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TITLE: Pharmacological and Nonpharmacological Methods of
Treatment for Fragile X Syndrome

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CONTRACTING ORGANIZATION: Children's Hospital of Pittsburgh
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13. ABSTRACT (Maximum 200 Words) Fragile X (FX) syndrome causes behavioral disturbances, such as labile mood, anxiety, hyperactivity, and aberrant behavioral response to stress. Affected males may suffer from learning disabilities, attention deficit disorders, retardation, or autism. We seek to address the most effective methods of treatment (pharmacological and nonpharmacological) for the symptoms and behavioral problems associated with FX syndrome. During the past year, we have recruited key members of the project team in order to establish a multidisciplinary clinical center, and outlined a near-final treatment protocol. Community education programs, in the form of reference libraries, newsletters, workshops, lectures, and support groups, have been implemented. We have also created a database to track the frequency of the disease with the goal of guiding future treatment through evidence based medicine.				
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INTRODUCTION

The Child Development Unit, Center for Neurosciences, and Division of Genetics of the Children's Hospital of Pittsburgh (CHP) will seek to address the most effective methods of treatment – both pharmacological and nonpharmacological – for the symptoms and behavioral problems associated with Fragile X (FX) syndrome.

This program will feature the recruitment of children with this disorder in order to conduct physiological and behavioral testing, with the goal of early intervention.

An intervention study will supply groundbreaking data on the behavioral phenotype of children with FX syndrome for a national registry database.

This program will establish a basis research program including development of genetically engineered mouse and primate models of the syndrome to determine the mechanism of, and potential novel treatments for symptoms of FX syndrome.

STATEMENT OF HYPOTHESIS

Fragile X syndrome causes behavioral disturbances such as labile mood, anxiety states, hyperactivity, and aberrant behavioral responses to stress. Affected males may suffer from learning disabilities, attention deficit disorders, retardation, or autism. The Child Development Unit, Center for Neurosciences, and Division of Genetics at the Children's Hospital of Pittsburgh (CHP) now seek to address the most effective methods of treatment – both pharmacological and nonpharmacological – for the symptoms and behavioral problems associated with FX syndrome. This initiative will feature the recruitment of children with this disorder in order to conduct physiological and behavioral testing, with the goal of early intervention. The resulting "interventional study" will supply groundbreaking data on the behavioral phenotype of children with FX syndrome for a national registry database. Finally, this initiative will establish a basic research program including development of genetically engineered mouse and primate models of the syndrome to determine the mechanism of, and potential novel treatments for symptoms of FX syndrome. Because it will concentrate on behavioral symptoms that also occur commonly in non-FX subjects and may affect the behavioral responses to stressful conditions, the overall program will have an impact on military personnel as well as children and families affected by FX syndrome.

OBJECTIVES

1. To establish a clinical center for diagnosis and treatment of individuals with Fragile X syndrome
2. To develop a registry for Fragile X patients and their families

3. To establish a basic research laboratory dedicated to studies on the pathobiology of neurobehavioral disturbances in Fragile X syndrome, with a particular focus on new genetically engineered animal models of the syndrome

ACCOMPLISHMENTS (Year 1 2/02/03 – 2/27/04)

Objective 1: To establish a clinical center for diagnosis and treatment of individuals with Fragile X syndrome

- We have recruited a director, Dr. Robert Noll. He will also become the co-principal investigator. Dr. Noll is an internationally recognized NIH-funded investigator with considerable experience in studies of behavioral outcome. He has just been recruited to CHP to become the Chief of the Division of Child Development/Behavioral Pediatrics.
- We have appointed a Clinical Director, Dr. Carol Delahunty. Dr. Delahunty is board certified in Developmental/Behavioral Pediatrics and has extensive experience with children affected with Fragile X syndrome through her training with Dr. Randi Hagerman, an internationally recognized expert in Fragile X syndrome. She regularly attends the International Fragile X conference and serves as medical consultant to a core group of parents and is actively involved in the development of a Fragile X clinic and parent support group. She is a member of both the National Fragile X Foundation and the FRAXA Research Foundation.
- We have recruited a Nurse Coordinator, Susan Van Cleef, who has extensive experience in coordinating pediatric clinical service lines.
- We have a protocol for the clinical care of Fragile X patients in the center.

