduce
Health Disparities in Access to Pediatric Care

12/01/09 – 6/30/10

*In-Kind

The purpose of this study is to conduct community-based research that will help to inform the development of intervention strategies to reduce disparities associated with non-urgent, inappropriate, and preventable use of the emergency department for pediatric care.

Role: Co-Investigator

5 R01 DA15638 (Kipke)
NIDA, NIH

09/01/03 – 06/30/09

3.60 calendar

Drug Use, Sexual Risk and Health Promoting Behaviors Among At-Risk Youth

This study involves community-based, theory-driven longitudinal research with an ethnically diverse cohort of at-risk young men to examine individual, familial, social, and interpersonal risk and protective factors associated with drug use and HIV risk behaviors.

Role: Principal Investigator

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE		
Poulsen, Marie Kanne	Professor of Pediatrics, USC Keck School of Medicine Chief Psychologist, USC UCEDD, CHLA Co-Principal Investigator, Project ABC/SAMHSA		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Southern California University Affiliated Program/Childrens Hospital Los Angeles	Postdoctoral Fellowship	1972	Interdisciplinary Leadership in Developmental Disabilities
University of Southern California	Ph.D.	1971	Psychology and Special Education

A. I am Professor of Pediatrics at the University of Southern California (USC) Keck School of Medicine, Chief Psychologist at the USC Center for Excellence in Developmental Disabilities and ATN Behavioral Scientist at the Boone-Fetter Clinic at Children's Hospital Los Angeles. My research interests include program development, service delivery and policy relating to infant-family and early childhood mental health, children with autism and other developmental disabilities and children in foster care.

B. Positions and Honors.

Positions and Employment

Academic Appointments

1974-1984 Adjunct Assistant Professor, Department of Educational Psychology, USC, Los Angeles.
1981-1990 Adjunct Assistant Professor, Department of Special Education, USC Los Angeles
1984 1998 Clinical Associate Professor of Pediatrics, School of Medicine, USC, Los Angeles.
1998-Present Professor of Pediatrics, USC Keck School of Medicine;
2005-2009 Clinical Professor of Psychology, College of Letters, Arts & Science, University of Southern California

Administrative Responsibilities

1981-1991 Project Director, Special Education Training Grant #G008530022, U.S. Department of Special Education, USC University Affiliated Program, Childrens Hospital Los Angeles.
1981-1994 Education Director, USC University Affiliated Program, Childrens Hospital Los Angeles.
1993-1996 Director, Region IX Infant Mental Health Leadership Project, USC University Affiliated Program, Childrens Hospital Los Angeles..
1994-1998 Project Assistant Director, California Connections Project, USC University Affiliated Program, Childrens Hospital Angeles.
1994-Present LEND Psychology Director, USC University Affiliated Program, Childrens Hospital Los Angeles.

1995-2004 Training Director, USC LEND program, Childrens Hospital Los Angeles.
2002-2008 Principal Investigator, Child Health-Works: An Interagency Health Resource Collaborative
2005-Present Principal investigator, Project ABC, Substance Abuse Mental Health Services Administration
2007-Present Director, California Early Childhood Mental Health Professional Training Guidelines Project

Clinical Responsibilities

1972-1994 Staff Psychologist, USC University Affiliated Program, Childrens Hospital Los Angeles.
1976-1985 Staff Psychologist, Department of Pediatrics, Neurology Division, Childrens Hospital Los Angeles.
1994-Present Chief Psychologist, USC University Affiliated Program/University Center for Excellence in Developmental Disabilities, Childrens Hospital Los Angeles

Other Experience and Professional Memberships

American Psychological Association
World Association of Infant Mental Health
International Professional Advisory Committee, Beit Issie Shapiro, Israel

National/Regional Advisory/Workgroups

DHHS, National Head Start Mental Health Advisory Group
National Infant Mental Health Summit, California Delegate
National Parent Leadership Project, Professional member
Region IX, Head Start Resource Access Project Steering Committee

State Advisory/Workgroups

California Interagency Coordinating Council on Early Intervention (Governor appointment)
California Child Development Policy Advisory Committee (Governor appointment)
California Early Start (Legislature mandated) Work Group (DDS appointment)
California Foster Care Advisory Board, Childrens Research Institute, Sacramento
California Department of Mental Health, Infant Mental Health Project Steering Committee
California Department of Health Services, Stakeholders Workgroup, Medi-cal Managed Care Division
California Department of Social Services, Welfare Reform Stakeholders Workgroup
California Infant Development Association Advisory Committee
California Early Intervention Technical Assistance Network, DDS
California Early Intervention Personnel Advisory Committee
California Little Hoover Commission

State Autistic Spectrum Disorder Advisory/Workgroups

1997 California Department of Education. Best Practices for Designing and Delivering Effective Programs for
Individuals with Autistic Spectrum Disorders
2009 California Department of Developmental Disabilities. Autistic Spectrum Disorders: Best Practices in
Inter-Organizational Collaboration

Local Advisory/Workgroups

Los Angeles County, Council on Perinatal Substance Abuse of Los Angeles – Board
Los Angeles County, Child Care Planning Committee (Board of Supervisors appointment)
Los Angeles County, LAUP National Research Advisory Committee
Los Angeles County, Department of Mental Health, Early Childhood Mental Health Steering Committee
Los Angeles County, Perinatal Mental Health Task Force

Honors

1966-1969	United States, Office of Education Fellow
1991	Belle Dubnoff Memorial Lecturer
1999	Distinguished Service Award, California Infant Development Association
1999	Invited Participant, White House Conference on Mental Health
2000	Education Award, AMMR– Region II
2004	Distinguished Professional Award, Family Resource Center Network of California

B. Selected peer-reviewed publications (in chronological order).

1. Swallow R, Poulsen MK. An exploratory study of Piagetian space concepts in secondary low vision girls. Research Bulletin. 1973. American Foundation for the Blind.
2. Hurff J., Poulsen MK. A library skills program servicing adults with mental retardation. American Journal of Occupational Therapy. 1991. 39(4):233-239.
3. Marcus CL, Nield T, Poulsen MK. Medical and psychosocial outcome of children by congenital central hypoventilation syndrome. Journal of Pediatrics. 1991. 119:888-895.
4. Poulsen MK. Strategies for building resilience in infants and young children at risk. Infants and Young Children. 1993). 6(2):29-40.
5. Poulsen MK. The development of policy recommendations to address the individual and family needs of infants and young children affected by perinatal substance use. Topics in Early Childhood special Education. 1994. 14(2):275-291.
6. Langenbacher D, Nield TA, Horton E, Poulsen MK. Neurodevelopmental outcome and potential for academic difficulties in ECMO survivors at five years of age. The American Pediatric Society/The Society for Pediatric Research. 1997. Abstract #2103340.
7. Nield TA, Langenbacher D, Poulsen MK. Neurodevelopmental outcome at 3.5 years of age in children treated with extracorporeal life support: Relationship to primary diagnosis. Journal of Pediatrics. 2000. 136(3):338-344.
8. Langenbacher D, Nield TA, Poulsen MK. Neurodevelopmental outcome of ECMO survivors at five years of age: The potential for academic and motor difficulties. Journal of Special Education. 2001. 35(3):156-160.
9. Betz CI, Baer MT, Poulsen MK. Secondary analysis of primary and preventive services accessed and perceived service barriers by children with developmental disabilities and their families. Issues in Comprehensive Pediatric Nursing. 2004. 27:83-106.
10. Knapp PK, Ammen S, Arstein-Kerslake C. Poulsen MK. Feasibility of Expanding Services for Very Young Children in the Public Mental Health Setting. Journal of American Academy of Child and Adolescent Psychiatry, 46:2, February 2007.
11. Clarke N, Shacks J, Kerr AR, Poulsen MK, Yin L. Use of a non-cycloplegic autorefractor to perform vision screening in preschools. Journal of School Nursing. 24(3): 158-163, 2008.
12. Yin L, Clarke N, Shacks J, Poulsen M. Otoacoustic emissions: A valid efficient first-line hearing screen for preschool children. Journal of School Health. 79(4):147-152
13. Yin L, Will H, Clarke N, Poulsen M. Cardiovascular risk in preschool children. Infant, Childhood and Adolescent Nutrition, 10(10): 1-8.

C. Research Support

On-going Research Support

2006-present Co-Principal Investigator, Child Mental Health Initiative, Substance Abuse and Mental Health Services Administration Center for Mental Health Services, Department of Health and Human Services, CFDA 93.104

2009-present Co-investigator, Autism in Urban Context

2010 Co-investigator, Boone-Fetter Clinic Patient Registry

Completed Research Support

2002-2008 Principal Investigator, Child Health-Works: An Interagency Health Resource Collaborative, First 5 Los Angeles,

1998-2001 Co-Investigator, California Infant Mental Health Development Project, First 5 California Commission

1990's Co-principal Investigator, Extracorporeal Membrane Oxygenation Research Project

Department of Neonatology and Pulmonology, Childrens Hospital Los Angeles

Investigator, Neurodevelopmental Outcome of Children after Apnea, Department of Neonatology and Pulmonology, Childrens Hospital Los Angeles

1980's Investigator, Psychoeducational Outcome of Children with Congenital Central Hypoventilation Syndrome, Department of Neonatology and Pulmonology, Childrens Hospital Los Angeles

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Volk, Heather E.	POSITION TITLE Assistant Professor of Research		
eRA COMMONS USER NAME volkhe			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of Notre Dame, Notre Dame, IN	BA	1996-2000	Pre-professional Studies
Boston University, Boston, MA	MPH	2000-2002	Epidemiology and Biostatistics
Saint Louis University, Saint Louis, MO	PhD	2003-2006	Public Health Studies- Epidemiology
University of Southern California, Los Angeles, CA	Postdoctoral Fellow	2006-2009	Environmental Genomics

A. Personal Statement

I am an Assistant Professor of Research in the Departments of Preventive Medicine and Pediatrics, and the Zilkha Neurogenetic Institute. My research interests include the study of gene-environment interaction in neurodevelopmental disease and the investigation of genetic and environmental risks for autism. In the current application we seek to examine predictors of complementary alternative medicine therapies in the Autism Treatment Network registry. My background in statistical genetics and psychiatric and environmental epidemiology includes hands on experience in the study design and analysis techniques central to this application.

B. Positions and Employment

2001	Research Assistant, Study of Tamoxifen and Raloxifene (STAR), Boston University School of Public Health, Boston, MA
2001-2002	Research Assistant and Data Analyst, Joslin Diabetes Center, Boston, MA
2002-2003	Genetics Coordinator and Epidemiologist, Pediatric Psychopharmacology Research Unit, Massachusetts General Hospital, Boston, MA
2003	Teaching Assistant, Epidemiology, Boston University School of Public Health, Boston, MA
2003-2005	Graduate Assistant, Department of Community Health, Saint Louis University School of Public Health, Saint Louis, MO
2003-2005	Graduate Assistant, Vietnam Era Twin Registry, Saint Louis VAMC, Saint Louis, MO
2003-2006	Graduate Assistant and Data Analyst, Department of Psychiatry, Division of Child Psychiatry, Washington University School of Medicine, Saint Louis, MO
2005	Teaching Assistant, Applied Linear Models II, Saint Louis University School of Public Health, Saint Louis, MO
2005	Orientation Instructor, Introduction to SPSS, Saint Louis University School of Public Health, Saint Louis, MO
2006-2009	Postdoctoral Fellow, Division of Biostatistics, Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA
2009-2010	Postdoctoral Research Associate, Division of Environmental Health Sciences, Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA

2010-current Assistant Professor of Research, Division of Environmental Health Sciences,
Department of Preventive Medicine, Zilkha Neurogenetic Institute, Keck
School of Medicine, University of Southern California, Community, Health
Outcomes and Intervention Research Program, the Saban Research Institute
Children's Hospital Los Angeles

C. Selected Peer-Reviewed Publications

1. Volk HE, Neuman RJ, Todd RD "A Systematic Evaluation of ADHD and Comorbid Psychopathology in a Population Based Twin Sample." *Journal of the American Academy of Child and Adolescent Psychiatry*. 2005 Aug; 44(8):768-75.
2. Reich W, Neuman RJ, Volk HE, Joyner CA, Todd RD "Comorbidity Between ADHD and Juvenile Bipolar Disorder in a Community Sample." *Twin Research and Human Genetics*. 2005 Oct; 8(5): 459-466.
3. Volk HE, Henderson C, Neuman RJ, Todd RD "Validation of Population-based ADHD Subtypes and Identification of Three Clinically Impaired Subtypes." *American Journal of Medical Genetics Part B, Neuropsychiatric Genetics*. 2006 Apr; 141(3): 312-318.
4. Volk HE, Todd RD "Does the Child Behavior Checklist Juvenile Bipolar Disorder Phenotype Identify Bipolar Disorder?" *Biological Psychiatry*. 2007 July; 62(2): 115-120.
5. Volk HE, McDermott K, Roediger HL, Todd RD "Genetic Influences on Free and Cued Recall in Long Term Memory." *Twin Research and Human Genetics*. 2006 Oct; 9(5): 623-631.
6. Volk HE, Scherrer JF, Bucholz KK, Todorov A, Heath AC, Jacob T, True WR "Evidence for Specificity of Transmission of Alcohol and Nicotine Dependence in an Offspring of Twins Design." *Drug and Alcohol Dependence*. 2007 Mar; 87(2-3): 225-232.
7. Reiersen AM, Constantino JN, Volk HE, Todd RD "Autistic Traits in a Population-Based ADHD Sample." *Journal of Child Psychology and Psychiatry and Allied Health Disciplines*. 2007 May; 48(5): 464-472.
8. Alkelai A, Baum A, Carless M, Crowley J, Dasbanerjee T, Dempster E, Docherty S, Hare E, Galsworthy MJ, Grover D, Glubb D, Karlsson R, Mill J, Sen S, Quinones MP, Vallender EJ, Verma R, Vijayan NN, Villafuerte S, Voineskos AN, Volk H, Yu L, Zimmermann P, Delisi LE. The XVth World Congress of Psychiatric Genetics, October 7-11, 2007: Rapporteur Summaries of Oral Presentations. *American Journal of Medical Genetics Part B, Neuropsychiatric Genetics*. 2008 Mar; 147B(2): 233-237.
9. Volk HE, Todorov AA, Hay DA, Todd RD. Simple Identification of Complex ADHD Subtypes Using Current Symptom Counts. *Journal of the American Academy of Child and Adolescent Psychiatry*. 2009 Apr; 48(4):441-450.
10. Volk HE, Hertz-Picciotto I, Delwiche L, Lurmann F, McConnell R, 2010 Residential Proximity to Freeways and Autism in the CHARGE study. *Environ Health Perspect*
doi:10.1289/ehp.1002835

D. Research Support

Ongoing Research Support

Individual Award (Volk)

07/01/11-06/31/2012

James H. Zumberge Research and Innovation Fund
A Birth Records Based Analysis of Autism in Anaheim

This project will using birth certificate and state service records to build the infrastructure needed for a case-control study nested in a birth cohort of children in Southern California and to examine preliminary associations between air pollution and autism in Anaheim, California.

1 R21 ES19002-02 (McConnell)

09/30/09-07/31/2012

(no cost)

NIH/NIEHS

Investigating Gene-Environment Interaction in Autism: Air Pollution x

This project examines the association of air pollution, a common exposure that induces inflammation and oxidative stress, with autism.

Role: Co-Investigator

Completed Research Support

T32 ES013678 (Azen)

07/01/06 - 06/30/11

NIEHS

Training Grant in Genomic Analysis and Interpretation

Goals were to provide training in the analysis and interpretation of gene-environment interaction in the context of integrating statistical genetics and genetic and environmental epidemiologic techniques.

Role: Post-doctoral fellow 2006-2009

5 P01 ES011627-09 (Gilliland)

08/1/07 - 05/31/12

NIEHS

Genetics, Air Pollution, and Respiratory Effects in Children

Pilot Project Grant (Volk)

Traffic Exposure as an Environmental Risk Factor For Autism: A Pilot Study (09/01/07 - 03/31/08)

This pilot project gathered preliminary data assessing the relationship between traffic exposure and autism

and developmental disabilities.

Role: PI

1 R01 DA12190 (Knowles)

07/01/00 - 06/30/07

NIDA

Genetic Risk Factors for Nicotine Addiction

The major goal of this project was to map the chromosomal positions of genes that predispose individuals to persistence in the use of nicotine.

Role: Statistical geneticist

F31 MH74272 (Volk)

05/01/05 - 07/10/06

NIMH

Integrative Examination of Comorbidity with ADHD

The goals of this project were to combine epidemiologic, statistic, and behavior genetic methods to systematically examine comorbidity with attention deficit hyperactivity disorder (ADHD).

Role: PI

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Blanche, Erna I.	POSITION TITLE Associate Professor of Clinical Occupational Therapy		
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Chile, Santiago, Chile	OT	1973	Occupational Therapy
State University of New York, Empire State College, New York	BS	1979	Human Services
Columbia University – Teachers College, New York	MA	1982	Special Education
University of Southern California, Los Angeles	MA	1988	Occupational Therapy
University of Southern California, Los Angeles	Ph.D.	1998	Occupational Science

A. Personal Statement:

With professional interests in Hispanic cultural health issues, sensory integration, and autism, I am internationally recognized as an expert occupational therapist possessing extensive experience in the conceptualization and delivery of culturally sensitive interventions for children and adults with disabilities. For over 25 years I have provided services to children with developmental disabilities and their families, both in the Los Angeles area and abroad. I have authored or co-authored publications related to assessment and provision of effective interventions for children with disabilities, including Autism Spectrum Disorders. I have experience conducting randomized controlled trials, as Co-Investigator on the NIH 1R01HD056267-01 *Pressure Ulcer Prevention Study (PUPS)* in which I supervise the intervention component which targets a low-income underserved population. Together, my expertise and experiences position me for successful fulfillment of my proposed role of consultant in this study.

B. Positions and Honors**Positions and Employment**

1973 - 1974	Occupational Therapist, Institute of Infantile Rehabilitation, Santiago, Chile
1975 - 1976	Staff Occupational Therapist, United Cerebral Palsy Association, Rochester, New York
1976 - 1979	Senior Occupational Therapist, Bernard Fineson Developmental Center, Queens, New York
1979 - 1983	Senior Occupational Therapist, Orthopedic Institute, New York, New York

1982 - 1983	Team Leader Preschool Program, Neuromuscular Center, Orthopedic Institute, Orthopedic Institute, New York, New York
1979 - 1983	Assistant Chief, Department of Occupational Therapy, Orthopedic Institute, New York, New York
1990 - present	Co- owner and co-founder of Therapy West, Los Angeles, California
1988 - 2002	Adjunct instructor - Department of Occupational Science and Occupational Therapy, University of Southern California, Los Angeles, California
2002 - 2003	Adjunct Assistant Professor – Department of Occupational Science and Occupational Therapy, University of Southern California
2003 - 2006	Assistant Professor of Clinical Practice – Clinical Doctorate Program Coordinator, Division of Occupational Science and Occupational Therapy, University of Southern California
2006 - present	Associate Professor of Clinical Practice – Director, Clinical Doctorate Program, Division of Occupational Science and Occupational Therapy, University of Southern California
2004 – present	Adjunct Associate Professor – School of Occupational Therapy, University of Chile, Santiago, Chile

Other Experience and Professional Membership

1973 – 1974	Chilean Occupational Therapy Association, Treasurer
1987 – present	Co-founder and co-developer: Therapy West Early Intervention Program
1993 – 1996	American Occupational Therapy Association, Member Standing Committee - Developmental Disabilities Special Interest Section Standing Committee
1995 – 1996	Member, Sensory Integration International - Board of Director's
1996 – 1999	American Occupational Therapy Association, Chair, Developmental Disabilities Special Interest Section Standing Committee
2001 – present	Co-founder and developer: <u>PLAY studio</u> , a center dedicated to the enhancement of quality of life for children and their families
2003 – 2004	National Board for Certification in Occupational Therapy: Practice Analysis Task Force
2004	National Board for Certification in Occupational Therapy: Standard Setting Study

Honors

1999	Penelope Richardson Award - Occupational Science and Occupational Therapy Department, University of Southern California
1999	Service Award - The American Occupational Therapy Association
2000	Fellow - The American Occupational Therapy Association
2004	Bridges to the Ivory Tower – Pediatric Therapy Network
2006	Honorary member: Asociación de Integración Sensorial, Argentina
2006	Honorary member: Asociación de Integración Sensorial, Chile
2007	Honorary member: Asociación de Ciencia de la Ocupación, Chile
2010	A. Jean Ayres Award – The American Occupational Therapy Foundation
2011	Award of Excellence – Occupational Therapy Association of California

C. Selected peer-reviewed publications (in chronological order).

1. Blanche, E.I., Bodison, S., Chang, M., Reinoso, G., (in press). Preliminary data on the comprehensive observations of proprioception. American Journal of Occupational Therapy.

2. Blanche, E.I., Reinoso, G., S., Bodison, S., Chang, M. (in press). Proprioceptive processing deficits in children with ASD. *American Journal of Occupational Therapy*.
3. Schaaf, R., & Blanche, E. J. (2011). Comparison of behavioral intervention and sensory-integration therapy in the treatment of challenging behavior [Letter to the editor]. *Journal of Autism and Developmental Disorders*, 41, 1436-1438. doi: 10.1007/s10803-011-1303-0.
4. Blanche, E., Fogelberg, D., Diaz, J., Carlson, M., Clark, F., (in press). Manualization of Occupational Therapy Interventions: Illustrations from the Pressure Ulcer Prevention Research Program. *American Journal of Occupational Therapy*.
5. Mailloux, Z., Mulligan, S., Smith Roley, S., Blanche, E.I., Cermak, S., Geppert Coleman, G., Bodison, S., Lane, C.J. (2011). Verification and clarification of patterns of sensory integrative dysfunction. *American Journal of Occupational Therapy*, 65, 143-151. doi: 10.5014/ajot.2011.000752
6. Vaishampayan, A., Clark, F., Carlson, M., & Blanche, E. I. (2011). Preventing pressure ulcers in people with spinal cord injury: Targeting risky life circumstances through community-based interventions. *Advances in Skin and Wound Care*, 24(6), 275-284.
7. Jackson, J., Carlson, M., Rubayi, S., Scott, M., Atkins, M., Blanche, E., Saunders-Newton, C., Mielke, S., & Clark, F. (2010). Qualitative Study of Principles Pertaining to Lifestyle and Pressure Ulcer Risk in Adults with Spinal Cord Injury. *Disability and Rehabilitation*, 32(7), 567-578.
8. Fogelberg, D., Atkins, M., Blanche, E.I., Carlson, M., Clark, F. (2009). Decisions and dilemmas in everyday life: Daily use of wheelchairs by individuals with spinal cord injury and the impact on pressure ulcer risk. *Topics in Spinal Cord Injury Rehabilitation*, 15(2), 16-32.
9. Koomar, J., Miller, L. J., Schoen, S. A., Brett-Green, B., Schaaf, R. C., Benevides, T., Lane, S. J., Reynolds, S., Parham, D., May-Benson, T. A., Teasdale, A., Mailloux, Z., Smith-Roley, S., Blanche, E. J., & Bodison, S. (2008). Collaborative research programs in sensory integration and processing. *Sensory Integration Special Interest Section Quarterly*, 31(4), 1-4.
10. Blanche, E.I. (2007). The expression of creativity through occupation. *Journal of Occupational Science*, 14(1), 21-29.
11. Blanche, E.I., & Reinoso, G. (2007). Revisión de la Literatura: Déficit de Procesamiento Sensorial en el Espectro del Autismo. *Revista Chilena de Terapia Ocupacional*.
12. Blanche, E. I., & Henny, E. (2000). The philosophy of occupational therapy, occupational science, and ideology: A proposed relationship. *Occupational Therapy International*. 7 (2), 99-110.
13. Blanche, E. I. (2002). Play and process: Adult play embedded in the daily routine. In J. Roopnarine (Ed.). *Conceptual, social-cognitive, and contextual issues in the field of play*, pp. 249-278. Westport, Conn: Ablex Publishing.
14. Blanche, E. (1996). Alma: Coping with culture, poverty and disability. *American Journal of Occupational Therapy*, 50(4), 265-276.