Neurobehavioral Assessment:

Children with Fragile X will be seen by a psychologist for a comprehensive evaluation at the time of the initial evaluation at the Fragile X (FX) Center. The evaluation will depend on the age of the child, development level, and behavioral differences.

Behavioral Consultation:

Children seen in the FX Center will be eligible to receive further behavioral consultation services. These services will be provided by FX Center staff, along with UCLID trainees and graduate students enrolled in the Applied Behavior Analysis program (Department of Special Education, University of Pittsburgh). These would include consultation with parents along with educators.

Comprehensive Medical Evaluation:

Children will be seen yearly for a medical evaluation completed by a developmental / behavioral pediatrician with expertise in FX. Individuals manifesting specific medical problems will be referred to appropriate specialists.

Psychopharmacology Evaluation:

For those FX children who are possible candidates for psychopharmacologic treatment, a consultation will be available. Medication management will be available for those families if distance is not prohibitive.

- We have developed a multidisciplinary clinic for this evaluation and treatment. Disciplines represented in the clinic include speech/language therapy, occupational therapy, psychology and developmental pediatrics with the goal of improving functional outcome for these children.

- ▶ Speech/language Therapists:
 - Kristine Campbell (South satellite)
 - Melissa Petyk (North satellite)
 - Joyce O'Keefe (East satellite)

- ▶ Occupational Therapists:
 - Kate Mali (South satellite)
 - Ken Reichl (CHP Oakland)

- We have established a collaborative relationship with the genetics clinic, including the referral from genetics of individuals with Fragile X syndrome for evaluation and treatment in the Fragile X clinic, as well as referrals to genetics clinic of children with Fragile X syndrome identified by the Child Development Unit for genetic counseling. Families with affected individuals are also able to learn about and participate in any research studies offered through the genetics clinic.

- We have established a community education program for FX syndrome. Fragile X clinic team members are offered the quarterly newsletter about research, tips on behavioral management, and information about upcoming educational events such as web casts. A set of educational materials, donated to the Fragile X clinic at Children's Hospital by the National Fragile X Foundation, forms the basis for the ongoing development of a lending library. This library is currently available to Fragile X clinic team members and families of children seen in the clinic. The families can use these materials for their own education or to educate their child's therapists or educators. Additionally, the National Fragile X Foundation has provided packets of information to be provided to parents of

newly diagnosed children with Fragile X. Dr. Delahunty has established a relationship with the National Fragile X Foundation and keeps them informed about the Fragile X clinic at Children's Hospital of Pittsburgh. I am listed in their directory as a professional serving children with Fragile X syndrome. Persons calling the National Fragile X Foundation to find resources in Western Pennsylvania or the surrounding area are provided with this information.

Community service and professional education about Fragile X syndrome has included the following:

An in-service lecture on Fragile X syndrome was given at the Children's Hospital South satellite location to speech-language therapists by team member Kristine Campbell, on October 16, 2003.

A workshop on Fragile X Syndrome was given by Dr. Carol Delahunty at Achieva on March 20, 2002.

A Pittsburgh Fragile X Support group has been started. Dr. Carol Delahunty serves as the medical consultant, while the parent leader, Bob Dudas, is the father of a child with Fragile X syndrome followed in the clinic. This group has been actively organizing over the past year. The group has a list of email addresses for interested families, so families can share information and resources and, if desired, set up "play dates" for the children. Dr. Delahunty has been working with Mr. Dudas, Candy Smith, Family Supports Director of the Arc of Greater Pittsburgh, and Nancy Murray, President of the Arc of Greater Pittsburgh to help the group organize and identify topics of interest for future meetings. The Arc of Greater Pittsburgh has offered meeting space, support services and refreshments free of charge to the group, as well as offering to house a lending library of materials on Fragile X provided to the group from the National Fragile X Foundation.

Objective 2: To develop a registry for FX patients and their families

- We have developed a database to assess the frequency of different medical, psychological and developmental disorders in individuals with FX syndrome. The database includes mutation status and IQ test results as well.