Books.

Blanche, E. J. (2007). *Sensory balance: A quick reference guide for parents and professionals*. Lulu Press.

Imperatore Blanche, E. (2002). *Observations based on sensory integration*. Torrance, Ca: Pediatric Therapy Network.

Smith-Roley, S. Blanche, E. I., & Schaaf, R. (Eds.). (2001). *Understanding the nature of sensory integration with diverse populations*. San Antonio, Tx: Therapy Skill Builders.

Blanche, E.I., Botticelli, T.M., & Hallway, M.K. (1995). *Combining neuro developmental treatment and sensory integration principles – An approach to pediatric therapy*. Tucson, Az: Therapy Skill Builders.

D. Research Support.

Active:

NIH - 1R01HD056267-01 (Clark, PI)

07/01/08 – 06/30/13

National Institute of Health

Lifestyle Redesign for Pressure Ulcer Prevention in Spinal Cord Injury

The specific aims of this study are to: (a) conduct a randomized clinical trial testing the intervention's efficacy in reducing the incidence of serious pressure ulcers in adults with SCI; (b) assess the cost-effectiveness and potential cost savings of the intervention; (c) examine the intervention's effects on quality of life; and (d) model the process mechanisms that mediate the effects of the intervention. A supplement, made available through the 2009 American Recovery and Reinvestment Act, was awarded to accelerate the pace of the science by creating employment opportunities.

Role: Co-investigator

Completed:

NIDRR H133G000662 (Clark, P.I.)

10/01/00 - 09/30/03

U.S. Department of Education

Daily Living Context and Pressure Sores in Consumers with Spinal Cord Injury.

The major goals of this project are to document how personality, lifestyle patterns and choices, and environmental context mutually interact within the individually constructed lives of consumers with spinal cord injury to influence the development of pressure sores for the purpose of developing (1) a consumer-oriented self-help manual, (2) a set of guidelines for rehabilitation practice, and (3) a lifestyle-oriented occupational therapy treatment model.

Role: Data Coordinator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Pena-Ricardo, Carolina.		POSITION TITLE Developmental Behavioral Pediatrics Fellow	
eRA COMMONS USER NAME None			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Universidad del Cauca, Popayan, Colombia.	M.D.	2000	Medicine
Albert Einstein Medical Center, Philadelphia, PA	Pediatrician	2006	General Pediatrics Resident
Children's Hospital Los Angeles/ USC, CA	Developmental Behavioral Pediatrician	2013	Clinical Fellow

A. Personal Statement:

Coming from Colombia, South America, where covering the basic needs is most of the times the priority, I was not aware of the field of Developmental and Behavioral Pediatrics. During my two core rotations in DBP as a resident, and then in my elective rotations in Child Psychiatry, DBP, and Genetics, I discovered this fascinating field and I decided this is what I want to do in my professional life. Ever since then I have been interested in the study and management of children with Autism and other developmental and behavioral disabilities. I received training to administer different developmental and behavioral tests as; ADOS, Bayley, Vineland, Mullen and PLS. worked as a Mental Health consultant for a Head Start Program in New Haven and was in charge of counseling parents and teachers on challenging child behaviors as well as the way to manage some medical problems, under the supervision of Developmental Behavioral Pediatrics attending at Yale University. Having been involved in the clinical management of children with Autism I'm now interested in taking an active role in research as a Developmental Behavioral Pediatrics fellow at Children's Hospital Los Angeles, USC.

B. Positions and Honors.**Positions and Employment (in chronological order)**

2000	Primary Medical Physician, worked in the ED, Outpatient and Inpatient wards (5 bed hospital), in a Native American Guambia tribe, Hospital Mama Dominga. Colombia.
2001	Primary Medical Physician, in the ED, Outpatient and Inpatient wards (5 bed hospital) in a rural isolated Afro-Colombian community, Centro de Salud Villa Rica. Colombia.
2001-2003	ED and Inpatient Hospitalist in an inner city Private Hospital, Clinica La Estancia. Popayan, Colombia.
2002	Primary Medical Physician and Counselor, in a government health project for the armed conflict displaced families. Popayan. Proyecto Vivir en Salud, Colombia.
2003	ED and Inpatient Hospitalist in an inner city Public Hospital, Hospital Susan Lopez de Valencia. Popayan, Colombia.
2003-2005	Inpatient Hospitalist in an inner city Private Hospital, Clinica de Occidente. Bogota, Colombia.
2009-2010	Research Assistant, Yale University Department of General Pediatrics and Developmental Behavioral Pediatrics, New Haven, CT.
2009-2010	Mental Health Consultant, LULAC Headstart Inc. New Haven, CT.
2010	Program Coordinator, Project Access (Federal Grant) USC UCEDD at Children's Hospital Los Angeles. CA.

Honors

1994	Honors as best Medical Student during the basic sciences semester. Universidad del Cauca. Colombia.
1999	Honors as best Medical student during the pediatric semester. Universidad del Cauca. Colombia.

C. Relevant peer-reviewed publications

1. Aller SK, Goldfarb FD, Vrabel CJ, Pena-Ricardo C, Zamora I, Williams ME. Family Navigator Clinic for Parents of Children with Autism. Submitted to Intellectual and Developmental Disabilities in August 2011.

Relevant peer-reviewed conference presentations/abstracts

None

D. Research Support

Active Research Support

None

Recently Completed Research Support

None

BIOGRAPHICAL SKETCH

NAME Cermak, Sharon A.	POSITION TITLE Professor of Occupational Science and Occupational Therapy		
eRA COMMONS USER NAME (credential, e.g. agency login) cermak.sharon			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Ohio State University, Columbus, OH	BS	1969	Occupational Therapy
Boston University, Sargent College, Boston, MA	MS	1971	Occupational Therapy
Boston University, School of Education Boston, MA	EdD	1981	Special Education

A. Personal Statement**B. Positions and Honors.****Positions and Employment**

1973-1994	Instructor / Assistant Prof/ Associate Prof of Occupational Therapy, Boston University
1994-2008	Professor of Occupational Therapy, Boston University, Boston MA
2009-present	Adjunct Professor of Occupational Therapy, Boston University, Boston MA
1999-2008	Director of Occupational Therapy Training, LEND Program, Children's Hospital, Boston MA
2004-2008	Director of Occupational Therapy Training, LEND Program, Shriver Center, University of Massachusetts Medical School, Worcester MA
2005-present	Adjunct Professor of Family Medicine and Community Health University of Massachusetts Medical School, Department of Family Medicine and Community Health, Worcester, Massachusetts
2009-present	Professor of Occupational Science and Occupational Therapy, University of Southern California, Los Angeles, CA
2011-present	Professor of Pediatrics, USC Keck School of Medicine, Children's Hospital Los Angeles, Los Angeles, CA

Other Experiences and Professional Memberships (selected)

1991-1992	Adjunct Professor, School of Occupational Therapy, Hebrew University of Jerusalem (Fulbright).
1999-2008	Member, Advisory Board MCH Training Grant, Maternal and Child Health Department, School of Public Health, Boston University. Boston MA
1999	Visiting Professor, Dept of Movement Sciences, University of Western Australia, Perth, AU
2008-present	Senior Research Fellow, Ono Academic College, Research Institute for Health and Medical Professions, Kiryat Ono, Israel
2008	Visiting Professor, University of Sydney, Lidcombe, Australia
2009	Visiting Professor, Lady Davis Fellowship, School of Occupational Therapy, Hebrew University of Jerusalem
2009-2011	Invited Member, Editorial Board, OTJR: Occupation, Participation and Health (research journal of American Occupational Therapy Association)
2009-2014	Invited Member, Editorial Board, Occupational Therapy International

Honors and Awards (selected)

1982	Fellow, American Occupational Therapy Association.
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1986	Charter Member, Academy of Research, American Occupational Therapy Foundation.
1986	Post-Doctoral Research Fellowship, American Occupational Therapy Foundation.
1990	Recipient of Fulbright Lecture Award.
1991	Recipient of the A. Jean Ayres Award (American Occupational Therapy Foundation).
1992	Member, Medical Relief Team, Heal the World (Michael Jackson). Bucharest, Romania.
1995	A. Jean Ayres Lecture Award, Sensory Integration International.
1998	Recipient of the R.K. Gray Research Fellowship (Australia).
2002	Bridges 2002 Award, Pediatric Therapy Network, for linking research to practice.
2002	Caroline Thompson Lectureship, University of Wisconsin at Madison.
2008	Visiting Professorship, University of Sydney, Sydney Australia
2008	Spiraling Toward Excellence Award. Spiral Foundation. Watertown, MA.
2009	Lady Davis Professorship, Hebrew University of Jerusalem, Jerusalem Israel
2010	Wilma West Lectureship (Occupational Science Symposium)