This will allow further refining of the recommendations set forth by the American Academy of Pediatrics in "Health Supervision for Children with Fragile X syndrome" (Pediatrics Vol. 98, No. 2, 1996, pp. 297-300). This would improve quality of care by primary care physicians for individuals with Fragile X syndrome.

Systemic evaluation of responses to interventions (medical, developmental and psychological) to guide future treatment through evidence based medicine. Evaluation of responses of individuals with Fragile X syndrome treated for

medical, psychological or developmental disorders will help clarify if response is similar to that of individuals without Fragile X syndrome.

We are now planning the following goals for next year.

- Development of clinical research programs for individuals with Fragile X syndrome. This would be made possible by increases in the number of individuals with Fragile X syndrome served by the clinic.
- Collaboration with existing research studies in progress at other institutions to increase the fund of knowledge about Fragile X syndrome. Examples are the studies of the Fragile X-associated Tremor/Ataxia syndrome and brain tissue studies through the M.I.N.D. Institute and the study of premature ovarian failure in permutation females at Magee Womens Hospital. Dr. Delahunty has been referring interested families to these studies. One of our patients with Fragile X syndrome had a brain tumor resected, and his donated tissue is the only tissue ever donated from a brain tumor in an individual with Fragile X syndrome. This child is the only individual with Fragile X known to have had a brain tumor and researchers were very excited at this opportunity to study the presentation of the tumor in an individual with Fragile X syndrome.

Objective 3: To establish a basic research laboratory

- A search committee of Dr. Perlmutter, PI, Dr. Bob Noll, Chief of Child Development, Dr. Jerry Vockley, Chief of Genetics, and Dr. Nina Schor, Chief of Neurology has been formed and several potential candidates identified.

REPORTABLE OUTCOMES

There have been no publications or grant applications this year.

CONCLUSIONS

We have just begun to set up the clinical center. This year, we plan to further develop the clinical center, establish the registry, decide on two research protocols and recruit the basic scientist.

BIOGRAPHICAL SKETCH

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

NAME Carol M. Delahunty		POSITION TITLE Clinical Assistant Professor	
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
Tulane University, New Orleans, LA	BSc.	1984	Biomedical Engineering
Univ. of Virginia, School of Medicine, Charlottesville, VA	MD	1991	Medicine

A. Positions and Employment:

- 1991-1994 Internship/Residency, Department of Pediatrics, University of North Carolina, Chapel Hill, NC
 1995-1997 Fellowship, Developmental/Behavioral Pediatrics, University of Colorado, Denver, CO
 1997-2000 Clinical Assistant Professor, Developmental/Behavioral Medicine, Department of Pediatrics, University of Florida, Gainesville, FL
 2000-present Clinical Assistant Professor, Developmental/Behavioral Medicine, Department of Pediatrics, University of Pittsburgh School of Medicine, Pittsburgh, PA

Specialty Certification and Professional Memberships

- 2003 American Academy of Pediatrics
 2002 Developmental and Behavioral Pediatrics Board Certification
 2002 American Board of Pediatrics Recertification
 1995 Society for Developmental and Behavioral Pediatrics
 1994 American Board of Pediatrics

B. Publications:Articles:

Bundy KJ, Kelly RG, Brown EL, Delahunty CM: pH Shifts and Precipitation Associated with Metal Ions in Tissue Culture. *Biomaterials* 6:89-96, 1985.

Book Chapters:

Delahunty CM: Medical management of pervasive developmental disorder. In: Maria BL (ed): Current Management in Child Neurology, 2nd edition, BC Decker Inc., Hamilton, 2002.

Other Publications:

Delahunty DM: Fetal alcohol syndrome. In: Genetics & Your Practice CD-ROM. Institute for Child Health Policy, 1999.

Delahunty CM: Premature children with grade III-IV intraventricular hemorrhage. Provided for the Practice Parameters for Early Intervention of Infants and Toddlers project, The Lawton and Rea Chiles Center for Healthy Mothers and Babies College of Public Health, University of South Florida, Tallahassee, FL, 1998.

BIOGRAPHICAL SKETCH

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

NAME		POSITION TITLE	
Robert B. Noll		Professor (Pediatrics and Psychiatry)	
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
Ohio University Athens, OH	BBA	1965-1969	Economics and History
University of California at Berkeley Berkeley, CA		1975	Psychology major
Michigan State University East Lansing, MI	PHD	1976-1983	Clinical child/developmental

A. Positions and Honors.**Positions and Employment**

1969-1974 Naval Aviator
 1983-1989 Assistant/Associate Professor, Dept. of Human Development, Michigan State University
 1989-2003 Associate/Full Professor, Dept. of Pediatrics, University of Cincinnati
 2004-present Professor, Director Child Development Unit, Assistant Medical Director for Behavioral Medicine, Children's Hospital of Pittsburgh, Dept. of Pediatrics, University of Pittsburgh

Other Experience and Professional Memberships

2001 Chair, Social and behavioral section, Psychology Discipline Committee, Children's Oncology Group
 2001 American Psychological Society, member
 1996 American Society of Pediatric Hematology and Oncology, member
 1980 Society for Research in Child Development, member
 1990 Vice-Chairman, Psychology Discipline Committee, Children's Cancer Study Group.
 1985 Co-Chairman, Children's Cancer Study Group longitudinal study of neuropsychological sequelae of treatment of acute lymphoblastic leukemia (CCG-105NP).

Honors

2004 Fellow, American Psychological Society
 2004 Society of Pediatric Psychology's Logan Wright Distinguished Research Award.
 2001 Guest editor, Journal of Pediatric Psychology special issue on methodology and design.
 1999 Article in the NY Times about our laboratory's research.
 1995 Psi Chi Outstanding Advisor Award, Dept. of Psychology, University of Cincinnati.
 1993 Certificate of Appreciation for clinical service. Young Adult Sickle Cell Association of Cincinnati.
 1992 Certificate of Appreciation for research mentoring of undergraduate students, Dept. of Psychology, University of Cincinnati
 1991 Belenky Award for outstanding teaching, Department of Psychology, University of Cincinnati
 1985 Alcohol Advisory Board, Michigan State University, Impact of Alcohol and Health.
 1983 Doctoral dissertation nominated for the Michigan State University Outstanding Dissertation Award.
 1981 Contributor, Fourth Special Report of the U.S. Congress on Alcohol and Health.
 1976-1979 NIMH Graduate Assistantship.
 1975 Phi Beta Kappa.
 1969 Beta Gamma Sigma.

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

(Publications selected from 67 peer-reviewed publications)