C. Selected Peer Reviewed Publications (chronological order) (selected from >150 publications)

- Ben-Sasson, A., **Cermak, S.**, & Orsmond, G., Carter, A., & Fogg, L. (2007). Can we differentiate sensory over-responsivity from anxiety in toddlers? Perspectives of occupational therapists and psychologists. *Infant Mental Health Journal*, 28(5), 536-558.
- Ben-Sasson, A., **Cermak, S.**, Orsmond, G., Tager-Flusberg, H., Carter, A., Kadlec, M.B., & Dunn, W. (2007). Extreme sensory processing behaviors in toddlers with autism spectrum disorders. *American Journal of Occupational Therapy*, 61, 584-592.
- Daunhauer, L., Coster, W.J., Tickle-Degnen, L., & **Cermak, S.** (2007). Effects of caregiver-child interactions on play occupations among young children institutionalized in Eastern Europe. *American Journal of Occupational Therapy*, 61, 429-440.
- Tirella, L., Chan, W., **Cermak, S.**, Litvinova, A., Salas, K.C., & Miller, L. (2008). Time use in Russian baby homes. *Child: Care, Health and Development*, 34(1), 77-86.
- Ben-Sasson, A., **Cermak, S.A.**, Orsmond, G.I., Tager-Flusberg, H., Kadlec, M.B., & Carter, A.S. (2008). Sensory clusters of toddlers with Autism Spectrum Disorders: Differences in affective symptoms. *Journal of Child Psychology and Psychiatry*, 49(8), 817-825. doi: 10.1111/j.1469-7610.2008.01899.x
- Chen, Y-W., Tseng, M-H, Hu, F-C., & **Cermak, S. A.** (2009). Psychosocial adjustment and attention in children with developmental coordination disorder using different motor tests. *Research in Developmental Disabilities*, 30(6), 1367-1377.
- Ben-Sasson, A., Hen, L., Fluss, R., **Cermak, S.**, Engel-Yeger, B. & Gal, E. (2009). A meta-analysis of sensory-modulation symptoms in individuals with autism spectrum disorders. *Journal of Autism and Developmental Disorders*, 39(1), 1-11. doi:10.1007/s.10803-008-0593-3
- Ben-Sasson, A., Simmell, K.E., & **Cermak, S.** (2009). Sequence of gestural representation in children with high functioning autism. *Israeli Journal of Occupational Therapy*, 8(4), E57-E73.
- Daunhauer, L.A., Coster, W.J., Tickle-Degnen, L., & **Cermak, S.A.** (2010). Play and cognition among young children reared in an institution. *Physical and Occupational Therapy in Pediatrics*, 30(2), 83-97.
- Cermak, S.A.**, Curtin, C., & Bandini, L. (2010). Food selectivity and sensory sensitivity in children with autism spectrum disorders. *Journal of the American Dietetic Association*, 110, 238-246.
- Bandini, L.G., Anderson, S.E., Curtin, C., **Cermak, S.**, Evans, E.W., Scampini, R., Maslin, M., & Must, A. (2010). Comparison of food selectivity in children with Autism Spectrum Disorders and typically developing children. *Journal of Pediatrics*, 157(2), 259-264.
- Stein, L.I., Foran, A.C., & **Cermak, S.** (2011). Occupational patterns of parents of children with Autism Spectrum Disorders: Revisiting Matuska and Christiansen's Model of Lifestyle Balance. *Journal of Occupational Science*, 18 (available online). Retrieved from <http://www.jos.edu.au.libproxy.usc.edu/article.asp?id=419>
- Stein, L., Polido, J., Mailloux, Z., Coleman, G., & **Cermak, S.** (2011). Oral care and sensory sensitivities in children with Autism Spectrum Disorders. *Special Care in Dentistry*. 31(3), 102-110. doi/10.1111/j.1754-4505.2011.00187.x/full
- Tseng, M-H., Fu, C-P., **Cermak, S. A.**, Lu, L., Shieh, J-Y. (2011). Emotional and behavioral problems in preschool children with autism: Relationship to sensory processing dysfunction. *Research in Autism Spectrum Disorders*, 5(4), 1441-1450.

- Mailloux, Z., Mulligan, S., Roley, S.S., Blanche, E., **Cermak, S.**, Coleman, G., & Lane, C.J. (2011). Verification and clarification of patterns of sensory integrative dysfunction. Accepted for publication, *American Journal of Occupational Therapy*, 65, 143-151.
- Stein, L., Polido, S., & **Cermak, S.** Oral care experiences and challenges in children with autism spectrum disorders. Accepted for publication, *Pediatric Dentistry*.

Invited Chapters and Articles

- Cermak, S.A.** (2005). Cognitive rehabilitation of children with Attention-Deficit/Hyperactivity Disorder. In N. Katz (Ed.), *Cognition and occupation across the lifespan (2nd ed.)* (pp. 277-302). Bethesda, MD: AOTA.
- Miller, L., Lane, S., **Cermak, S.**, Anzaone, M., & Osten, B. (2005). Regulatory-sensory processing disorders in the children. In S. Greenspan (Ed.), *Interdisciplinary Council on Developmental and Learning Disorders (ICDL) Diagnostic manual or infancy and early childhood (ICDL-DMIC)*. Bethesda, MD: Interdisciplinary Council on Developmental and Learning Disorders
- Gal, E., & **Cermak, S.**, & Ben-Sasson, A. (2007). Sensory and motor issues and intervention. In R.L. Gabriels & D.E. Hill (Eds.), *Growing up with Autism: Working with school-aged children and adolescents* (pp. 95-123). NY: Guilford.
- Daunhauer, L., & **Cermak, S.** (2008). Play occupations and the experience of deprivation. In D. Parham & L. Fazio (Eds.), *Play in occupational therapy for children, 2nd ed.* Pp. 251-262. St. Louis, MO: Mosby Elsevier.
- Cermak, S.** (2009, June, August) Deprivation and sensory processing in institutionalized and post-institutionalized children, *Sensory Integration Special Interest Section Quarterly*, 32 (2), 1-3. (Part I), 32 (3), 1-4. (Part II)
- Miller, L.J., **Cermak, S.**, Lane, S., Anzalone, M., & Koomar, J. (2010). Position statement on terminology related to sensory integration dysfunction. In K. Morris (Ed.), *Insights into sensory issues for professionals*, pp. 117-122. Arlington, TX: Sensory World.
- Cermak, S.**, & Hartman-Maier, A. (in press). Cognition and ADHD. In N. Katz (Ed.), *Cognition, occupation, and participation across the life span (3rd ed.)*. Rockville, MD: American Occupational Therapy Association.
- Werner, J., Aziz-Zadeh, L., & **Cermak, S.A.** (2011, September/October) Praxis and imitation in children with autism spectrum disorder. (Feature article) Neurodevelopmental Therapy Association Network (online).
- Cermak, S.** (2011). Twenty five years of research in developmental dyspraxia. In Ayres, A.J. (2011). *Developmental dyspraxia and adult onset apraxia*. Torrance, CA: Pediatric Therapy Network.

Books

- Cermak, S.**, & Larkin, D. (2002). *Developmental coordination disorder*. Albany, N.Y.: Delmar Thompson Learning.

D. Research Support

Ongoing Research /Training Support

2011-2013

Sensory adapted dental environment to enhance oral care in children with autism spectrum disorders. (2-year R34 Planning and Pilot Data) Funded by NIH National Institute of Dental and Craniofacial Research (NIDCR)
 Role: Principal Investigator
 Overall goals of the project: This is a planning and pilot study grant designed to examine the effectiveness of an intervention to adapt the sensory characteristics of the dental environment in order to decrease anxiety and negative behavioral responses of children with ASD, thus enhancing their oral care.

2010

Coding children's behavior during routine oral care. A reliability and validity study. Faculty seed grant, USC Herman Ostrow School of Dentistry.
 Role: principal investigator:
 Overall goals of the project: The specific aims of this study are to develop a rating scale of challenging behaviors exhibited during dental care and examine its reliability and validity.

2009-2011

Autism in urban context: Linking heterogeneity with health and services disparities (R01). NIH (MH089474)
 Principal Investigator: O. Solomon

Role: Co-Investigator

Overall goals of the project: This multi-method ethnographic study examines health and service disparities in Autism Spectrum Disorders diagnosis of African American children living in Los Angeles.

2009

Enhancing social communication for children with High Functioning Autism

Funding Agency: Autism Speaks

Principal Investigator: PL Weiss, N. Bauminger

Role: Consultant

Overall goals of the project: To evaluate the effectiveness of an intervention using a co-located cooperation enforcing interface, the Story Table, a multi-user touchable device, to enhance structured positive social interaction with peers.

CoSpatial: Communication and Social Participation: Collaborative Technologies for interaction And Learning

Funding Agency: European Union FP7 ICT STREP,

Principal Investigator: PL Weiss and E. Gal (Co-PI)

Role: Consultant

Overall goals of the project: This project is designed to develop collaborative technologies to promote the learning of 'social competence' by children with ASD using two types of technology: virtual environments, (3D simulations of everyday situations) and active surfaces (shared co-located systems based on large interactive surfaces [tabletop' devices]) to encourage pairs of children to work together

Completed Research/ Training Support

2006-2009

Physical Activity, Fitness and Obesity in Children with Coordination Disorders,

Funding Agency: National Institutes of Health (R21HD051861)

Principal Investigator: S. Cermak

Overall goals of the project: To examine physical activity, fitness and risk for obesity in children with coordination disorders

2006-2009

Diet, Activity, and Obesity in Children with Autism,

Funding Agency: National Institutes of Health (R21HD48989)

Principal Investigator- L. Bandini

Role: Co-Investigator

Overall goals of the project: To examine food selectivity, sensory sensitivity, physical activity and risk for obesity in children with autism spectrum disorders

2003-2009

Project Loving Arms: Cranaleith Child Development Center and the Elise Gilbert Family Connection

Funding Agency: Foundation: Orphan Reach (NGO)

Role: Author and Project Director

Overall goals of the project: To provide caregiver training and enhance quality of life for children in Romanian orphanages

2004-2008

Leadership in Education and Neurodevelopmental Disabilities (LEND)

Funding Agency: Maternal and Child Health Bureau

University of Massachusetts Medical School

Principal Investigator: K. Braden, MD

Role: Director of Occupational Therapy (.20 FTE)

Overall goals of the project: Interdisciplinary training in leadership in developmental disabilities

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Linda Marie Randolph		POSITION TITLE Division Head of Medical Genetics, Assistant Clinical Professor of Pediatrics	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
George Washington University	M.D.	1982	Medicine
University of California, Irvine	M.A.	1980	Social ecology; genetics
University of Redlands	B.S.	1975	Biology; minor in chemistry

A. Personal Statement

Linda Marie Randolph, M.D., is the Head, Division of Medical Genetics, Assistant Clinical Professor of Pediatrics, at University of Southern California, Keck School of Medicine. After earning her M.D. degree from George Washington University, Dr. Randolph completed her pediatrics residency at Children's Hospital National Medical Center, now known as Children's National Medical Center. She then did her postgraduate fellowship in clinical and molecular genetics at Harbor-UCLA Medical Center in Torrance, CA, and Cedars-Sinai Medical Center in Los Angeles. Dr. Randolph is Board Certified in pediatrics, clinical genetics and clinical cytogenetics. Her professional interests and major research areas include neurofibromatosis, other neurocutaneous disorders, retinoblastoma, dysmorphology, autistic spectrum disorders and other developmental disabilities, phenylketonuria and prenatal genetics.

B. Positions and Honors

2004 – present	Assistant Clinical Professor of Pediatrics, Keck School of Medicine of the University of Southern California
2003 – 2004	Visiting Assistant Professor of Pediatrics, Keck School of Medicine of the University of Southern California
1998 – 2000	Part-time faculty, California State University Northridge, Department of Biology
1985 – 1987	Adjunct Instructor in Genetics, Harbor-UCLA Medical Center,

C. Selected Peer-review Publications

1. "Discordant Blood Chimerism in Dizygotic Monochorionic Laser-Treated Twin-Twin Transfusion Syndrome" Assaf SA, Randolph LM, Benirschke K, Wu S, Samadi R, Chmait RH. Obstetrics and Gynecology. August 2010, Part 2 Volume 116-Issue 2.