1. Davies, W.H., Noll, R.B., DeStefano, L., Bukowski, W.M., & Kulkarni, R. (1991). Differences in the child rearing practices of parents of children with cancer and controls: The perspectives of parents and professionals. Journal of Pediatric Psychology, *16*, 295-307.
2. Davies, C.M., Noll, R.B., Davies, W.H., & Bukowski, W.M. (1993). Mealtime interactions and family relationships for families with children who have cancer in long term remission and controls. Journal of the American Dietetic Association, *93*, 773-776.
3. Noll, R.B., Bukowski, W.M., Davies, W.H., Koontz, K., & Kulkarni, R. (1993). Adjustment in the peer system of children with cancer: A two year follow up study. Journal of Pediatric Psychology, *18*, 351-364.
4. Noll, R.B., Swiecki, E., Gartstein, M., Vannatta, K., Kalinyak, K.A., Davies, W.H., & Bukowski, W.M. (1994). Parental distress, family conflict, and the role of social support for caregivers with and without a child with sickle cell disease. Family Systems Medicine, *12*, 281-294.
5. Noll, R.B., Gartstein, M.A., Hawkins, A., Vannatta, K., Davies, W.H., & Bukowski, W.M. (1995). Comparing parental distress for families with children who have cancer and matched comparison families without children with cancer. Family Systems Medicine, *13*, 11-28.
6. Noll, R.B., Yosua, L.A., Vannatta, K., Kalinyak, K.A., Bukowski, W.M., & Davies, W.H. (1995). Siblings of children with sickle cell anemia: Social competence. Journal of Pediatric Psychology, *20*, 165-172.
7. Noll, R.B., Vannatta, K., Koontz, K., Kalinyak, K.A., Bukowski, W.M., & Davies, W.H. (1996). Peer relationships and emotional well-being of children with sickle cell. Child Development, *67*, 423-436.
8. Noll, R.B., Zeller, M., Vannatta, K., & Davies, W.H. (1997). Potential bias in classroom research: Comparison of children with permission and those who do not receive permission to participate. Journal of Clinical Child Psychology, *26*, 36-42.
9. Noll, R.B., MacLean, W.E., Whitt, J.K., Kaleita, T.A., Stehbens, J.A., Waskerwitz, M.J., Ruyman, F.B., & Hammond, G.D. (1997). Behavioral adjustment and social competence of long term survivors of childhood leukemia: Parent and teacher reports. Journal of Pediatric Psychology, *22*, 827-841.
10. Vannatta, K., Zeller, M., Noll, R.B., & Koontz, K. (1998). Social functioning of children surviving bone marrow transplantation. Journal of Pediatric Psychology, *23*, 169-178.
11. Noll, R.B., McKellop, J.M., Vannatta, K., & Kalinyak, K. (1998). Child-rearing practices of primary caregivers of children with sickle cell disease: The perspective of professionals and caregivers. Journal of Pediatric Psychology, *23*, 131-140.
12. Vannatta, K., Gartstein, M.A., Short, A., & Noll, R.B. (1998). A controlled study of peer relationships of children surviving brain tumors. Journal of Pediatric Psychology, *23*, 279-288.
13. Noll, R.B., Gartstein, M.A., Vannatta, K., Correll, J., Bukowski, W.M., & Davies, W.H. (1999). Social, emotional, and behavioral functioning of children with cancer. Pediatrics, *103*, 71-78.
14. Gartstein, M.A., Vannatta, K., Short, A.D., & Noll, R.B. (1999). Psychosocial adjustment of children with chronic illness: An evaluation of three models. Developmental and Behavioral Pediatrics, *20*, 157-163.
15. Gartstein, M.A., Vannatta, K., & Noll, R.B. (2000). Childhood aggression and chronic illness: Possible protective mechanisms. Journal of Applied Developmental Psychology, *21*, 315-333.
16. Sahler, O.J.Z., Varni, J.W., Fairclough, D.L., Butler, R.W., Noll, R.B., Dolgin, M.J., Phipps, S., Copeland, D.R., Katz, E.R., & Mulhern, R.K. (2002). Problem-solving skills training for mothers of children with newly diagnosed cancer: A randomized trial. Journal of Developmental and Behavioral Pediatrics, *23*, 77-86.
17. Reiter-Purtill, J., Gerhardt, C.A., Vannatta, K., Passo, M., & Noll, R.B. (2003). A controlled longitudinal study of the social functioning of children with juvenile rheumatoid arthritis. Journal of Pediatric Psychology, *28*, 17-28.
18. Gerhardt, C.A., Vannatta, K., McKellop, J.M., Zeller, M., Taylor, J., Passo, M., & Noll, R.B. (2003). Comparing family functioning, parental distress, and the role of social support for caregivers with and without a child with juvenile rheumatoid arthritis. Journal of Pediatric Psychology, *28*, 5-15.
19. Zeller, M.H., Vannatta, K., Schafer, J., & Noll, R.B. (2003). Behavioral reputation: A cross-age perspective. Developmental Psychology, *39*, 129-139.
20. Noll, R.B., Gerhardt, C.A., & Vannatta, K. (2003). Neurocognitive functioning after cancer: Is that all there is to QOL? Journal of Pediatric Hematology/Oncology, *25*, 5-7.
21. Trzepacz, A., Vannatta, K., Stehbens, J., Davies, W.H., & Noll, R.B. (2003). Social, emotional, and behavioral functioning of children with hemophilia. Journal of Developmental and Behavioral Pediatrics, *24*, 225-232.
22. Kazak, A., & Noll, R.B. (in press). Child death from pediatric illness: Conceptualizing intervention approaches from a family/systems and public health perspective. Professional Psychology.
23. Koontz, K., Short, A.D., Kalinyak, K.A., & Noll, R.B. (in press). A randomized controlled pilot trial of a school intervention for children with sickle cell anemia. Journal of Pediatric Psychology.