2. "L1CAM mutation in association with X-linked hydrocephalus and Hirschsprung's disease." Jackson S, Guner YS, Woo R, Randolph L, Ford HR, Shin CE. *Pediatr Surg Int.* 2009 Dec 5.
3. "Hypoplastic left heart syndrome in patients with Kabuki syndrome." Kung GC, Chang PM, Sklansky MS, Randolph LM. *J Cardiol.* June 2009
4. "Agenesis of the ductus venosus in a fetus with non-mosaic trisomy 22." Kung GC, Chang PM, Sklansky MS, Randolph LM. *J Cardiol.* June 2009.
5. "Intrauterine Exposure to Mycophenolate Mofetil and Multiple Congenital Anomalies in Newborn Infant: Possible Teratogenic Effect." Jackson P, Paquette L, Watiker V, Randolph L, Ramanathan R, Seri I. *Am J Med Genet* 2009; Part A 149A:1231-1236.
6. "Efficacy of Sapropterin dihydrochloride in increasing phenylalanine tolerance in children with phenylketonuria: a Phase III, randomized, double-blind, placebo-controlled study." Trefz F, Burton B, Longo N, Bechuk J, Christ-Schmidt H, Martinez-Pardo Casanova M, Grushkin D, Dorenbaum A, Hennermann J, and Sapropterin Research Group, including L.M. Randolph. *J Pediatr* 2009; 154:700-7
7. "A Phase III randomized placebo-controlled study of the efficacy of sapropterin dihydrochloride (tetrahydrobiopterin, 6R-BH₄) in reducing phenylalanine levels in subjects with phenylketonuria." Levy HL, Milanowski A, Chakrapani A, Cleary M, Lee P, Trefz FK, Whitley CB, Feillet F, Feigenbaum AS, Bechuk JD, Christ-Schmidt H, Dorenbaum A, Randolph LM for the Sapropterin Research Group. *Lancet* Vol. 370, Issue 9586, 11 August 2007, Pages 504-510.
8. "An unusual duplication 3q syndrome phenotype in a patient with der(22)t(3;22)(q26.3;p13)." R. Habibiyan, A. Hajianpour, L. Dong, R. Tefft, L.M. Randolph, L. Drugan, M.J. Hajianpour. A614, accepted as poster presentation at American Society of Human Genetics meeting, October 26, 2007.
9. "Cardiac rhabdomyoma diagnosed prenatally in a boy diagnosed after birth with Silver-Russell syndrome: a new form of tumor associated with the syndrome." M. Sklansky¹, L.M. Randolph² 1) Pediatric Cardiology, Childrens Hospital Los Angeles; 2) Pediatrics-Medical Genetics, Childrens Hospital Los Angeles, Los Angeles, CA. A774, accepted as poster presentation at American Society of Human Genetics meeting, October 26, 2007.
10. "Safety and efficacy of sapropterin dihydrochloride treatment over 22 weeks in patients with phenylketonuria." L Randolph, J Baker, J Bergoffen, P Harmatz, A Morris, E Crombez, M Seashore, H Christ-Schmidt, A Dorenbaum. A2240, accepted as poster presentation at American Society of Human Genetics meeting, October 24, 2007.
11. "Recommendation for Evaluation of Responsiveness to Tetrahydrobiopterin (BH₄) in Phenylketonuria and its use in Treatment." SAPROPTERIN NATIONAL ADVISORY BOARD (BioMarin Pharmaceutical Inc.) H. Levy, B. Burton, C. Scriver, S. Cedarbaum, E. Cromboz, R. Singh, D Grange, L. Randolph, H. Andersson. *Molecular Genetics and Metabolism*.
12. Book Review: *Potter's Pathology of the Fetus, Infant and Child*, vols 1 & 2.

MS #JAMA07-3494. R. Chmait, L. Randolph. *JAMA* (in press).

13. "Retinoblastoma and the Rb1 Cancer Syndrome." A. Linn Murphree, R.D. Clark and L.M. Randolph. In: *The Principles and Practice of Medical Genetics*, fifth edition, D.L. Rimoian, J.M. Connor, R.E. Pyeritz and B.R. Korf, eds. Churchill Livingstone, Inc., Philadelphia, PA, 3241-3264, 2007.
14. "Prenatal Cytogenetics." L.M. Randolph. In: *The Principles of Clinical Cytogenetics*, second edition, S. Gersen and M. Keagle, eds. Humana Press, Inc., Totowa, NJ, 259-315, 2005. First edition, same textbook, 1999.
15. "Cytogenetics of Infertility." L.M. Randolph. In: *The Principles of Clinical Cytogenetics*, second edition, S. Gersen and M. Keagle, eds. Humana Press, Inc., Totowa, NJ. , 2005.

D. Research Support

N/A

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME TANNER, AARON M.		POSITION TITLE Lead Speech Pathologist	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of Redlands	MS	1997	Communicative Disorders
California State University, Northridge	BA	1995	Communicative Disorders

A. Personal Statement:

Aaron M. Tanner, MS, BA is a speech pathologist, specializing in the assessment and treatment of communication disorders in children. He has been providing comprehensive speech-language evaluation and therapy services to children with autism and their families over the past 14 years. He also serves as Lead Craniofacial and Cleft Center Speech Therapist and is responsible for training of all speech staff.

B. Positions and Honors

1997 – Present Speech Pathologist IV Inpatient & Outpatient Supervisor, Children's Hospital Los Angeles, CA
 1997 Speech Pathologist CFY, Gardner-Manzella Inc. Los Angeles, CA.
 1992 – 1997 Physical and Occupational Therapy Tech., St. Josephs Medical Center Burbank, CA.

Professional Memberships

1996 Certificate of Clinical Competence (CCC) and Licensed in the State of California (#10802.)
 1996 Member in good standing with the American Speech-Hearing-Language Association (#12020200)
 1998 Member of American Cleft Palate-Craniofacial Association (ACPA)

C. Selected Peer-review Publications (Select from 35 peer-reviewed publications)

None

D. Research Support

None

RESOURCES

Clinical:

Children's Hospital Los Angeles (CHLA)

Located at 4650 Sunset Boulevard in the Hollywood/Wilshire Health District of Los Angeles, Children's Hospital Los Angeles (CHLA) is the largest pediatric facility in the western United States and is the principal pediatric center in the Southern California. Founded in 1901, CHLA has been dedicated to serving the needs of critically and chronically ill children with compassion, dedication, and excellence. As a community-based medical center with an international impact, CHLA provides specialized, multi-disciplinary treatment and prevention services for children and youth. Guided by a century of medical care, its mission is "to advance preventive services, medical education and research in response to the needs of our community and in an atmosphere of love, compassion and respect for people." In 1932, CHLA and the University of Southern California signed an affiliation agreement that made CHLA the principal pediatric teaching facility for the Keck School of Medicine. Full time physicians (176) at CHLA have appointments in the Departments of Pediatrics, Surgery, Pathology, Neurology, and Radiology at the Keck School of Medicine while the full time basic science faculty (36) holds appointments in the Departments of Biochemistry, Cell Biology, Microbiology, and Physiology.

CHLA is unique because few pediatric hospitals in the world combine a freestanding clinical center with an on-campus research facility – The Saban Research Institute. This link offers the ability within a single institution to rapidly move discoveries from the research laboratories to the bedside of children suffering from complex and life-threatening disease. Dedicated to advancing the limits of knowledge, the researchers at CHLA seek solutions for childhood cancer, infections, genetic disease, development disabilities, and healthcare success.

Saban Research Institute at CHLA

The Saban Research Institute of Children's Hospital Los Angeles is responsible for providing the scientific direction and the support for all research activities at CHLA. The Research Institute's Mission is to foster an environment of scientific excellence where interdisciplinary biomedical research will improve our fundamental understanding of childhood development and lead to the implementation of new procedures to diagnose, treat, or prevent pediatric disease and promote child health. In 2009, the Research Institute was the recipient of \$37.4 million in peer review extramural funding including \$21.9 million from NIH.

The Research Institute occupies a total of 136,000 net sq. ft. of research space on the CHLA campus including a 10 story Smith Research Tower, a 5 story Saban Research Building, an 8,000 sq. ft. Clinical Investigation Center, a 2,000 sq. ft. Clinical Research Imaging Center and a 10,000 sq. ft. Community Health, Outcomes and Intervention Research Unit. The Research Institute is home to a centralized Office of Research Administration and Advancement located on the 1st floor of the Saban Research Building, which includes the Office of Facilities and Operations, the Office of Pre-Award Support Services, the Office of Post-Award Financial Services, and the Office of Technology Transfer. The Institute is supporting a series of core facilities fully equipped with state of the art instrumentation to facilitate research at CHLA.

Autism Treatment Network Center of Clinical Excellence

In 2011, CHLA joined the Autism Treatment Network (ATN) as a Center of Clinical Excellence with the goal of improving medical care for children with autism spectrum disorders (ASD) through participation in a multi-institutional network of ASD experts and researchers. Individuals with ASD often have co-morbid medical conditions that, when left untreated, may compromise not only physical health, but also behavioral, developmental, and educational outcomes. In some cases, when the underlying medical condition is treated, behaviors improve and individuals with ASD appear to be better able to take advantage of services provided. The ATN is a network of treatment and research centers dedicated to improving medical care for children and adolescents with autism by establishing standards of clinical care based on research and shared clinical practice. The ATN works to establish these standards of care in the medical community through open research collaborations trainee mentorship, medical education and participation in conferences. The ATN currently includes 17 sites in the United States and Canada, and represents the first collaboration of its kind

to define, implement and spread best practices in medical care for children with ASD.

The ATN Center of Clinical Excellence at CHLA offers the gold-standard of comprehensive diagnosis, treatment, and care for children with ASD, together with a network of research centers that engage in projects to advance understanding of the disease, develop new treatments and find a cure. Through the ATN, CHLA has access to a well-established research infrastructure across multiple institutions, including a large patient registry of more than 3200 individuals receiving care at ATN sites. This research infrastructure and multidisciplinary network of experts serves as a platform for cutting edge research to facilitate the discovery of novel interventions and affective therapeutics.

Community, Health Outcomes & Intervention Research (CHOIR) Program

Established by Michele Kipke, PhD in 2001, the overarching mission of the CHOIR program is to conduct, coordinate, facilitate, and disseminate research intended to: 1) prevent childhood and lifelong health problems; 2) promote healthy development 3) reduce disparities in children's health that may be associated with socioeconomic status, health coverage and insurance, access to care, and race/ethnicity and immigration status; 4) restore function and prevent disability among children with special needs; 5) ensure the delivery of quality care through health outcomes research. CHOIR conducts research that is interdisciplinary, collaborative, cumulative, applied, and closely linked to policy and practice. Moreover, CHOIR's work emphasizes the importance of adopting a developmental framework that focuses attention on the differing needs, circumstances, and key transitions that children, adolescents, and young adults experience as they grow and develop. Whenever possible, CHOIR works closely with faculty and staff across the various Departments and Divisions at CHLA and USC to ensure that there are clear and tangible linkages among research, clinical care, and program development. Finally, considerable effort is made to disseminate the research findings widely and strategically to key stakeholder groups (e.g. federal, state, and local policy makers, health providers, advocacy groups, the media, and parents.)

Members of the CHOIR program, also participate in a range of formal and informal staff support, research and technical training meetings convened on a regular basis, including a weekly staff meetings, regular and ongoing seminars convened by researchers who are conducting children's health services and behavioral and social science research as part of several funded research projects, and ongoing technical support and training meetings. Qualitative and quantitative researchers meet regularly to discuss their work, analytic approaches used for various types of research, and mathematical models that can be used/applied to advance our work.