C. Research Support

Ongoing Research Support

NIH-NCI RO1 CA 83936 Butler (PI)

9/26/00 - 8/31/04

Noll (Site PI)

Title: Cognitive Remediation for Childhood Cancer

This project investigates the efficacy of a multi-modal Cognitive-Remediation Program (CRP) specifically designed to improve survivors' attentional deficits which occurred, presumably, as a consequence of cancer and its treatment. A randomized, controlled design will be used, and we will also apply an analytic strategy that permits the partial differentiation of specific improvements in attention/concentration from nonspecific factors in the CRP. Noll is the site principal investigator in Cincinnati and helped with development of the research plan and writing of the grant application.

NIH-NIAMS PO1 AR 47784 D Glass (PI)

9/01/01 – 6/30/06

Noll (Project 2 PI)

Title: Psychosocial functioning of adolescents with juvenile onset fibromyalgia.

This study will systematically evaluate psychosocial adjustment and emotional well-being in adolescents with JPFS compared to matched classroom comparison peers (MCCPs) using information from peers, teachers, mothers, fathers, and child self-report and multiple data collection strategies. The proposed research will compare measures of (a) peer relationships, (b) emotional well-being, and (c) family functioning and parental well-being of adolescents with JPFS and their parents to MCCPs and their parents. Noll is the principal investigator of this project and developed of the research plan.

ACS --Vannatta (PI)

07/01/03-06/30/08

Noll (CI)

Title: Psychosocial Outcomes of Pediatric Brain Tumor Survivors

The goal of this multi-site project is to evaluate the psychosocial functioning of survivors of pediatric brain tumors and their families. Tests of mediating and moderating variables will be conducted to identify specific factors that can be manipulated in intervention trials to ameliorate difficulties for these families.

NIH/NCI RO1 CA Kodish (PI)

03/01/03-02/28/07

Noll (Site PI)

Title: Improving Consent in Childhood Cancer Trials

The goal of this multi-site project is to improve the quality of informed consent in clinical trials that occur in pediatric oncology.

NIH/NCI RO1 Sahler (PI)

07/01/03-06/30/08

Noll (Site PI)

NIH/NCI

Maternal Problem-Solving Training in Childhood Cancer

The goal of this multi-site project is to reduce distress in mothers of recently diagnosed pediatric oncology patients.

NIH K23 Zeller (PI)

2001-2006

Noll (Co-primary mentor)

Title: Exploring barriers to treatment: Pediatric obesity.

NIH K01 Mitchell (PI)

2002-2007

Noll (Co-mentor)

Title: Depression and nutrition in pediatric sickle cell disease.

Completed Research Support

NIH-NCI RO1 CA 83267 E Kodish (PI)

1/21/99 - 12/31/02

Noll (Site PI)

Title: Informed Consent in the Children's Cancer Group

The specific aims of this study were to: 1) generate and analyze qualitative and quantitative data that will inform scientific understanding of the process of informed consent for clinical trials in childhood cancer; 2) identify potentially vulnerable sub-groups, which may include minorities and non-English speaking parents, who may benefit from targeted interventions to improve informed consent, 3) work together with a group of parents to identify barriers to informed decision making, and recommend measures to improve the consent process; and 4) describe similarities and differences in the consent process between pediatric and adult cancer patients who are candidates for clinical trials. Noll was the site principal investigator in Cincinnati and helped with development of the research plan, analyses, and manuscript preparation.

American Cancer Society PS-99-270-01-PBP Gerhardt (PI)

7/01/99 - 6/30/02

Noll (Sponsor)

Title: The impact of treatment on the quality of life of childhood cancer survivors.

This was an initial career developmental award to Dr. Gerhardt. The primary objective of this work was to evaluate the social, emotional, and behavioral quality of life for children who are long term survivors of childhood cancer and case controls. Noll assisted with the development of the application and mentored Gerhardt during the award.