The proposed research will be conducted in the Boone Fetter Clinical, Diagnostic and Research Center. The Boone Fetter Clinic, established in 2008, delivers comprehensive services to children with autism spectrum and other neurodevelopmental and behavioral disorders, and supports clinical research with these children and their families. Working with the CHLA-USC Institute for the Developing Mind, the Boone Fetter Clinic engages in innovative translational and clinical research programs to better understand and meet the complex healthcare needs of children with neurodevelopmental disorders. The model involves conducting research alongside and in coordination with clinical and diagnostic services, so that these efforts can inform and support each other in real-time. The Boone Fetter Clinic holds monthly clinical and research meetings to foster stronger interdisciplinary collaboration, and to support the efforts of clinicians and researchers to provide efficient coordinated care. In 2011, this program received an Autism Treatment Network Center of Clinical Excellence award. As a part of this network of 17 sites (16 in the US and 1 in Canada), CHLA is contributing the development of clinical guidelines, critical research and training and education to improve the quality of care and services for children with autism spectrum disorders.

Between July 2001 and June 2009, the CHOIR program managed projects with a combined budget of more than \$35 million of extramural funding, of which 80% was awarded by NIH, and is now home to over 30 scientists, of which 8 are full-time faculty. In addition, CHOIR receives intramural support from three endowments: The Saban Family Foundation, the Las Madrinas Endowment for Autism Evaluation and Intervention Research and the McAlister Endowment in Clinical Research. Currently, these endowments generate 5% interest annually, which are used to provide administrative support to CHOIR, as well provide seed funding for new research.

Southern California Clinical and Translational Science Institute

The University of Southern California (USC) and Children's Hospital Los Angeles (CHLA), in partnership with three leading clinical and 21 community organizations, have created the Southern California Clinical and Translational Science Institute (SC CTSI) aimed at addressing the most pressing health needs of our

population. The vision of the CTSI is to create better health in this diverse urban environment and, in doing so, to gain knowledge that we can share with others to improve health in urban settings and megacities across the globe. The mission is to transform our academic-clinical-community partnership into a preeminent clinical and translational science institute focused on better health for diverse, urban communities by achieving the following goals:

- a. Create an academic home that places high priority on clinical and translational science.
- b. Generate new research teams and projects to address high priority needs and opportunities, leveraging the unique location and resources of USC and CHLA.
- c. Through education and training, create a cadre of people with a major career focus on clinical and translational research, particularly research in diverse populations.
- d. Implement and disseminate what we learn to improve health locally and advance translational research regionally and nationally.

Established in 2006, the CTSI is organized around seven different offices, centers and programs that facilitate and support translational research at pre-clinical, clinical and community levels. The CTSI Office of Community Engagement (OCE) leads the effort to identify and prioritize community and health research needs; foster and maintain bi-directional partnerships focused on community-driven research; and disseminate research findings into the community.

In partnership with the Office of Community Engagement (OCE) of the Southern California Clinical and Translational Science Institute (SC-CTSI), the CHLA ATN site has developed a community advisory board (CAB) comprised of individuals who work with children with autism including representatives from schools, law enforcement, providers, and advocacy groups as well as parents of children with ASD. The CAB is tasked with the following goals:

- a. Ensuring that community needs are heard and methods to meet those needs are discussed.
- b. Building community capacity to better understand and address the needs of children with ASD.
- c. Making recommendations for programs and studies that can be launched to address community needs.
- d. Identifying methods to disseminate evidence-based practices to parents and community providers.

This group will be integral to interpreting and understanding the results of the data analysis. Specifically, this group meets on a bimonthly basis and at least one meeting will be devoted to presenting the results of the data analysis of this study. We will engage this group in a guided discussion to identify research studies and/or education/capacity building opportunities that can best address the results of the data analysis. Based on this and other discussions, we will work with our OCE partners to assist us in building research teams and/or disseminating training opportunities to community clinical providers. The OCE currently has among its partner the Community Clinic Association of Los Angeles County, a consortium of 47 community clinics, and COPE Health Solutions a public-private partnership with 17 clinic organizations, both of which provide ample opportunities for dissemination and training sessions.

Animal:

No animals will be involved.

Computer:

CHLA research investigators have access to research computing facilities at the following sites: 1) workstations in their offices, and 2) PC work stations in the Biostatistics lab located at CHLA. A computer lab is designated for data entry, management and statistical support staff. CHLA provides statistical database, spreadsheet, word-processing, desktop publishing, accounting, and a variety of utility software programs to all platforms. E-mail and Internet access is provided to all staff. In addition, the USC University Computing Services provides a comprehensive computing environment to support instructional and research goals of the University and its affiliated campuses including CHLA. Facilities and services include campus-wide networking, a variety of central host systems, public user rooms, and support for distributed systems, hardware maintenance, and user support services. It provides support for and access to departmental and shared campus computing resources, library information systems, and regional, national, and international information resources. USC utilizes the most up-to-date hardware equipment and supports a variety of communication and scientific hardware and software systems. CHLA is connected to USC's health sciences network. Every research faculty and staff member has a computer on his or her desk for database and statistical analysis, simulation, spreadsheet work, and text processing and has the capability to communicate electronically.

Preprocessing: Several workstations are currently owned by DCNL for rotating use among image analysis staff. These include 3 Intel G5 desktops, 3 PPC G5 desktops, 4 Intel iMacs, 1 PPC G4 desktop, 4 Dell desktops, 1 Intel Powerbooks, 2 PPC Powerbooks, and 1 Dell laptop. The G5 and G4 desktop computers are used by full-time staff for graphic/processor-intensive image analyses and media preparation. The Dell desktops are used for windows-specific software such as Brainsuite and Systat that are not available to the Mac platform. The laptops are used for stimuli presentation for scans, presentations, neuropsych score recording and subject bookkeeping.

Office:

The Boone Fetter Clinic is located at 1300 North Vermont Avenue (2,775 sq./ft). All key personnel, as well as administrative staff available to support the project, will be housed at this location. This space accommodates nearly 60 research and CHOIR administrative staff.

Other:

The Children's Hospital Health Sciences Library provides resources and services to CHLA staff. In addition to its collection of 3500 print books and 170+ current print journal subscriptions, the library supplies access to over 200 electronic books and 2000 electronic journals. Online access is available anywhere in the hospital or from remote computers that connect to the USC network.

In addition to books and journals, the library also provides local and remote access to various journal article databases including: Ovid MEDLINE, Ovid CINAHL, PubMed, PsycINFO, Science Citation Index, and Journal Citation Reports. The library's book and journal catalog, as well as that of the USC Norris Medical Library (with whom the CHLA library has reciprocal borrowing agreements), is searchable online as well.

Library services include mediated literature searching (searches conducted by a librarian), interlibrary loan borrowing (for obtaining materials that the CHLA library does not own), Ovid AutoAlerts (a current awareness service that delivers weekly citations that match a researcher's predefined topic), and HouseCalls (one-one-one, time-of-need meetings where the librarian can instruct users on a variety of topics including database searching, PowerPoint, or EndNote).

MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

All key personnel at CHLA up-to-date computers with Internet connection and software for spreadsheet work and text processing. Statistical software packages, including SPSS and SAS, are supported by the USC's computing services. In addition, a project designated server will be used to store the research data collected by the study, including qualitative and quantitative datasets, transcripts, password protected files containing patient locator information, etc.



We Treat Kids Better

Michele D. Kipke, Ph.D.

Professor of Pediatrics and Preventive Medicine
Vice Chair of Research, Department of Pediatrics
Co-Director, Southern California Clinical and Translational Science Institute

November 2, 2011

Kathryn Smith, RN, DrPH
Senior Site Coordinator
Autism Treatment Network Center of Clinical Excellence
Children's Hospital Los Angeles
Los Angeles, CA 90027

Dear Kathryn:

As Co-Director, Southern California Clinical and Translational Science Institute and Director of the Autism Treatment Network (ATN) Center of Clinical Excellence at Children's Hospital Los Angeles (CHLA), I am committed to working with you and the research group that you have assembled here at CHLA and serve as your research mentor on your AIR-P proposal. Your proposal "Use of Complementary and Alternative Medical (CAM) Treatments in the ATN Population" will provide valuable information about the types of CAM treatments used by families and the families who choose to use them. The information obtained from this study can be broadly disseminated, by way of our Office of Community Engagement, to inform providers about families' treatment choices.

I am able to provide any additional information that you may need for your AIR-P proposal. Good luck with your application.

Sincerely,

A handwritten signature in black ink, appearing to read "Michele D. Kipke", with a long, sweeping underline.

Michele D. Kipke, PhD

November 2, 2011

Kathryn Smith, RN, Dr.P.H.
Children's Hospital Los Angeles
USC University Center for Excellence in Developmental Disabilities
4650 Sunset Boulevard
Los Angeles, CA 90027

**Herman Ostrow
School of Dentistry
of USC**

Division of
Occupational Science
and Occupational Therapy

Dear Dr. Smith:

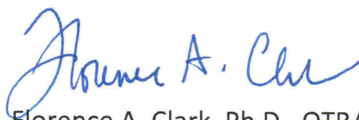
I would like to indicate my support for your data analysis proposal to the Autism Intervention Research Network on Physical Health (AIR-P). I understand that your proposed study is designed to compare the use of complementary alternative medicine with traditional therapies for children with autism, in order to inform clinicians about the prevalence of use of different therapies and to provide direction for future research.

Dr. Erna Blanche and Dr. Sharon Cermak, both of whom are internationally renowned, will lend the project combined expertise and experience in Hispanic cultural health issues, occupational therapy, sensory integration, autism, and the conceptualization and delivery of culturally sensitive interventions for children and adults with disabilities. I am so pleased that the USC Division of Occupational Science and Occupational Therapy and the USC University Center for Excellence in Developmental Disabilities at Children's Hospital Los Angeles will have the opportunity to partner in this interdisciplinary collaboration.

As Associate Dean of the Division of Occupational Science and Occupational Therapy at the University of Southern California, I support and approve Dr. Blanche's and Dr. Cermak's proposed commitment of 1% each for their service as unpaid investigators/consultants to your project.

I wish you the best on your submission.

Sincerely,



Florence A. Clark, Ph.D., OTR/L, FAOTA
Professor and Associate Dean

IRB Acknowledgement

The Principal Investigator and all Co-Investigators are aware and understand the requirements for institutional IRB review of this proposal. The PI has carefully considered the timing of the protocol review and fully understands the staff time needed to coordinate the effort as well as potential obstacles/delays. If funded, the proposal will be submitted for review to the Institutional Review Board at CHLA (Committee on Clinical Investigation).

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report Printed on 7/22/2010

Learner: Kathryn Smith (username: kasmith1030)

Institution: Children's Hospital Los Angeles (CHLA)

Contact Department: General Pediatrics

Information Phone: 323 361 8301

Email: kasmith@chla.usc.edu

Social/Behavioral: Researchers and research staff (including faculty, staff, and students) who are engaged, primarily or exclusively, in research in the Social and/or Behavioral Sciences.

Stage 2. Refresher Course Passed on 07/19/10 (Ref # 4671185)

Required Modules	Date Completed	
Defining Research with Human Subjects - SBR	07/19/10	5/5 (100%)
The Regulations and The Social and Behavioral Sciences - SBR	07/19/10	5/5 (100%)
Assessing Risk in Social and Behavioral Sciences - SBR	07/19/10	5/5 (100%)
Informed Consent - SBR	07/19/10	5/5 (100%)
Privacy and Confidentiality - SBR	07/19/10	2/3 (67%)
Research with Prisoners - SBR	07/19/10	4/4 (100%)
HIPAA and Human Subjects Research	07/19/10	2/2 (100%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

[Return](#)

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report Printed on Wednesday, December 16, 2009

Learner: larry yin (username: lyin@chla.usc.edu)

Institution: Children's Hospital Los Angeles (CHLA)

Contact Information: 4650 Sunset Blvd
Los Angeles, CA 90027 USA
Department: General Pediatrics
Phone: 323-660-2450
Email: lyin@chla.usc.edu

Biomedical: Researchers and research staff (including faculty, staff, and students) who are engaged, primarily or exclusively, in research in the Biomedical Sciences.

Stage 2. Refresher Course Passed on 12/11/09 (Ref # 3835512)

Required Modules	Date completed
Basic Institutional Review Board (IRB) Regulations and Review Process	12/11/09
Informed Consent	12/11/09
Research With Protected Populations - Vulnerable Subjects: An Overview	12/11/09
Vulnerable Subjects - Research Involving Minors	12/11/09
FDA-Regulated Research	12/11/09
HIPAA and Human Subjects Research	12/11/09

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiler Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator



Learner Name:	Michele Kipke
Title of Course:	CHLA - CCI Recertification for Human Subjects Protection
Completion Date:	Thursday, February 05, 2009
Certified By Company:	Childrens Hospital Los Angeles

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report Printed on 6/8/2010

Learner: Marie Poulsen (username: mariepoulsen)
Institution: Children's Hospital Los Angeles (CHLA)
Contact Information 4650 Sunset Boulevard, #53
 Los Angeles, California 90027 USA
 Department: General Pediatrics
 Phone: 323 361 3819
 Email: mpoulsen@chla.usc.edu

Social/Behavioral: Researchers and research staff (including faculty, staff, and students) who are engaged, primarily or exclusively, in research in the Social and/or Behavioral Sciences.

Stage 2. Refresher Course Passed on 05/28/10 (Ref # 4412560)

Required Modules	Date Completed	
Defining Research with Human Subjects - SBR	05/13/10	5/5 (100%)
The Regulations and The Social and Behavioral Sciences - SBR	05/18/10	5/5 (100%)
Assessing Risk in Social and Behavioral Sciences - SBR	05/19/10	4/5 (80%)
Informed Consent - SBR	05/20/10	4/5 (80%)
Privacy and Confidentiality - SBR	05/27/10	3/3 (100%)
Research with Prisoners - SBR	05/28/10	4/4 (100%)
HIPAA and Human Subjects Research	05/28/10	2/2 (100%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
 Professor, University of Miami
 Director Office of Research Education
 CITI Course Coordinator

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CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report

Printed on Tuesday, November 3, 2009

Learner: Heather Volk (username: hvolk)

Institution: University of Southern California

Contact Information: CHP 222

CHP 222

Los Angeles, CA 90033 United States

Department: hvolk@usc.edu

Phone: 323 442-1815

Email: hvolk@usc.edu

Health Sciences Investigators, Key Personnel, and HSIRB Members/Staff:

2008 USC Curriculum

Stage 2. Refresher Course Passed on 11/02/09 (Ref # 3708414)

Elective Modules	Date completed	Score
Refresher Course 101 Introduction	11/02/09	0
101 Refresher Course - History and Ethics	11/02/09	100
101 Refresher Course - Regulations and Process	11/02/09	100
101 Refresher Course - Informed Consent	11/02/09	100
101 Refresher Course - Social and Behavioral Research	11/02/09	100
101 Refresher Course - Records Based Research	11/02/09	0

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.

Professor, University of Miami

Director Office of Research Education

CITI Course Coordinator

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report Printed on Monday, September 27, 2010

Learner: Erna Blanche (username: blanche@usc.edu)

Institution: University of Southern California

Contact Division of Occupational Science and Therapy

Information: University of Southern California

1540 Alcazar St., CHP 133

Los Angeles, Ca 90089-9003 USA

Department: Occupational Science and Occupational
Therapy

Phone: 323-442-1857

Email: blanche@usc.edu

Health Sciences SBR Investigators: This group has been established for Social & Behavioral Research investigators who submit IRB applications to the Health Sciences IRB (HSIRB)

Stage 1. Basic Course Passed on 09/22/10 (Ref # 4635284)

Elective Modules	Date completed	Score
Belmont Report and CITI Course Introduction	09/08/10	100
Basic Institutional Review Board (IRB) Regulations and Review Process	09/15/10	100
Informed Consent	09/15/10	75
Social and Behavioral Research for Biomedical Researchers	09/22/10	75
Records-Based Research	09/15/10	100
Vulnerable Subjects - Research Involving Minors	09/15/10	100
International Research	09/15/10	100
Hot Topics	09/15/10	0

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiler Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report Printed on 11/1/2010

Learner: Carolina Pena-Ricardo (username: caritopr2)

Institution: Children's Hospital Los Angeles (CHLA)

Contact 4650 Sunset Blvd. Los Angeles, CA, 90027

Information 3250 Wilshire Blvd, Third Floor. Los Angeles, CA 90010

Los Angeles, California 90027 United States of America

Department: General Pediatrics

Phone: 3233614647

Email: cpena-ricardo@chla.usc.edu

Social/Behavioral: Researchers and research staff (including faculty, staff, and students) who are engaged, primarily or exclusively, in research in the Social and/or Behavioral Sciences.

Stage 1. Basic Course Passed on 11/01/10 (Ref # 5182217)

Required Modules	Date Completed	
History and Ethical Principles - SBR	10/31/10	4/4 (100%)
Defining Research with Human Subjects - SBR	11/01/10	4/5 (80%)
The Regulations and The Social and Behavioral Sciences - SBR	11/01/10	4/5 (80%)
Assessing Risk in Social and Behavioral Sciences - SBR	11/01/10	5/5 (100%)
Informed Consent - SBR	11/01/10	4/5 (80%)
Privacy and Confidentiality - SBR	11/01/10	3/5 (60%)
Research with Children - SBR	11/01/10	4/4 (100%)
Research in Public Elementary and Secondary Schools - SBR	11/01/10	4/4 (100%)
International Research - SBR	11/01/10	2/3 (67%)
Internet Research - SBR	11/01/10	4/4 (100%)
Research and HIPAA Privacy Protections	11/01/10	3/6 (50%)
Workers as Research Subjects-A Vulnerable Population	11/01/10	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects	11/01/10	1/2 (50%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

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CITI Collaborative Institutional Training Initiative**Human Research Curriculum Completion Report**

Printed on 4/17/2010

Learner: Linda Randolph (username: lmrandolph)
Institution: Children's Hospital Los Angeles (CHLA)
Contact Information 4650 Sunset Blvd
MS 90
Los Angeles, CA 90027 USA
Department: Pediatrics
Phone: (323) 361-2178
Email: lrandolph@chla.usc.edu

Biomedical: Researchers and research staff (including faculty, staff, and students) who are engaged, primarily or exclusively, in research in the Biomedical Sciences.

Stage 2. Refresher Course Passed on 04/17/10 (Ref # 4330248)

Required Modules	Date Completed	
Basic Institutional Review Board (IRB) Regulations and Review Process	04/17/10	5/5 (100%)
Informed Consent	04/17/10	4/4 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	04/17/10	4/4 (100%)
Vulnerable Subjects - Research Involving Minors	04/17/10	3/3 (100%)
FDA-Regulated Research	04/17/10	5/5 (100%)
HIPAA and Human Subjects Research	04/17/10	2/2 (100%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiler Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

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CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report Printed on 10/31/2011

Learner: aaron tanner (username: aarontanner)

Institution: Children's Hospital Los Angeles (CHLA)

Contact

Phone: 323-361-1840

Information

Email: atanner@chla.usc.edu

Biomedical: Researchers and research staff (including faculty, staff, and students) who are engaged, primarily or exclusively, in research in the Biomedical Sciences.

Stage 2. Refresher Course Passed on 10/04/11 (Ref # 6820373)

Required Modules	Date Completed	
Basic Institutional Review Board (IRB) Regulations and Review Process	10/04/11	5/5 (100%)
Informed Consent	10/04/11	3/4 (75%)
Research With Protected Populations - Vulnerable Subjects: An Overview	10/04/11	4/4 (100%)
Vulnerable Subjects - Research Involving Children	10/04/11	3/3 (100%)
FDA-Regulated Research	10/04/11	3/5 (60%)
Research and HIPAA Privacy Protections	10/04/11	5/5 (100%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

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CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report Printed on 4/11/2011

Learner: Sheree Schrager (username: sschrager)

Institution: Children's Hospital Los Angeles (CHLA)

Contact Department: DRCYF

Information Phone: x18413

Email: sschrager@chla.usc.edu

Social/Behavioral: Researchers and research staff (including faculty, staff, and students) who are engaged, primarily or exclusively, in research in the Social and/or Behavioral Sciences.

Stage 2. Refresher Course Passed on 04/08/11 (Ref # 5874315)

Required Modules	Date Completed	
Defining Research with Human Subjects - SBR	04/08/11	5/5 (100%)
The Regulations and The Social and Behavioral Sciences - SBR	04/08/11	5/5 (100%)
Assessing Risk in Social and Behavioral Sciences - SBR	04/08/11	5/5 (100%)
Informed Consent - SBR	08/27/10	5/5 (100%)
Privacy and Confidentiality - SBR	04/08/11	5/5 (100%)
Research with Prisoners - SBR	04/08/11	4/4 (100%)
Research and HIPAA Privacy Protections	04/08/11	10/11 (91%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

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CITI Collaborative Institutional Training Initiative

Human Research Curriculum Completion Report Printed on 12/14/2010

Learner: Marcia Higareda (username: mhigareda)

Institution: Children's Hospital Los Angeles (CHLA)

Contact Department: Div. of Research on C Y F

Information Phone: 323.361.8444

Email: mhigareda@chla.usc.edu

IRB Members:

Stage 1. Basic Course Passed on 12/01/10 (Ref # 5254789)

Required Modules	Date Completed	
History and Ethical Principles - SBR	11/23/10	3/4 (75%)
History and Ethical Principles	11/23/10	7/7 (100%)
Defining Research with Human Subjects - SBR	11/23/10	5/5 (100%)
The Regulations and The Social and Behavioral Sciences - SBR	11/23/10	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process-	11/23/10	5/5 (100%)
Assessing Risk in Social and Behavioral Sciences - SBR	11/23/10	5/5 (100%)
Informed Consent - SBR	11/24/10	5/5 (100%)
Privacy and Confidentiality - SBR	11/24/10	5/5 (100%)
Social and Behavioral Research for Biomedical Researchers	11/24/10	4/4 (100%)
Records-Based Research	11/29/10	2/2 (100%)
Genetic Research in Human Populations	11/29/10	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	11/29/10	4/4 (100%)
Research with Children - SBR	12/01/10	4/4 (100%)
Vulnerable Subjects - Research Involving Minors	12/01/10	3/3 (100%)
Research in Public Elementary and Secondary Schools - SBR	12/01/10	4/4 (100%)
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	12/01/10	3/3 (100%)
International Research - SBR	12/01/10	3/3 (100%)
Internet Research - SBR	12/01/10	4/4 (100%)
Group Harms: Research With Culturally or Medically Vulnerable Groups	12/01/10	3/3 (100%)

FDA-Regulated Research	12/01/10	5/5 (100%)
Research and HIPAA Privacy Protections	12/01/10	11/11 (100%)
Workers as Research Subjects-A Vulnerable Population	12/01/10	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects	12/01/10	2/2 (100%)
The IRB Member Module - "What Every New IRB Member Needs to Know"	12/01/10	3/6 (50%)

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

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STATEMENT OF INTENT

Prime PI: **JAMES PERRIN, MD**Prime Institution: **MASSACHUSETTS GENERAL HOSPITAL**

Project Title: Use of Complementary and Alternative Medical Treatments in the ATN Population

Cooperating Institution: Children's Hospital Los Angeles

PI Name: Kathryn A. Navarette Smith, Dr.P.H

Tel: 323 361 8301

Fax: 323.361.8043

Email: Kasmith@chla.usc.edu

Project Period: 04/01/2012-03/30/2013 Direct Costs: **40,000**

F&A Costs: 24,000

Performance site: Children's Hospital Los Angeles

Cooperating Institutional Business Contact Information:

Name: Bonji Saliwan Address: 4650 Sunset Blvd., Mailstop #84 Los Angeles, CA 90027

Tel: 323.361.6463

Fax: 323.361.8054

Email: swestcott@chla.usc.edu

Project information:	Yes	No	Assurance#:	Approval Date or Pending:
Human subjects:	X	<input type="checkbox"/>	FWA # FWA00001914	IRB pending
Vertebrate animals:	<input type="checkbox"/>	X		
Human Embryonic Stem Cells:	<input type="checkbox"/>	X		
Inventions and Patents: (for renewal applications)	<input type="checkbox"/>	X		
Program Income:	<input type="checkbox"/>	X		

Certifications:

In signing below and offering to participate in this research program, the Cooperating Institution certifies that neither they nor their principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from receiving funds from any federal department or agency and are not delinquent on any federal debt; they are in compliance with the Drug Free Workplace Act of 1988; they are in compliance with U.S. Code, Section 1352, restrictions on the use of federal funds for the purpose of lobbying; they have filed annually with the Office of Scientific Integrity a PHS form 6349 governing Misconduct in Science; they have filed with DHHS compliance offices certification forms governing Civil Rights (441), Handicapped Individuals (641), Sex Discrimination (639-A), and Age Discrimination (680); they are in compliance with PHS policy governing Program Income; they have established policies in compliance with 45 CFR Part 46, Subpart A (protection of human subjects); the Animal Welfare Act (PL-89-544 as amended) and the Health Research Exchange Act of 1985 (Public Law 99-158); and that they are in compliance with NIH guidelines regarding human pluripotent stem cell research, transplantation of fetal tissue, recombinant DNA and human gene transfer research, and inclusion of women, children & minorities in research.

The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the PHS-NIH consortium grant policies and are prepared to establish the necessary inter-institutional agreements consistent with those policies. In signing below, the Cooperating Institution certifies it has implemented and is enforcing a written policy of conflicts of interest consistent with the provisions of 42 CFR Part 50, Subpart F & 45 CFR Subtitle A, Part 94. If a conflict is identified by the Cooperating Institution during the period of the award contemplated under this agreement, the Cooperating Institution will report to the Prime Awardee the existence of the conflict, including the grant title, PI (if different from the investigator with the financial interest) and the specific method the Cooperating Institution adopts for addressing the conflict (managing, reducing, or eliminating it). The Cooperating Institution will rely on the Prime Awardee to report the existence of the conflict to NIH.

Cooperating Institution Business Official:

Bonji Saliwan

Director of Financial Services

The Saban Research Institute

Typed Name & Title


 Signature
Date 11/7/11



DEPARTMENT OF HEALTH & HUMAN SERVICES

Program Support Center
Financial Management Service
Division of Cost Allocation

DCA Western Field Office
90 7th Street, Suite 4-600
San Francisco, CA 94103

JUN 18 2010

Rus Blackford
Controller
Children's Hospital of Los Angeles
4650 Sunset Boulevard
Los Angeles, CA 90027

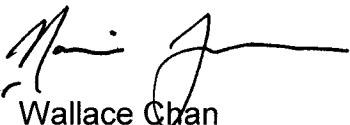
Dear Mr. Blackford:

A copy of an indirect cost/fringe benefits Negotiation Agreement is attached. This Agreement reflects an understanding reached between your organization and a member of my staff concerning the rate(s) that may be used to support your claim for indirect costs on grants and contracts with the Federal Government. Please have the Agreement signed by a duly authorized representative of your organization and return it to me BY FAX, retaining the copy for your files. We will reproduce and distribute the Agreement to the appropriate awarding organizations of the Federal Government for their use.

In order to implement the FINAL indirect cost rate contained in the enclosed Agreement, an adjustment to the indirect costs claimed under your Federal awards may be required. For HHS project grants these adjustments must be made in accordance with the procedures for settlement of indirect costs on HHS project grants with final negotiated rates described in the appropriate "Guide" book for your institution. Adjustments under HHS contracts must be made in accordance with the provisions of the contracts. Adjustments under awards with other Federal agencies must be made in accordance with the policies of those agencies.

An indirect cost and fringe benefits rate proposal together with required supporting information must be submitted to this office for each fiscal year in which your organization claims indirect costs under grants and contracts awarded by the Federal Government. Thus, proposals for your fiscal year ending June 30, 2010, will be due no later than December 31, 2010.

Sincerely,


for
Wallace Chan
Director

Enclosures

PLEASE SIGN AND RETURN THE NEGOTIATION AGREEMENT BY FAX

HOSPITALS RATE AGREEMENT

EIN:

DATE:06/17/2010

ORGANIZATION:

FILING REF.: The preceding
agreement was dated
07/09/2009

Children's Hospital of Los Angeles
4650 Sunset Boulevard
Los Angeles, CA 90027

The rates approved in this agreement are for use on grants, contracts and other agreements with the Federal Government, subject to the conditions in Section III.

SECTION I: INDIRECT COST RATES

RATE TYPES: FIXED FINAL PROV. (PROVISIONAL) PRED. (PREDETERMINED)

EFFECTIVE PERIOD

<u>TYPE</u>	<u>FROM</u>	<u>TO</u>	<u>RATE(%) LOCATION</u>	<u>APPLICABLE TO</u>
FINAL	07/01/2008	06/30/2009	60.00 On-Site	Research
FINAL	07/01/2008	06/30/2009	30.00 Off-Site	Research
FINAL	07/01/2008	06/30/2009	35.00 All	Other Spon Act
PROV.	07/01/2009	06/30/2011	60.00 On-Site	Research
PROV.	01/01/2009	06/30/2011	30.00 Off-Site	Research
PROV.	06/01/2009	06/30/2011	35.00 All	Other Spon Act

*BASE

Total direct cost less items of equipment and other capital expenditures, hospitalization and other fees related to patient care, fellowships, and that portion over \$25,000 of each subgrant or subcontract.

The Hospital's direct cost base includes salaries and benefits of University of Southern California (USC) personnel who are paid by USC and for which USC is reimbursed by the hospital. No fringe benefits of the Hospital are applicable to USC; however, the indirect cost rate cited herein is applicable to the total amount reimbursed.

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SECTION I: FRINGE BENEFIT RATES**

<u>TYPE</u>	<u>FROM</u>	<u>TO</u>	<u>RATE(%)</u>	<u>LOCATION</u>	<u>APPLICABLE TO</u>
FIXED	7/1/2010	6/30/2011	20.90	All	All Employees

**** DESCRIPTION OF FRINGE BENEFITS RATE BASE:**

Salaries and wages of faculty and staff including vacation, holiday and sick leave pay and other paid absences of only the faculty and staff. Rate does not apply to student employees, research or teaching assistants.

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SECTION II: SPECIAL REMARKS

TREATMENT OF FRINGE BENEFITS:

The fringe benefits are charged using the rate(s) listed in the Fringe Benefits Section of this Agreement. The fringe benefits included in the rate(s) are listed below.

TREATMENT OF PAID ABSENCES

Vacation, holiday, sick leave pay and other paid absences are included in salaries and wages and are claimed on grants, contracts and other agreements as part of the normal cost for salaries and wages. Separate claims are not made for the cost of these paid absences.

OFF-SITE DEFINITION

For all activities performed in facilities not owned by the organization and to which rent is directly allocated to project(s), the off-site rate will apply. If more than 50% of the project salaries and wages is performed off-site, the off-site rate will apply to the entire project.

DEFINITION OF EQUIPMENT

Equipment is defined as tangible nonexpendable personal property having a useful life of more than one year and an acquisition cost of \$1,000 or more per unit.

The following fringe benefits are included in the fringe benefit rate:
FICA, UNEMPLOYMENT INSURANCE (SELF INSURED), WORKERS COMPENSATION, GROUP LIFE AND HEALTH INSURANCE, PENSION PLAN, GROUP DISABILITY, AND DENTAL INSURANCE.

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SECTION III: GENERAL

A. LIMITATIONS:

The rates in this Agreement are subject to any statutory or administrative limitations and apply to a given grant, contract or other agreement only to the extent that funds are available. Acceptance of the rates is subject to the following conditions: (1) Only costs incurred by the organization were included in its indirect cost pool as finally accepted; such costs are legal obligations of the organization and are allowable under the governing cost principles; (2) The same costs that have been treated as indirect costs are not claimed as direct costs; (3) Similar types of costs have been accorded consistent accounting treatment; and (4) The information provided by the organization which was used to establish the rates is not later found to be materially incomplete or inaccurate by the Federal Government. In such situations the rate(s) would be subject to renegotiation at the discretion of the Federal Government.

B. ACCOUNTING CHANGES:

This Agreement is based on the accounting system purported by the organization to be in effect during the Agreement period. Changes to the method of accounting for costs which affect the amount of reimbursement resulting from the use of this Agreement require prior approval of the authorized representative of the cognizant agency. Such changes include, but are not limited to, changes in the charging of a particular type of cost from indirect to direct. Failure to obtain approval may result in cost disallowances.

C. FIXED RATES:

If a fixed rate is in this Agreement, it is based on an estimate of the costs for the period covered by the rate. When the actual costs for this period are determined, an adjustment will be made to a rate of a future year(s) to compensate for the difference between the costs used to establish the fixed rate and actual costs.

D. USE BY OTHER FEDERAL AGENCIES:

The rates in this Agreement were approved in accordance with the cost principles promulgated by the Department of Health and Human Services, and should be applied to the grants, contracts and other agreements covered by these regulations subject to any limitations in A above. The hospital may provide copies of the Agreement to other Federal Agencies to give them early notification of the Agreement.

E. OTHER:

If any Federal contract, grant or other agreement is reimbursing indirect costs by a means other than the approved rate(s) in this Agreement, the organization should (1) credit such costs to the affected programs, and (2) apply the approved rate(s) to the appropriate base to identify the proper amount of indirect costs allocable to these programs.

BY THE INSTITUTION:

Children's Hospital of Los Angeles

(INSTITUTION)

(SIGNATURE)

(NAME)

(TITLE)

(DATE)

ON BEHALF OF THE FEDERAL GOVERNMENT:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

(AGENCY)

(SIGNATURE)

Wallace Chan

(NAME)

Director, Western Field Office

(TITLE)

6/17/2010

(DATE) 0127

HHS REPRESENTATIVE: Jeanette Lu

Telephone: (415) 437-7820